

Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

Responses

Contents

[Response 1 – Royal Liverpool and Broadgreen University Hospital Trust - Individual](#)

[Response 2 – London School of Hygiene and Tropical Medicine - Individual](#)

[Response 3 – Individual](#)

[Response 4 – Individual](#)

[Response 5 – Individual](#)

[Response 6 – Baroness Ruth Deech, House of Lords](#)

[Response 7 – Individual](#)

[Response 8 – Individual](#)

[Response 9 – Burton Hospitals NHS Foundation Trust ; Individual](#)

[Response 10 – Nottingham Universities Hospital Trust - Individual](#)

[Response 11 – Future Health Biobank](#)

[Response 12 – BMI Healthcare Ltd](#)

[Response 13 – Scottish National Blood Transfusion Service](#)

[Response 14 – Health Research Authority](#)

[Response 15 – Individual](#)

[Response 16 – Addenbrookes Hospital - Individual](#)

[Response 17 – University of Sheffield – Individual](#)

[Response 18 – Leeds Teaching Hospitals NHS Trust and University of Leeds](#)

[Response 19 – Individual](#)

[Response 20 – Parkinson’s UK](#)

[Response 21 – Brunel University Research Ethics Committee](#)

[Response 22 – Biovault Ltd](#)

[Response 23 – Association of Biomedical Andrologists](#)

[Response 24 – Human Fertilisation and Embryology Authority](#)

[Response 25 – Individual](#)

[Response 26 – Individual](#)

[Response 27 – British Transplantation Society](#)

[Response 28 – University of Reading – Individual](#)

[Response 29 – Sheffield Teaching Hospitals NHS Foundation Trust, Centre for Reproductive Medicine and Fertility](#)

[Response 30 – Comment on Reproductive Ethics \(CORE\)](#)

[Response 31 – Loughborough University](#)

[Response 32 – Project Group on Assisted Reproduction \(PROGAR\)](#)

[Response 33 – National Childbirth Trust \(NCT\)](#)

[Response 34 – Independent Cancer Patients Voice](#)

[Response 35 – UK Donor Link](#)

[Response 36 – Scottish Transplant Group](#)

[Response 37 – Royal College of Nursing](#)

[Response 38 – Individual](#)

[Response 39 – ESRC Genomics Policy and Research Forum](#)

[Response 40 – King’s College Hospital NHS Foundation Trust](#)

[Response 41 – Northern Institute for Cancer Research](#)

[Response 42 – Association of Clinical Embryologists](#)

[Response 43 – National Gamete Donor Trust](#)

[Response 44 – Donor Conception Network](#)
[Response 45 – Royal College of Obstetricians & Gynaecologists](#)
[Response 46 – Natural History Museum](#)
[Response 47 – Sheffield Teaching Hospitals NHS Trust - Individual](#)
[Response 48 – Royal College of Surgeons](#)
[Response 49 – The Royal College of Pathologists](#)
[Response 50 – Mid Yorkshire Hospitals \(Dewsbury & District Hospital\)](#)
[Response 51 – King’s College London – Individual](#)
[Response 52 – Confederation of Cancer Biobanks](#)
[Response 53 – Multiple Births Foundation](#)
[Response 54 – Individual](#)
[Response 55 – Cym Taf Health](#)
[Response 56 – British Medical Association](#)
[Response 57 – Human Tissues Group](#)
[Response 58 – Stratum \(Strategic Tissue Repository Alliances Through Unified Methods\)](#)
[Response 59 – British Heart Foundation](#)
[Response 60 – Individual](#)
[Response 61 – NHS Blood & Transplant](#)
[Response 62 – Health Ethics and Law, University of Southampton](#)
[Response 63 – All Party Parliamentary Group on Stem Cell Transplantation](#)
[Response 64 – Professional Guidelines and Practices \(Anatomy\) Committee](#)
[Response 65 – Cardiff University - Governance & Compliance Division](#)
[Response 66 – Cancer Research UK](#)
[Response 67 – Centre for comparative and Clinical Anatomy, University of Bristol – Individual](#)
[Response 68 – Society and College of Radiographers](#)
[Response 69 - Bereavement Services Association](#)
[Response 70 – NHS National Services Scotland](#)
[Response 71 – University of Bristol – Human Tissue Working Group](#)
[Response 72 – Bereavement Advice Centre](#)
[Response 73 – Mission and Public Affairs Council of the Church of England](#)
[Response 74 – South Eastern Health and Social Care Trust](#)
[Response 75 – Genetic Alliance UK](#)
[Response 76 – Wellcome Trust Sanger Institute](#)
[Response 77 – Anthony Nolan](#)
[Response 78 – Royal College of Physicians](#)
[Response 79 – Individual](#)
[Response 80 – Right to Life](#)
[Response 81 – GE Healthcare](#)
[Response 82 – Human Tissue Working Group, University of Bristol](#)
[Response 83 – The Academy of Medical Sciences](#)
[Response 84 – PHG Foundation](#)
[Response 85 – Human Tissue Authority](#)
[Response 86 – Progress Educational Trust](#)
[Response 87 – Belfast Health and Social Care Trust](#)
[Response 88 – Institute of Biomedical Sciences](#)

[Response 89 – Belfast Health and Social Care Trust Regional Fertility Centre](#)
[Response 90 – UK Accreditation Service](#)
[Response 91 – Care Quality Commission](#)
[Response 92 – Bioindustry Association](#)
[Response 93 – The Wellcome Trust](#)
[Response 94 – British Association for Tissue Banking](#)
[Response 95 – BOC Healthcare](#)
[Response 96 – Breast Cancer Campaign](#)
[Response 97 – Christian Medical Fellowship](#)
[Response 98 – Christian Action Research Education \(CARE\)](#)
[Response 99 – Hull York Medical School - Individual](#)
[Response 100 – Medical Research Council](#)
[Response 101 – British Fertility Society](#)
[Response 102 – Association of Medical Research Charities](#)
[Response 103 – Infertility Network UK](#)
[Response 104 – GlaxoSmithKline](#)
[Response 105 – Natalie Gamble Associates](#)
[Response 106 – The British Infertility Counselling Association](#)
[Response 107 – Scottish Council on Human Bioethics](#)
[Response 108 – British Neuroscience Association](#)
[Response 109 – University Research Ethics Committee – University of the West of England - Individual](#)

Response 1 – Royal Liverpool and Broadgreen University Hospital Trust - Individual

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
No.

It is apparent that CQC is having difficulty with its current role. HTA is a highly specialised area of work and CQC will not be able to undertake it. In practice I expect most of the staff from HTA will transfer to HTA in order to provide CQC with the resources it needs. The process of transfer will be disruptive to all stakeholders and expensive.

The HTA works well and may not do so if transferred to CQC.

The consultation implies that the government accepts the functions the HTA performs need to continue and so moving the HTA to the CQC will move bureaucracy around rather than abolish it.

I have read the case for disbanding the HTA on the DH website and find it rather weak.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

I work in renal transplantation. We are working hard to improve our living donor kidney transplants which require HTA approval. If HTA is transferred to CQC it is likely that there will be a period of disruption / miscommunication etc. During this time obtaining approval for these transplants will be more difficult. If some expertise is lost during the transfer then these difficulties will persist. It is worth pointing out that these transplants benefit the economy enormously due to savings in the cost of dialysis treatment – around £200k for each transplant.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Unable to comment – not my area.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

It would make more sense for HTA to be combined with NHS_BT as they work in similar fields

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

This, of course, would make sense. I am unconvinced that transferring their functions to other organisations will save money. Please do not underestimate the disruption (and cost) to front line services of these sort of reorganisations.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

I would but it the other way round – what is the evidence that transferring HTA functions elsewhere will lead to significant savings. You are merely moving regulation around – not removing it.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The functions of HTA are relatively limited and probably cannot be separated. HTA is doing quite a good job and any reorganisation may risk this. It might be

possible for some of the training functions of the HTA to be out sourced.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

You are assuming that the senior management team of the HTA can be removed. I am not convinced this will be possible if the HTA transfers to another regulatory body. You will need to retain at least some senior managers of equivalent expertise.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

The HTA and associated legislation has been a step forward in transplantation. It has achieved the correct level of regulation – not too heavy or too light.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

No

11. Can you provide examples of costs and benefits of these proposals?

No

12. Do you have any comments on the consultation Equality Analysis?

No

Response 2 – London School of Hygiene and Tropical Medicine - Individual

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

YES

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

It should make little difference to the local level users but should save management costs.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Our work does not involve contact with HFEA, therefore we have no opinion.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

No

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

No

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

No

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

None

10. Do you have any other comments on the consultation proposals that you would like to share with us?

None

11. Can you provide examples of costs and benefits of these proposals?

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12. Do you have any comments on the consultation Equality Analysis?

None

Response 3 - Individual

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

I do not agree that this is a sensible or logical way forward at this moment in time. The CQC is a broad-scope organisation and I believe a transfer of function would be a backwards step that would undoubtedly diminish the detailed and sensitive regulation that this sector requires. In addition to this, the CQC has been a less than 'gold-standard' regulator, with serious issues at a strategic and operational level leading to a performance and capability review (DH, 2012), the resignation of the Chief Executive, and a large number of very negative press and Government reports questioning whether the organisation can deliver effective governance with the resources it currently has.

Against this backdrop, I can see no benefit in adding to the workload and scope of a regulator already failing to meet its current commitments – indeed I believe that the excellent work carried out by the HTA in rebuilding public confidence in the sector would be damaged by transferring oversight to an ALB in whom the public has already lost confidence.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

I believe the scrutiny currently present would decrease, leading to more breaches of the HT Act and a corresponding reversal in public confidence. In extremis, I fear another tissue retention scandal.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

With my limited knowledge of research-related issues, I suspect that this may be a beneficial proposal, due to the specific nature of the function being transferred and the body taking responsibility.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No, I firmly believe that HTA is best placed to lead quality assurance, governance and regulation. After all, that was the remit it was given initially, and which has been successfully carried out since.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

I believe that the HTA is an already efficient organisation, requiring very little Government funding (c. £1.2m), and more or less breaking even through licence fees. The proposed savings indicated in your documentation seem to stem from reduction in staff. It must be recognised that such a reduction will bring an inevitable and

possibly irreversible reduction in available expertise, with all the associated risks this brings.
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify
Perhaps the infrastructure of certain functions (i.e. physical inspection of establishments) could be shared with other similar bodies already carrying out similar work in this sector, such as CPA (Clinical Pathology Accreditation), with whom the HTA has already forged some common links. For instance, if establishments were inspected against criteria amalgamated from both organisations at the same time, costs could be significantly reduced – not least staff costs, which is the HTA’s biggest expenditure.
7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
No.
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?
I feel an opportunity is being missed. Why transfer function to an organisation with no experience in the sector, when the HTA’s function could be combined with that of CPA (who are wholly owned by UKAS, and have great experience of inspecting establishments in the Pathology sector); generating savings from staff rationalisation, yet avoiding what you yourselves term ‘fragmentation of expertise’?
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
See previous answers.
10. Do you have any other comments on the consultation proposals that you would like to share with us?
I would urge you to consider why the HTA was founded – I have no confidence that the CQC could protect those aims and deliver effective regulation.
11. Can you provide examples of costs and benefits of these proposals?
Similar in detail to your current proposals, however, the function would be shared rather than transferred. This would still allow the core savings to be realised through senior staff reduction.
12. Do you have any comments on the consultation Equality Analysis?
No.

Response 4 - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	I do not agree with the abolishing of these organisations. More specifically I do not agree that the HTA being abolished is in the interest of the general public or our respective professions.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	Prior to the existence of the HTA, mortuary/post mortem work was self regulated and there are many examples of poor practice and illegal behaviour in mortuary departments in the press from those times. Despite most facilities being also licenced to practice under ISO and CPA regulations, they were treated as poor cousins to laboratories and left to flounder with respect to staff and practice development. It was not until HTA being founded that the mortuary professions saw major improvements in the support they received to implement service quality and improvement. We as a profession are still seeing the hangover of decades of neglect and this can no more adequately be evidenced than by actions taken by the HTA after inspections that have been made so far. One case in 2009 saw a facility shut down to ensure that there were no adverse effects on the community it served. This will undoubtedly be something that will not happen again as the focus on quality mortuary and bereavement care could be diluted in favour of what is deemed more direct patient care as has been the case historically.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	I feel that this could be appropriate due to the new bodies focus on research.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	It could be possible that the HTA under the umbrella of the CQC may have more teeth within a hospital environment. However, I believe that it would still need to maintain some of it's autonomy due to the specialist areas it regulates. Abolishing the HTA as an entity would again dilute its ability to act effectively. Research and public display may well sit better under the HRA from both HTA and HFEA.
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	My experiences with the HTA have always been positive. I have not seen any frivolous waste of resource. I recognise that there are always ways of practicing in a more LEAN fashion, but to abandon a succesful arm's length body purely for effeciency of resource would be to the detrement of the profession and those it serves.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify
	I do not feel I can give a useful answer to this question as I do not have a deep enough understanding of the manner in which any of the organisations under discussion are funded or how they utilise their resources.

<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>I think it could be possible to transfer the public display and research sectors of the HTA and HFEA to CQC and HRA. As the CQC and HRA are already providing similar services pertaining to these sectors as mentioned in the consultation document. This may streamline and simplify access for support in these sectors and undoubtedly reduce workload pressures and costs of the HTA and HFEA.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?</p>
<p>Although the savings look good on paper, I do not believe that they are significant enough to justifying abolishing the HFEA and HTA two very succesful bodies that have changed the face of healthcare science in a very short period of time. No more so than the HTA.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>I think there is one obvious answer, amalgamate the overlap responsibilities and maintain the specialist responsibilities within the arm's length bodies. Reduced resource costs are then found within the bodies and very little increase in costs will be experienced in the CQC and HRA due to current staff being in a position to undertake the duties.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>
<p>Speaking selfishly for my profession and the public we serve, I see the HTA as the main reason we have been able to implement regulated change to protect the public. Our professional association has been working closley with HTA, through this our members have been able to see the benefit of having a body like this regulating us. Previously we have been umbrella regulated and this has not been sufficient to maintain quality standards. To revert to umbrella regulation would take our profession back much further than the inception of the HTA and the act.</p>
<p>11. Can you provide examples of costs and benefits of these proposals?</p>
<p>No</p>
<p>12. Do you have any comments on the consultation Equality Analysis?</p>
<p>No</p>

Response 5 – Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	Transfer of the HFEA functions to the CQC and HRA would inevitably lead to a massive decrease in the quality of governance arrangements that are in place for the sector. This, in turn, would increase risk to individual NHS Trusts and the patients/public. The knowledge and skills, relating specifically to a highly specialised, complicated and unique field, that the HFEA has attained in the last 21 years would, largely, be lost. Regulation of this controversial sector would not be adequate in the absence of a specialist regulatory body.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	Currently the centre has strong links with the HFEA through an individually assigned specially trained inspector/co-ordinator, incidents are reported and investigated in a timely, efficient and proportionate manner. Communication in this rapidly evolving field is currently good. The HFEA disseminate relevant information quickly and efficiently and there are well established mechanisms for feedback from centres and other stakeholders. The local impact on the Centre and patients if the HFEA were to be abolished would be immediate and negative.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	Transfer of the research functions of the HFEA to the HRA would decouple what is currently a relatively seamless process from new technologies and techniques being researched through to their application in a clinical setting. The advantages of HFEA maintaining oversight of both arms of governance are enormous. I do not agree that the HFEA should transfer research functions to the HRA.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	HFEA functions should remain with them as stated above
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	Yes, HFEA and HTA should retain existing functions but should be expected to deliver further efficiencies. Realistic targets for efficiencies, based on the current economic climate should be set and performance against these targets should be monitored/policed.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	The HFEA could deliver further efficiencies by concentrating on core, legislative duties such as inspection and the data register and looking closely at any activity it performs that is not required by the legislation.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	No advantage to transferring any of the functions of the HFEA or HTA
8.	Do you have any comments on our assessment of the efficiencies associated

with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
The assumptions made are erroneous. The HFEA in general, and the core inspection team particularly, are a highly specialised group. It would not be a simple matter of transferring functions. No individual CQC inspection team would have the detailed knowledge of the field or the legislation to be able to draw any valid conclusions from inspection, the knock on governance effects of this are negative. The public could not be assured of good/safe practice in Centres.
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
No comment
10. Do you have any other comments on the consultation proposals that you would like to share with us?
No comment
11. Can you provide examples of costs and benefits of these proposals?
No comment
12. Do you have any comments on the consultation Equality Analysis?
No comment

Response 6 – Baroness Ruth Deech, House of Lords

I declare an interest as a former Chair of the HFEA, 1994-2002. Some of the questions posed by the Consultation Paper overlap in subject matter, so it may be that my answers do not always correspond exactly to the question.

Q1. Answer, No. This is a very broad topic, and I have divided my response into 3 areas: 1, Transfer to the CQC, 2. Abolition of the HFEA, 3. HRA and research

1. *Transfer to the CQC.* It is too big an organisation for the delicate case-by-case type of work done by the HFEA, and, as a new organisation it is untried in many ways and some of the stories about its work have given it poor reputation for scrutiny. Throughout the consultation, the wish of the DH to reduce the number of quangos in the field is clear, and yet in the area of health we see the establishment of new ones, for example, Monitor, Healthwatch England and the HRA itself, so the rationale for abolishing one or two small ones disappears. The complexity of the IVF field would not be reduced in the course of disbanding the HFEA, regulation risks being much less effective, the providers would find inspections, cost and paperwork no less, public confidence and international reputation would suffer.

The CQC has never handled a register like the HFEA one before (nobody has), so the report suggests possibly transferring it to the HSCIC, which would amount to more fragmentation of functions. Personnel would have to be trained, and there is a failure to appreciate that the HFEA register has wider purposes beyond data collection, which are inseparable from treatment, patient information, counselling and research. This is no simple computer operation.

Dividing regulation of IVF etc. between a new medical research organisation and the allegedly overburdened CQC is misguided. There is no improvement in public confidence to be gained, on the contrary, the public will not be persuaded that embryos will be treated with the respect they feel should be accorded to them. They will not be persuaded that bounds will be put on embryo research if regulation is taken away from the accountable and expert figures of the HFEA. How would the CQC and the HRA provide the equivalent of the public meetings, meetings with stakeholders, the website, the handbooks and inquiry service that the HFEA provides? Regulation of this hypersensitive subject would become less transparent, merged with the other functions of the CQC. The UK would lose the one distinctive voice that it has had for more than 20 years, punching above its weight in this field and speaking for British research internationally. The CQC does not have expertise in this field and would have to build it up, no doubt by hiring as many staff as are presently at the HFEA at some cost. Transitional costs may well be greater than estimated in the IA. Only 4 years ago the Lords Prelegislative Scrutiny Committee came out firmly against the then proposed merger of the HFEA and the HTA; nothing has changed since then. To quote Sir Ian Kennedy in the 2007 Report, (<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/16908.htm> , para. 67): “in all such amalgamations history tells us that very often you go back to ground zero” and that “such mergers or amalgamations really lose you two years of expertise and administrative skills as you catch up.”

Some of the stakeholders say that the CQC has said that it does not want the HFEA functions, seeing little benefit and significant risks in taking them on.

The consultation paper has insufficient assessment of the interests of patients, parents, donors and children. For example, how would the conveying of startling information to donor conceived children from the register be handled? To suggest outsourcing it (always an expensive option) when the skills to handle this have already been acquired, is not very practicable. Those who conveyed the information, in this new scenario, would be separated from the staff who work with the clinics, and the staff who input the information into the register. There is no mention of the proposed destination of the register of pre1991 donors.

2. *Abolition.* It seems from the paper that primary legislation would be required to ensure that the HFEA functions relating to the whole of the UK could be transferred to the CQC, which has a more devolved limit. Any attempt to enact fresh primary legislation would be met both in the Lords and the Commons with amendments designed to limit research or to change abortion law. This has been the experience of governments in the past, and the successful tactic has been adopted of enacting the most flexibly worded legislation (HFEA 1990 and 2008) in order to minimise the need to return to Parliament for years, avoiding the wrecking amendments that are always presented in this field by opponents of abortion and embryo research. Changing the law to ensure smooth transfer to the CQC could take a long time and reopen these issues.

A strong case in favour of the retention of the HFEA is the gathering in one place of data, research and treatment issues. They are in reality indivisible in securing the best treatment. If functions are transferred to the CQC and the HRA, rearrangements of all external relations carefully maintained by the HFEA will have to be undertaken; no foreign countries can understand why this is being suggested, when they are trying to emulate us in the successful regulation of IVF, e.g. Canada. Following the overhaul of the NHS now being undertaken, this is the very time when consumers of IVF need most protection and continuity. Patients are used to having a single port of call for information and complaints; to disband the HFEA sends the message that the government does not trust the way infertility and embryology is handled in this country, and it is a message that will go right around the world.

IVF is not “routine”, as some clinicians have alleged, at least not in the eyes of the public. Any one treatment can throw up not only ethical issues but also new clinical ones as the science progresses every day. One cannot separate the collection of embryos and eggs from their storage, their storage from donation for research, donation for research from new research and stem cell work, and none of these from the great HFEA database of identities and treatments, from patient guidance, reliable statistics and health screening of donors. The HFEA is used to handling the aggressive and widespread press reaction to new developments, an area that will not be welcomed by other bodies. In my experience the DH found the HFEA useful in deflecting the embarrassment or blame that could result if anything went wrong in IVF treatment (which it has, albeit rarely) and in giving reassurance to the public that, for example, animal-hybrid embryos or the growth of eggs from tissue will be responsibly monitored.

There is good regulation and there is bad regulation. It is necessary and desirable where there would be a risk to the public as a whole from the activity, especially where there is asymmetry of information and costs born by the public; their welfare, their rights and future children's health are at stake if there were no specialised regulation of a private or professional activity.

3. *Research* Dividing functions between the CQC and the HRA will obliterate the rationale for reform because it will be complicated; decisions will have to be taken somewhere about what is research and what is treatment. The HRA would be new to the field of expert decision making about ethics and new treatments using embryos, whereas the HFEA has built up years of expertise, precedents and careful overview and monitoring. One cannot easily separate the licensing of embryo research, the release of identifying treatment data to researchers where it is not practicable to obtain consent, and the provision of guidance to researchers, or all of these from the maintenance of the register of treatment. Keeping ethics, treatments in clinics and research in laboratories under the same umbrella is very beneficial to all of them, and increases the learning process.

Q2. I have divided my response into issues affecting patients and providers.

Patients There needs to be an understanding in this consultation of the part played by the emotions of the public and patients, and their experience, relating to the safety of treatment and its acceptability. It is well known that the HTA came about because of a massive reaction to the holding of tissue, and that this is now well under control. Clinicians who want to see the end of the HFEA tend to say that IVF is routine and does not need special attention. That is not the government's view, because the statutory controls are being maintained. Nor is it the view of the public, whose emotions and intelligence are engaged by every new development and who hope for cures for terrible diseases. The uniting of eggs and sperm and the resultant possibilities can never be routine, except to a hardened clinician, and these are the very people whose ambitions need to be kept in line with public acceptance. The Guardian newspaper reported: "the abolition of the HFEA will leave a major policy vacuum in biotech ethics. Without intervention it will be filled by the Daily Mail." (29 July 2010) The New Statesman: "the regulation of fertility and embryology will now be hidden within the remit of the CQC. There will be repercussions. Without a distinct, visible body to oversee reproductive ethics, scientists in the field stand to lose public trust." (5 August 2010)

This consultation ought to be about the maintenance of public confidence in this experimental field. It is easy for legislators, researchers and specialists to forget how sensitive the issue of embryos is, and how very concerned the public is. The most striking event during the passage of the HFE Bill in 2008 was the protest staged by hundreds of members of the public at Westminster against the possible extension of embryo research to animal hybrids. If your name is associated with embryo research, as mine was, you are the recipient of hundreds of letters about it, not always calm, rational or unthreatening ones. As Baroness Warnock said in her esteemed report of 1984, the public want to know that *some* principles are involved. It is also not to be overlooked that most of the infertility treatment in this country is private: a great deal of money is involved, and the need for protection is all the greater. There is no question of abolishing the controls, but what is at issue here is the perception of

independence. The HFEA is sometimes disliked, but its independence of the profession is acknowledged. Rightly or wrongly, that would not be the perception if it were absorbed into the CQC. It is better for regulation to be conducted at arms' length from government (ie the DH), for it may be that government failings are sometimes at the root of failures in the regulated activities. That is why the HFEA is largely funded by clinics and patients, not by the government, and it is thought to be independent of DH policies. Regulation could fall to Parliament directly, or to organisations representing patients, researchers or clinicians, national or hospital ethics committees; the individual patient and her doctor; religious organisations or an independent statutory authority composed of scientists and lay members chosen for their expertise in open competition. Clearly the last is best and while such a board might still exist within the CQC, the value of it, which lies in the perception of independence, will be lost.

There is no evidence in the IA that the patient experience will improve if the HFEA is disbanded (para.37). The risks outlined in paras. 122-125 are considerable. There is a risk that public acceptance of responsible embryo research and new treatments will diminish. There will be a loss of specialised help to clinics, such as is given by the HFEA, and during a lengthy transition period to the new regulators there is a risk of more errors or incidents while inspectors are regrouped and retrained. Patient safety is the most important factor to weigh.

The consultation paper states that the CQC would be a *focal point* for ethics; whereas the HFEA actually undertakes ethical analysis at a high level, involving public consultation. It is hard to see how progress on resolving difficult ethical issues, e.g. payment to donors, would be as satisfactorily maintained within the CQC.

2. *Providers* Opposition to these proposals has been voiced by the major organisations in the field – ACE, BMA, BFS, RCN, BICA, RCOG, Infertility Network UK, have all expressed doubts but are of course willing to see efficiencies. The main support for the government has come from the most experimental and daring individual clinicians and researchers who, understandably, chafe against control of their activities, which they think should be left to be controlled by their own discretion. They appear to think that regulation will be lessened if the changes proposed in the consultation paper are implemented. But of course they will not be, as there will be no substantive change in the law. These researchers and clinicians will be just as unhappy under a new regime, for the processes in the CQC will not be any quicker or less bureaucratic or cheaper; maybe even more expensive if there is a need to make cuts, and slower if they are not given priority within the organisation. While inspections of clinics/hospitals might be streamlined, they would take longer because there are special questions to be asked of IVF clinics and patients within hospitals, so no time will be saved. The cost of private treatment is unlikely to diminish, and this is not something within the remit of the HFEA or the CQC, although it is a subject of widespread dissatisfaction. It is also unlikely that the NHS will provide more infertility treatments in this period of recession. If most of it was provided by the NHS, the answers to this consultation might be different.

Q3. No. See above.

Q4. No. See above. This would increase fragmentation even more than Option 1.

Q5. Yes. IA para. 119. The HFEA has already delivered cost savings by relocating. It could have made greater savings if it had not reduced the licence fee. It needs more efficient ways of suspending doctors who are suspected of unlawful practice. The legal costs at the moment are very severe for the HFEA, which is dependent on extra DH funding to fight a case, while the doctors under suspicion have the financial backing of the BMA. During the passage of the Public Bodies Bill, it was suggested that there be an independent review of the functions of the HFEA and the HTA to search for efficiencies. This has not been carried out, as far as I am aware, and it should be a priority and a precedent to any reforms. The sums involved however are minimal. The grant in aid is about £2m, a sum which sadly is reportedly spent every day on rather less important issues elsewhere.

Q6. Yes, although as already stated, the sums involved are relatively very small, and well worth it for peace of mind.

The grant in aid could be removed, leaving the HFEA to charge more to patients and clinics. Patients pay so much for treatment that an extra sum for the HFEA would be of minor significance.

The HRA could agree with the HFEA, the HTA and the CQC on streamlining site visits by individual regulators.

The IA itself is doubtful about savings to be made from disbanding the HFEA, because the running costs would be transferred to the CQC and the HRA, not lost (paras.45, 48, 49). It is hard to understand why the consultation expresses confidence that efficiency gains would materialise in the proposed transfer (para. 45) but scepticism about efficiency if the HFEA and the HTA are retained and required to make savings (para. 127).

The Chair and Members of the HFEA could receive reduced remuneration. I did the job for £8k for most of the time, and I and most members regarded it as a privilege, for which the receipt of expenses alone might have been enough. The most recent information I have, a few years ago, is that the Chair's remuneration is £55K pa., which is a very large sum indeed for most quango chair positions.

There would be savings in time, if not in cash terms, from abandoning the need for primary legislation to effect the transfer of all UK IVF functions to the CQC.

Q7. None

Q8. They are too small to make much difference. A saving of £3.7 over 10 years is not a reliable saving, especially with all the incalculables evident in the IA. The cost of training new staff and inspectors, the re-direction of patient and clinic inquiries, the management of informing the world that there had been a change, would probably add up to an equal amount, not to mention the physical space required (although that has already been taken account of.)

Q9. There should be an independent review of the tasks carried out by the HFEA and HTA to see if savings can be made without abolishing them.

Q10. No

Q11. The HFEA is already almost self sufficient with a very small grant in aid, and in reality little more can be required.

Q12. A significant number of private patients come from overseas to be treated here. There must be a good contribution to the UK's earnings, which ought not to be jeopardised. As I learned on clinic visits, they particularly value the relative privacy and independence of treatment in our clinics, and might feel less confident about using them without the HFEA brand.

Response 7 - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	I am concerned that the transfer of the donor register in particular to the CQC will endanger the mental health and well being of the donor conceived children who need specialist support in dealing with this information that the CQC has no experience of. The idea the CQC will find room for anyone from the donor conception or fertility world on its stakeholder committee, already 22 strong, seems extremely doubtful.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	Please see above
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	No comment
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	As mentioned earlier
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	I believe that the HFEA has developed some far ranging experience that the CQC simply does not possess and cannot develop in a short space of time. The HFEA has a specialist board that is carefully composed to include, scientists, clinicians, patients, philosophers, and religious representatives – to ensure that it can bring balanced views to some of the difficult ethical issues that it faces. Its staff have built up specialist experience over the years. In addition to the well-publicised sector wide issues, such as the payment of donors, or the acceptability of certain embryo treatments, there are also individual cases, involving sensitive situations where things have gone wrong, information has been wrongly released, or gametes or embryos misplaced. Placing the handling of these situations onto generalist hospital inspectors would be hugely inappropriate
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? The voluntary register of pre 1991 donors and donor conceived individuals. is held and operated by UK DonorLink a DH funded charity, this could be given over to the HFEA
	This is held and operated by UK DonorLink a DH funded charity could be
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any

views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Response 8 – Individual

Consultation on Proposals to Transfer Functions of the
Fertilisation & Embryology Authority and the Human Tissue Authority

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CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No. These are two bodies that have worked very well. Why change this?

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Currently the arrangements for approving live transplants work quickly & efficiently. I cannot imagine any change doing anything but causing delays in this process.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No: why interfere with something that isn't broken?

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

I believe that they should retain existing functions. The HTA appears to me to be a highly efficient body already. I have worked with it since it was set up, & know that many people, like me, who do work for the HTA do it entirely voluntarily: the HTA has never been charged for the work I do for it.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

I suspect that altering an already efficient system is likely to lead to additional demand on the public purse.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

Only to say that the overall assumption is that things have to change- why?

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

- | | |
|-----|--|
| 11. | Can you provide examples of costs and benefits of these proposals? |
| 12. | Do you have any comments on the consultation Equality Analysis? |

Response 9 - Burton Hospitals NHS Foundation Trust - Individual

Q1. I have no objections to the functions of the HFEA being transferred. Where these functions sit is immaterial as long as they are carried out and in an efficient manner

Q2. I see the transfer of these functions having little to no impact on my organisation

Q3. I am not currently involved in research so cannot comment, I have been in the past however and my view is that the separation of the clinical aspects of the HFEA function and research will not be helpful as an in depth clinical view must always inform research

Q4. There seems little point in creating a new body and I can think of no other body that would be appropriate

Q5. There would be some merit in this, it would ensure that the necessary knowledge and skills were not lost but it is important that they are not rendered non viable by too many cuts

Q6. I find it hard to see how this might be achieved

Q7. If the HFEA were to be retained I would see the reverse being the case with it assuming a wider remit to assume sole responsibility for accrediting clinics so that the clinics are not subject to multiple inspection, one fee. It is the multiple bodies involved at the moment that appears to cause most distress.

Q8. The impact assessment appears fair. I cannot comment on the figures. I would agree with many of the points made however see comments in section 9 below, there appears to be an assumption that transferring the HFEA functions to the CQC would see an automatic benefit/improvement, I am not convinced given my view of the current CQC approach that this would be the case

Q9. The proposals very largely hinge on the assumption that the CQC is the fit and proper body to either provide or "host" the functions of the HFEA. It is my opinion from my own experience of the way both these bodies currently function that the CQC has much to learn from the HFEA which already has many years experience of regulatory function. The CQC has too wide a remit and consequently lacks focus and at times appears to be very random. It also consumes a vast amount of organisational resources which the HFEA does not. I would not wish this approach to become the approach of those responsible for ensuring adherence to the Terms of the HFEA (Act) 1989. None the less I would accept that the functions of the HFEA could be slimmed down further as there has been a considerable degree of "mission creep", I remain to be convinced that a move to the CQC would improve this in any way.

I would also wish to add that in discussions with colleagues who have had little if any contact with the CQC there is a feeling that "losing" the HFEA would free them from what they perceive to be an overbearing regulatory body. They may feel differently once they have had contact with the CQC

Q10. No comments

Q11. I cannot

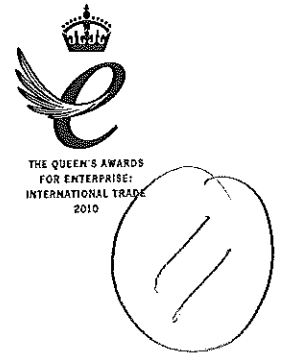
Q12.No Comment

Response 10 – Nottingham Universities Hospital Trust - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	<p>I do not think this is the best option although it would keep the majority of HTA functions together. From a transplant perspective there are a number of concerns:</p> <p>i) The CQC already has a wide ranging portfolio and there is widespread concern as to whether they have the capacity to take on a number of very specialised areas that are currently included within the HTA and HFEA portfolio.</p> <p>ii) Transplantation is a complex, highly specialised and constantly evolving area of practice and if included within the CQC portfolio would need a specialist team to manage not just the regulation, but the associated advice and guidance and policy development. The option of moving the specialist team from the HTA to the CQC would be one way of delivering this, but this would not deliver any cost savings.</p> <p>iii) The regulation of living donors requires two levels of approval; currently one level by the HTA executive and a second and growing level requiring the approval by a panel of three members of the Authority. Is this a function that the CQC board would be willing and able to take on?</p> <p>iv) Organ donation and transplantation is a specialist and high-profile area and any loss in public/patient confidence has the potential to significantly affect transplant rates, which would have a significant impact on those waiting for transplants.</p>
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	<p>If this were the option to be implemented the impact would fall in two main areas: i) regulation of living donor transplantation and ii) licensing under the EU Organ Donation Directive.</p> <p>i) As stated above there needs to be timely advice and guidance available for living donor transplants where there are complexities. Currently the turnaround times for live donor transplant approval are very speedy and have the confidence of the transplant community. There also needs to be an effective mechanism to develop policy to accommodate changes and innovation in this area.</p> <p>ii) Again because transplantation is a highly specialised area and performed in a limited number of institutions (<50), the licensing and inspection process under the EUODD would most likely have to be delivered by a specialist team within the CQC - and not be done by the existing CQC inspection team who are currently assessing across more generic standards across all institutions.</p>
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	No opinion
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	I agree with the consultation document that it would not be appropriate for NHSBT to

<p>self regulate living donor transplantation or to be the competent authority for the EUODD. To ensure high levels of patient and professional confidence it is important that there is an independent regulator, who nevertheless works effectively with NHSBT. There is no other obvious body that is currently positioned to take on this responsibility.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>I do think this is the best and the preferred option. Both organisations have an established track record in the areas that they regulate and have built up relationships and confidence with patients, public and the professional sectors. Certainly the HTA have sought to deliver according to the principles of better regulation.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>Savings are already being made and I'm aware that the HTA has delivered 27% savings in the last year, and in the grand scheme of things the actual cost of the HTA is very small in comparison to much else that is happening. Most of the HTA activity is funded by license income, but the transplant sector does not currently pay licence fees and therefore the regulation of living donor transplantation is covered by grant-in-aid - and presumably this would need to continue under whatever final arrangement is agreed.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>No</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>I accept that there are potential savings in reducing the number of chairs and CEOs, but correspondingly this means an increased workload and knowledge requirement for the existing Chair and CEO who will be the public face of regulation. The CQC has not been viewed entirely positively in the media of late - and adding areas of great sensitivity needs to be borne in mind. Because transplantation is such a specialist area (as are many other areas the HTA and HFEA cover) this it is likely there will still need to be specialist teams within CQC to manage these areas with therefore few areas of duplication and little scope for further savings</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>None</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>
<p>No</p>
<p>11. Can you provide examples of costs and benefits of these proposals?</p>
<p>No</p>
<p>12. Do you have any comments on the consultation Equality Analysis?</p>
<p>No</p>

Response 11 – Future Health Biobank



RESPONSE TO DH CONSULTATION ON TRANSFER OF FUNCTIONS FROM HTA / HFEA

By Future Health Biobank- 24/08/2012

1. Introduction

Future Health Biobank (FHBB) welcomes the opportunity to comment on the proposed transfer of functions from the Human Tissue Authority (HTA) to the Care Quality Commission (CQC), as set out in the Department's *Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority*.

FHBB is licensed by the HTA as a stem cell bank (cells derived, for example, from cord blood and cord tissue) in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which in turn derive from the EU Tissues and Cells Directive 2004.

In fact, Future Health was the first Private UK family stem cell bank to receive a full HTA licence.

2. FHBB Experience of Regulation by HTA

FHBB strongly supports effective regulation of stem cell banking. Future Health Biobank's Code of Practice states: "We welcome the strict regulatory regime in the UK, and are committed to full compliance with it. Clients who come to us can accordingly be assured of the highest possible standards, expertise and levels of service." It is vitally important for a sector which is still relatively new, and at the leading edge of technology, to be seen to be effectively regulated. Our customers can have the confidence that high standards are being maintained because a knowledgeable and effective regulator is working with industry to ensure that they are.

Of course, as a commercial concern, it would be idle to pretend that we do not sometimes find the way in which regulation is applied irksome. As in many areas of EU-derived regulation, there is always a suspicion that the UK authorities transpose the regulations in every last detail into UK law and then apply them with a rigour unmatched elsewhere in Europe. However, even this can work to the advantage of UK companies, since the fact that a UK-based concern is regulated to the very high standards expected in the UK means that regulators and consumers in other countries also have confidence in the standards being maintained. In our own experience, as a company which stores stem cells collected from more than 40 countries, we are fully aware that the Human Tissue Authority is well-known and highly respected outside the UK.

3. Looking to the Future



Partly for this reason, and partly because our experience of current regulation is that it works well, we are opposed to any change in the current arrangements and therefore support Option 3. We would certainly also support the government's intention that the HTA continue to pursue efficiencies, in order to keep the cost of regulation down.

If, on the other hand, the HTA were to be subsumed within the CQC, we would have serious concerns. First, the remit of the CQC is already very wide; arguably it has had some difficulty in establishing its credibility in some areas. It would seem much more sensible for CQC to concentrate on improving the quality of regulation across all its regulated sectors before taking on more.

For FHBB, as a regulated entity, the concern would be that our interests would be a very small part of the CQC's activities; it is difficult to envisage CQC, because of its sheer size and complexity, predominantly focused on the acute sector and adult social care, being able to focus effectively on stem cell and tissue services.

It would also, we believe, be potentially detrimental to our business if the highly-respected name of the HTA were to disappear, particularly in relation to our overseas business. As a company which is proud to have been awarded the Queen's Award for Enterprise for our services to the export sector in stem cell services, this is a matter of considerable concern to us.

Finally, the HTA is a relatively small, highly-focused regulator. Its annual expenditure is minute when compared even with the CQC, let alone the NHS Budget or the total bill for Public Bodies. It is very difficult to believe that abolishing the HTA and transferring functions would save very much money; indeed, when transitional costs are taken into account, it might cost money in the short term.

4. Conclusion

For all these reasons, Future Health Biobank supports Option 3 - the HTA remaining a stand-alone regulator, wholly focused on its area of expertise. We also support the government's intention to require HTA to achieve further efficiencies in its operating costs.

Yours Sincerely

Roger J Dainty MBE

UK Managing Director

Response 12 – BMI Healthcare Ltd

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No I do not believe this would be beneficial to the patient.

HFEA was set up , post Warnock-committee, to protect the interests of the child, including any children already in the family unit. Their remit was huge – establishing / monitoring compliance within the UK.

They used established best practice and monitored / advised regarding statue compliance. HFEA worked within a difficult environment where practice was evolving and improving –with the sole ethos of protecting patients.

The area of Assisted Reproduction healthcare is unusual in that the majority of the work performed has typically been completed in the private sector . The private sector has to balance the needs of the patient with the financial realities of running a service –in non-regulated countries this has led to maximising outcome for the clinics (a great marketing tool) whilst not always protecting the well being of the child or the potential parents. For example, in the US it was common practice to transfer higher numbers of embryos , to achieve higher pregnancy rates (great marketing tool) with less regard to the effect of multiple births (higher mortality rates, higher incidence of health problems, social problems in the child, increased health costs).

HFEA have established what good & best practice is , it ensures compliance and monitors outcomes.

They have a specialist role and perform it to a high standard.

The current government, quite rightly , set out to reduce the cost of the services it maintains. One aspect was the reviewing of “QANGO’s” -the main goal to reducing costs through eliminating inefficiency.

When HFEA (and the Interim Licencing Authority) were established , the funding was through treasury and licencing fees. The ratio was on a sliding scale, as time went by more and more of the funding was to be through licencing fees. This has led to a peculiar position of where a QANGO is actually making money !

This was crucial to enabling the “industry” to grow and develop –within the boundaries set by parliament. HFEA was fundamental to the growth process –in an industry that helps many thousands of people every year, seek safe treatments. The regulation of research has been beneficial in many ways : enabling structured research (when other countries where not –giving the UK a lead in an exciting area of medicine) and whilst still preserving the special status of the human embryo.

To summarise ; HFEA provide a unique solution in a VERY specialised area of medicine in a cost effective manner. They have empowered the industry to grow and succeed –ensuring Units provide safe, monitored and regulated treatments. They have enabled robust and effective research to occur –whilst protecting the special status of the human embryo.

HFEA are already cost-effective and there is little added value in their demise / absorption.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

As a Fertility Manager it would make my life more difficult. I find HFEA helpful and useful in my role in providing fertility care. As a practicing embryologist, the guidance and framework provided by HFEA is crucial in reassuring my patients about the quality of the work we perform. As a patient-advocate, HFEA maintain a safe environment and through it's data collection "standardisation" of information given out by clinics can occur.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No, the regulation of research has been beneficial in many ways. HFEA are working in a specialised environment and have enabled structured research (where other countries are not –giving the UK a lead in an exciting area of medicine) and whilst still preserving the special status of the human embryo.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

I believe that it is a good thing that the functions of all of these organisations are reviewed. However, I believe HFEA have worked (and continue to do so) in a specialised and cost effective manner.

I am unsure the other organisations have either the capacity or the knowledge to absorb HFEA's role.

To flip the question : if they have the capacity or surplus of resources , would it not make more sense to trim them down until their profile met their remit ?

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

I support the position that all of the organisations need to be reviewed in terms of function, service provided and cost effectiveness.

I have already described why I believe HFEA are already cost effective and provide a useful role.

In terms of improving efficiency of HFEA , one area to consider is the location of ALL government agencies within the south east is expensive – real estate is significantly more expensive, local taxes , transport etc etc are all more expensive in the south east of the UK . Might it be more cost effective to either move out of London or de-centralise ?

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

HFEA have developed and adapted to their role and many argue that they have achieved "expert" status –this was not achieved over night.

In terms that it is obviously, already cost effective, I do not understand what savings will be made.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

I believe HFEA / HTA are already well equipped to perform their functions . I also believe their functions are relevant to their goal.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

I have read the “Impact Assessment” and the document “Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue” – again I am unconvinced that any true savings will be made and at a huge loss : HFEA are performing well and are already cost effective.

The saddening part of the proposed exercise is the redundancy etc costs associated with closing a successful and efficient body.

Again, I suggest if government wants to reduce costs; de-centralisation and moving from expensive geographical locations seem the way forward. In this modern digital age -must we have people physically attending meetings? Is anyone aware of video conferencing - something everybody with a computer and internet can achieve?

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Please de-centralise and / or move out of London. The cost of being based in the capitol must be enormous and is extremely wasteful.

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

I have read it and understand it. No comments required.

Response 13 : Scottish National Blood Transfusion Service

CONSULTATION QUESTIONS
<p>1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.</p>
<p>No.</p> <p>The Scottish National Blood Transfusion Service (SNBTS) is the preferred provider of bones, tissues and other cell therapies in Scotland. We have been at the forefront of clinical tissue/cell banking activity for a number of years and have been involved in the evolution of the regulation of tissue banking activities from the start. Initially we were part of the voluntary accreditation scheme (inspected by MHRA), followed by inspections by HTA and HFEA and more recently again by MHRA as regulation evolved and our range of activities increased. We are also aware that HTA is the newly appointed competent authority in the UK for organ donation purposes. This is relevant since a significant proportion of tissues are derived from organ donors as well.</p> <p>The inspections from HTA and HFEA (the subjects of this consultation) have been handled well, they are proportionate and risk based and we have built a good degree of mutual trust and respect. This has, in no small way helped to build and maintain professional and in particular, public confidence in clinical tissue and cell banking and transplantation.</p> <p>We are aware that the role of HTA in Scotland is limited to the licensing of clinical tissue establishments to ensure compliance with the EUTCD (2004/23/EC) and to a few other UK retained functions (particularly in relation to live organ donation) and our response needs to be seen with that in mind. There are a number of concerns from a Scottish perspective:</p> <ul style="list-style-type: none">A. The CQC has no locus in Scotland and it is our understanding that primary legislation would be required for this to change.B. The inspection processes are geared towards the safety and quality of the products we release for therapeutic use (human application) and to ensure that all consent processes are ethical. Although we have no experience of CQC, it seems to us that their processes are mostly geared towards standards of patient care-not product related /regulatory issues. These are specific and require an in depth knowledge of regulation concerning complex manufacturing processes.C. The HFEA and HTA have, over the past years, in their roles of competent authorities built significant expertise and knowledge of regulations and therefore our preferred choice would be to maximise the synergies between the 2 organisations to meet the necessary financial savings rather than replace them with an inexperienced organisation.
<p>2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?</p>
<p>Different EU and national directives in relation to tissue and cell banking have been transposed into UK law in a way that some tissue establishments including ours, are inspected by 3 different regulatory authorities- HTA for tissues and some cells, HFEA for gametes and MHRA for Advanced therapeutic medicinal products (ATMPs). Whilst this ensures high levels of safety and quality of all products, it does mean separate inspections from each regulator (in our case 3 on a biannual basis) resulting</p>

<p>in different requirements (some important, some less so) and different processes (e.g. SOPs/validations) for each group of products as each set of inspectors interpret the rules slightly differently. This causes inspection saturation, some confusion (all products should be of a similar quality and safety standards) and a significant degree of duplication of effort.</p> <p>We feel that synergies amongst the 3 regulators should be fully explored and exploited. It is somewhat strange that the possible extended role of MHRA has not been explored further in this consultation exercise. MHRA has extensive experience in regulating and licensing blood and it was the first competent authority to inspect tissue establishments (under the voluntary accreditation scheme).</p> <p>Currently the 3 regulators have already started to cooperate (either by having joint inspections or by accepting the findings of another regulator during a previous inspection). Such synergies should be fully and further explored to streamline inspection processes significantly and to produce the required financial savings both within the regulators themselves and within regulated organisations.</p>
<p>3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.</p>
<p>Not applicable</p>
<p>4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?</p>
<p>Possibly.</p> <p>As discussed in our response to Q2. The synergies of the regulatory functions of HTA and HFEA should be fully exploited as well as looking at possible synergies between them and those of MHRA.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>This would be a viable option. As already stated, streamlining of inspection processes would be very beneficial to all parties. Financial savings can also be made through either joint inspections or mutual recognition of inspections of common areas of interest. Clearly further savings can be made if management of either organisation is more integrated with each other.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>Yes.</p> <p>Both by reducing the regulatory burden and by management streamlining. See response to Q5</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>Possibly. In Scotland the HTA functions are limited to licensing of tissue and cell establishments, so difficult to comment. As a principle however, it is important that expertise, wherever possible should reside in one body. This ensures a critical mass of knowledge in specialised (eg regulatory) matters.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>SNBTS is not in a position to comment. Further synergies with e.g MHRA may produce further financial benefits</p>
<p>9. This consultation focuses specifically on where functions might sit and</p>

implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

It is our view that the regulatory functions should be streamlined, either by integrating regulatory management or streamlining the inspection processes in ways described above. It is important that the regulation of clinical tissue/cell banking remains integrated from the consent stage to retrieval, processing storage and release.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

No

11. Can you provide examples of costs and benefits of these proposals?

N/A

12. Do you have any comments on the consultation Equality Analysis?

No

Response 14 – Health Research Authority

Health Research Authority response to the consultation on the future of the Human Tissue Authority / Human Fertilisation and Embryology Authority

The Health Research Authority (HRA) is committed to creating an environment for research in the UK where greater numbers of patients can and do take part in research, and continue to feel safe when they do; applying to do research is simpler; and, researchers find it easier to do good quality ethical research. The HRA has set out an ambitious programme of work that will see it provide a unified approval process building on the success of the National Research Ethics Service (NRES) and the Integrated Research Application System (IRAS). Through NRES, the HRA has demonstrated how organisations can work effectively to deliver tangible improvements. The NRES and Human Tissue Authority (HTA) have a memorandum of understanding that ensures the roles of the NRES and HTA are mutually understood, respected and conducted so that activities are streamlined and there is no duplication. The success of this partnership and the improvements as they relate to research involving tissue are widely acknowledged and has made more tissue available for research. The HRA will continue to work effectively with the HTA and the successful partnership will be essential to further improvement.

The HRA recognises the opportunity for closer working with the Human Fertilisation and Embryology Authority (HFEA). The HFEA is an IRAS partner although the implementation of IRAS system improvements has not been previously prioritised because of the relatively low level of research applications to the HFEA. It will be important as the HRA takes forward the wider agenda to improve the research environment that the research activities of the HFEA are fully streamlined within a unified approval process.

The HRA believes it would be feasible under option two to transfer the HFEA research approval functions to the HRA. As a policy decision, the HRA would not include an inspection function within the HRA. If responsibility for inspection transferred to the HRA it would seek to delegate this to a suitable organisation. Equally, the HRA is confident that the required improvements and closer working could be delivered from the other options presented for the HFEA, and recognises that the research activity of the HFEA is relatively small part of the current remit. It is essential that this highly specialised research is supported effectively and that the potential and benefits from research are fully utilised.

13th September 2012

Response 15 - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	No - see attachment
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	No - see attachment
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	No - see attachment
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	Yes for HFEA, agnostic for HTA
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
10.	Do you have any other comments on the consultation proposals that you would like to share with us?
	Lumping HFEA and HTA together for this consultation is unhelpful because of the very different types of issues faced by these bodies
11.	Can you provide examples of costs and benefits of these proposals?
12.	Do you have any comments on the consultation Equality Analysis?

I am sympathetic to the general principle of reviewing and rationalising the extensive network of current NDPB's.

I do not think a case has been made for treating HTA and HFEA as part of a “package”. Although they both deal with regulation of some aspects of medical and research activity, the detail of what they do is very different; and in these specialised situations specific expertise is critically important – I would not want a heart surgeon, however skilled in his art, to operate on my brain. HFEA deals with a far more complex and rapidly changing set of bioethical issues; a more limited number of clinical providers; much more private sector activity; and a much more prominent and organised lobby of hostile opinion. HTA, although it does have some sensitive matters to regulate, is in my view much more of a monitoring organisation now; and the matters it deals with are not as technical and do not require the same level of specific knowledge to understand and manage – at all levels, from the technical inspection to the public presentation of difficult issues.

HFEA regulates clinical activity; but also interprets and explores the changing interface between the law and the ever-changing science in a rapidly developing area. It has managed this public interface with skill and sensitivity for decades, and the UK record of regulation in this area is enviable. It has built and retained real expertise in the area, at both inspectorate and advisory level. Unless the good governance of the field is to be sacrificed, which would be very retrograde indeed, this expertise will need to be retained and this will greatly limit any potential financial savings. Public and professional trust in a regulating body depends largely on its demonstrable competence and expertise, not on its broad management structure. Although there are certainly some valid criticisms of HFEA (perhaps in the detail of its clinical regulatory activity) it enjoys considerable public and professional trust, earned over decades of successful operation.

The CQC is a very different organisation. It covers a huge spectrum of activities over such a breadth that maintaining high level expertise is an impossible task; it is predominantly concerned with minute monitoring of healthcare organisations rather than reflective interpretation of new science; it is relatively new and does not have an unblemished record on which to base public trust. It has no relevant expertise and would essentially need to absorb the HFEA personnel, with attendant cost. They would be diluted within a large structure with other priorities. The senior management would not be able to speak authoritatively when new issues arise in this field. The consultation document suggests a possible saving from merging HFEA into CQC to be about £22k/year. To risk the decades-long record of good governance in a highly emotive area for such a small saving seems far too great a risk to me and I would unequivocally support retaining HFEA as a separate organisation, although certainly subject to review of the efficiency of its operation.

The HRA is brand new, has a wide and very different field to concentrate on, and I would not support giving it this additional distraction, at least until it has gained some years operating experience. The strength of HFEA rests on its coherence and field - specific expertise and any move to dilute this is unlikely to work as well.

Response 16 : Addenbrookes Hospital - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	Yes. This will make research regulation more streamlined and efficient. I believe it's best to do so in order that the UK maintains its status as a worldwide contributor in research. Industry from overseas and at home would welcome this approach.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	More efficient providers, benefits to NHS organisations
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	HRA is a new body created to regulate research related activities in England. Currently only ethics has been transferred. The transfer would sit well with their functions.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	No
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	No. The HTA have been constantly changing but without delivering any real efficiencies. Their functions are not so specialised and I haven't seen any real progress. I don't believe the public confidence they proclaim to have is there.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	Not at all. I envisage this will cost more to retain over the long run.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	I don't see the need of separate regulators related to research now the HRA have been created. Things should be streamlined – this was the mission
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	3.8M over 10 years is a significant saving to the public
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
	N/A
10.	Do you have any other comments on the consultation proposals that you would like to share with us?
	N/A
11.	Can you provide examples of costs and benefits of these proposals?
	N/A

12. Do you have any comments on the consultation Equality Analysis?

N/A

Response 17 – University of Sheffield – Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	Yes there are too many regulators in the same area with overlapping and sometimes conflicting policies and regulations.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	This could make substantial savings and reduce fees for service providers which pass the costs on to patients
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	Yes – the HFEA is primarily involved in regulating clinical practise. The fees charge to regulate research are disproportionately large and the process is bureaucratic.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	No
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	No – I believe it is time to scrap these bodies and fully revise the regulators
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	No – multiple regulators cannot efficient
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
10.	Do you have any other comments on the consultation proposals that you would like to share with us?
11.	Can you provide examples of costs and benefits of these proposals?
12.	Do you have any comments on the consultation Equality Analysis?

Response 18 - Leeds Teaching Hospitals NHS Trust and University of Leeds

CONSULTATION QUESTIONS	
<p>1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.</p>	<p>The CQC is an NHS facing organisation, many elements of the work of the HTA cover non NHS organisations, and particularly the University sector.</p> <p>This would reduce the profile of the regulation to the general public, the HTA regulating the compliance with the Human Tissue Act is obvious and the direct connection easily understood.</p> <p>There is no obvious link to it in the public perception</p> <p>The CQC is too big as it is without additional sectors.</p> <p>Merging with CQC would lead to pooling of expertise and staff as a matter of economy, the likely outcome that the HTA/HFEA type issues may come to be inspected by people working outside their comfort zone and knowledge base.</p> <p>HTA expertise will be lost as the CQC wave a big stick often without the understanding of what they are doing and why. This would be no good for public confidence and the work the HTA has already done to abolish the old public perceptions of organ / tissue retention.</p>
<p>2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?</p>	<p>This will be a significant risk with regard to effective communication.</p> <p>Seeking advice on issues may be harder to obtain.</p> <p>100s of University, Trust, Departmental Policies and Standard Operating Procedures to name a few would have to be re-written to take account of changes of name, address, contact telephone numbers, website details and links to all HTA relevant documents.</p> <p>All other controlled documents within the Trust Divisions Document Control system relating to or referencing the HTA would have to be changed, reprinted and reissued.</p> <p>The Trusts Intranet HTA website and University website page would have to have to be re written.</p> <p>The cost to the Trust and University's across the country to complete the above would be significant. IF a central government saving it certainly would be a saving to local establishments. Would it not be a case of a 'robbing Peter to pay Paul' scenario?</p> <p>The role of the HTA Manager in Leeds would no longer exist in its current form.</p>
<p>3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.</p>	<p>NA to our HTA Licences</p>
<p>4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?</p>	<p>If the HTA has to be abolished the MHRA would have the expertise to work effectively with HEI's as they increasingly already do for cTIMPS.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but</p>	

deliver further efficiencies? Please explain why you think this.
<p>This was the overall preferred option of most respondents. (The only exceptions were 2 new PDs who felt they did not have the knowledge base to make an informed decision rather than preferring other options).</p> <p>The HTA provides an effective and timely service which provides a clear external facing regulatory support and audit function which delivers public confidence. Clear organising bodies but internal review could identify areas of savings e.g. duplication of roles / tasks.</p> <p>Remaining intact as it is, the HTA would keep beaurocracy reduced and allow a dedicated and focused system to operate.</p> <p>Change now would result in loss of work so far and the public wouldn't understand. Retain existing HTA but money could be saved with an even lighter touch to inspections which focus on advising best practice and spotting overt flagrant law breeches rather than small print issues.</p> <p>HTA to remain as is but provide evidence of the benefits of promoting research.</p>
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
<p>Dealing with failure to manage statutory responsibilities creates a significant cost, without the HTA the load on HEI's, which are publicly funded, will increase particularly dealing with a regulator without experience of the sector.</p> <p>Yes but more work would be needed to ensure any cost cutting did not impact on the vital service provided.</p> <p>Joint working with CPA, better management of microscope slide retention and traceability.</p>
7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
For the HTA no
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
No
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
No
10. Do you have any other comments on the consultation proposals that you would like to share with us?
No
11. Can you provide examples of costs and benefits of these proposals?
No
12. Do you have any comments on the consultation Equality Analysis?

No

Response 19 – Individual

Please give consideration to our viewpoint as the parents of a child conceived using a donor.

I am EXTREMELY concerned that the HFEA is being looked at purely as a record-keeping, administrative agency. This agency is vastly more important than this, and as such should NOT be slotted into the CQC.

We are a family created with the reassurances provided by the HFEA. Our daughter may wish to contact the HFEA for vital information regarding future relationships, whether in relation to a sexual partner, or knowing about siblings, or about the donor. Children younger than her will be finding out, in years to come, life-changing information about their donor.

These are HUMAN issues with potentially enormous psychological impact on all concerned, including the donors and their families. The HFEA MUST be a separate body, that will have to expand its remit to cover counselling, and support, and will probably for evermore be embroiled in ethical issues around the whole issue of assisted fertility.

I am aware I am ignorant of the workings of the HFEA, and also how efficient it is/isn't. What I would like to convey is that although this entire consultation is on finances, savings, efficiencies, I am despondent to see no reference to the human element. What if the human need outweighs the need for savings?

CONSULTATION QUESTIONS	
1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.	No I do not agree. I believe the HFEA has a significant role in regard to duty of care to the families created. This is not a medical or tissue issue, it is a human issue. In particular I am concerned about their most important role in being the first contact for children born using donor gametes, and their need for information to be handled sensitively and with counselling opportunities.
2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?	I do not think something as important and significant as this should be absorbed into the CQC which is already struggling for any kind of regard. We are talking about regulation in regard to human beings and their future lives. I fear that a young adult making first enquiries would not get the level of understanding that the HFEA as a separate unit would have.
3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.	I believe that research should stay in the remit of the HFEA. Again, there are ethical considerations which I think would be best handled by the HFEA.
4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?	There is no better organisation than the one already here in the form of the HFEA. I think it should stand alone. If you are worried by inefficiencies, this can be improved without losing them.
5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.	I accept that there may be areas where efficiency could be improved if everyone was

under one roof. However I believe that the independence of the HFEA is important. Therefore if they are able to deliver further efficiencies RATHER than being moved to within another agency, so be it.
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
I have no idea – my concerns are for the human beings that are at the centre of this.
7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
If anything there will be a need to expand and add functions, such as counsellors, as stated before.
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
10. Do you have any other comments on the consultation proposals that you would like to share with us?
As you may see, my main concern is that although savings may be at the heart of this consultation, and I am prepared to accept that efficiency may be improved, above all I feel that the HFEA is too important to families to be absorbed into another agency, and should remain separate and available to us.
11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?

Response 20 - Parkinson's UK

Overview of Parkinson's UK

Parkinson's is a progressive neurological disorder for which there is currently no cure. It results from the loss of the chemical messenger dopamine within the brain and affects learned voluntary movements such as walking, talking, writing and swallowing. As the condition progresses it impacts on all aspects of the person's life and the lives of those around them.

As well as the symptoms that affect movement, people with Parkinson's can find that other issues, such as tiredness, pain, depression and constipation, can have an impact on their day-to-day lives.

Every hour, someone in the UK is told they have Parkinson's. One in 20 is under the age of 40. There are approximately 127,000 people with Parkinson's in the UK.

We bring people with Parkinson's, their carers and families together via our network of local groups, our website and free confidential helpline. Specialist nurses, our supporters and staff provide information and training on every aspect of Parkinson's.

As the UK's Parkinson's support and research charity we're leading the work to find a cure, and we're closer than ever. We also campaign to change attitudes and demand better services.

Our work is totally dependent on donations.

Future of the current functions of the HFEA and HTA

- In terms of the Government's consultation on where the current functions of the HFEA and HTA should lie, Parkinson's UK believe option 1 is the preferred option:
 - transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA; and abolish the HFEA and HTA.
- Parkinson's UK has for a long time expressed concerns regarding the HFEA and stated that it needs radical change.
- Back in 2004, Parkinson's UK (as the Parkinson's Disease Society) responded to the House of Commons Science and Technology Inquiry into the HFEA.
- In this response we stated that it is limiting to have the same authority dealing with the ethics of human reproduction, the policing of practice, ethics of use of products, human reproduction for research and treatment and policy of research practice.

- The responsibilities of the HFEA are too wide ranging and this has resulted in areas of great importance – such as the research agenda - not receiving proper consideration. Explicitly, our view is that the research agenda, which is a high priority for Parkinson’s UK and its members, proceeds at a faster pace than HFEA is able to regulate and inspect.
- We believe that research does not have a high enough priority within the HFEA meaning that research in this country is being hampered.
- It is now 8 years on since our response to that Inquiry, and Parkinson’s UK position on this issue remains unchanged.
- Parkinson’s UK therefore supports the proposal to remove the research remit of the HFEA and transfer this to HRA, with the following caveats regarding the role and remit of the HRA (we will also submit the following comments into the upcoming consultation on the draft Care and Support Bill which covers the setting up of the HRA as a statutory Non Departmental Public Body):
 - Patient and public involvement needs to be built into the system – getting this right is central to public confidence in the regulation of health research. The HRA needs to outline how it will achieve this important function
 - What powers will the HRA have to streamline the regulation of health research? Obtaining all the necessary local NHS R&D permissions is recognised as a big barrier to research projects getting off the ground. However, the HRA is not planned to take control of these permissions. Instead a 70-day target has been introduced and NIHR research funding is contingent on it being achieved. How effective will this target be in practice in streamlining R&D permissions, and how will this target be coordinated with the streamlining work of the HRA?
 - How will the HRA be able to support and develop a culture of research across the NHS?
 - What is the HRA’s role in regulating access to identifiable patient data for research? Currently the Secretary of State for Health is responsible for approving exceptional research projects which need to access identifiable data without consent. This responsibility is planned to transfer to the HRA by April 2013. We are concerned to ensure this regulatory role finds the right balance of protecting patient confidentiality and allowing valuable research to go ahead.
- In regards to the non-research functions of the HEFA and HRA which will transfer to the CQC, we have concerns around this transfer, which mainly stem from a lack of confidence in the CQC. We would like the following to be taken into consideration:
 - The CQC has a huge remit – to independently regulate, inspect and review all health and social care services in England
 - In addition, the newly created HealthWatch England is also to be a statutory part of the CQC

- The CQC has been under intense scrutiny over the last few years, with separate inquiries by the Department of Health, National Audit Office and Commons Public Accounts Committee. These were prompted by a series of criticisms of the organisation's ability to do its job.
 - We are therefore concerned that the CQC may not have the skills or resources to take on board the highly specialized functions from the HEFA and HTA.
 - We seek clarity from the Government, regarding how the CQC is fit for purpose, and in particular, how it is fit for purpose in terms of the skills and resources required to take on these additional functions.
 - We also believe that the specialist functions of HEFA and HTA – for example, functions such as maintaining a formal register of donors, treatments and children born as a result of treatments – should be kept as separate function within the CQC.
 - Parkinson's UK is concerned that by moving these many functions to the CQC, the result will be a body that has too wide a remit to give the various functions the right attention, thus defeating the purpose of this integration and mirroring the issues that we have experienced with the HEFA over the previous few years
- Parkinson's UK would be happy to expand on any points made in this consultation response

Response 21 - Brunel University Research Ethics Committee

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	Yes, this move can consolidate the regulating landscape and make it more efficient by reducing the number of health care related ALBs.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	Depending on whether service providers are currently regulated by more than one body (often already CQC, HFEA and HTA), the burden of being regulated (bureaucracy, fees) can be lightened. If a provider is mainly working with one regulator (e.g. HTA), than impact of transferring functions will largely be dependent on the improved efficiency, quality and fee structure of the new regulating entity. Care will also have to be taken that the expertise of specialized ALBs is not lost when transferred over in a larger body that covers a wide scope or services.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	Yes, if the HTA and HFEA are to be dissolved, than it would be appropriate to house the specific research related function of the HFEA under the HRA, as the nature of this aspect of HFEA's work is probably more aligned with the remit of the HRA than that of the CQC.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	Not really.
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	This could prove a satisfactory model if service providers were predominantly regulated by one body only. As at present service providers are often regulated by more than one body at the same time, it would be better to merge the activity under one umbrella.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	If the specialist knowhow and practice of the HFEA and HTA can be maintained while bringing their regulatory functions under one efficient body, that would be the best approach as it will guarantee maintaining standards with less bureaucracy.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	One could discuss whether not only HFEA's research function, but also that aspect of HTA regulation focused on human tissue research should be considered to go under HRA.
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	/

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

/

10. Do you have any other comments on the consultation proposals that you would like to share with us?

/

11. Can you provide examples of costs and benefits of these proposals?

/

12. Do you have any comments on the consultation Equality Analysis?

/

Response 22 - Biovauld Ltd

Dear Sirs,

Please find my organisation's comments in response to the consultation regarding the future of the HTA. The context is that these comments largely apply to the HTA as a regulator of the storage of tissue for Human Application and the briefest experience of HFEA in applying for a licence.

Aligning the human application function of the HTA's remit with the CQC would be retrograde as there is little or no synergy or understanding of the technical issues or legal functions. The concept that efficiency will be achieved by "only one organisation being responsible for inspections" is simplistic.

Within the framework outlined in the first paragraph, the HTA is a responsive, streamlined regulating Authority with a proportional approach to their activities. From the regulated institutions viewpoint they appear to be largely self-funding from the Licence fees. The Authority has proven to be an effective, lean organisation which, if their annual reports have been accurate, has been run at low cost to the tax payer while significantly raising standards in the sector. To lose this in the mush of the CQC, who are clearly struggling to fill their current, disparate remit, would be less than sensible.

A confusing presentation of the background reasons leading to a consultation of the future of these organisations does not help the analysis of the true situation and "facts" can be tailored to fit any argument. The problem with assessing the true drive behind this initiative is that the only issue raised prior to this consultation has been the HTA's status as a quasi-autonomous non-governmental organisation with no direct responsibility to a Minister. The issue of "efficiency" has never been dominant. Indeed the HTA has worked very hard to be, and be seen to be, efficient. It is funded (Grant-in-Aid) centrally for its statutory duties, which will remain extant regardless of any action following this review, and the remainder is funded by the licenced organisations. The regulatory burden is not going to change unless there is a review of the relevant Act; this is not proposed. The expert resource required to achieve the regulatory activity is largely not going to change. The proposal is down to labelling and the saving of some peripheral administration roles. Any net savings made will be swamped by the costs of changes to, and the disruption in, the sector. The actual result of change will be simply moving the cost burden around, largely within publicly funded departments.

In sum, real efficiency (which in this context is probably being measured only as a saving in public funding) is unlikely. Conversely, savings in other publically funded areas (the NHS as licenced establishments) will not materialise as similar resources, from all parties, will be required to satisfy the licencing requirements. "Savings" in one area will, simply lead to "cost" in another; great for the proponents of the change, but not really effective in the wider view.

We hope this consultation is not a forgone conclusion or a another effort to appear to be efficient and effective by introducing unnecessary change. The indicative sums to

be saved, even if achieved, are not worth the effort of the consultative process let alone the turbulence it would produce in the sector, the loss of focussed expertise, or the reputation of the UK in leading the thought processes regarding Human Tissue. The reality will be unnecessary disruption in a sector which has only just settled down under the HTA.

Specific Consultation Response

Q1. **Strongly disagree.** Within the context above the HTA function in the Human Application sector does not align all with that of the CQC and is better either left alone or, in extremis, placed elsewhere. In this sector there is no synergy in expertise between the CQC and HTA. The consultation paper implies that many NHS establishments are inspected by both the CQC and the HTA; a true, but totally irrelevant observation. The point here is that detailed inspections by experts will be required regardless of how these individuals are labelled, there will be no fewer inspections (the HTAct requires a fixed frequency), no fewer staff and no reduction on the sector to pay for the resource required; the proposal is flawed.

Q2. It would potentially be a **retrograde step**, diluting the focussed experience amassed in the HTA, reducing the contribution the UK makes in the control of tissue, introducing new and not necessarily productive factors into the equation for the regulated establishments while producing, at the best, zero benefit in terms of the quality of tissue used to treat the patient.

Q3. No view in this respect.

Q4. **Agree, but only if no option for the HTA to remain unchanged.**

The Human Application function of the HTA partially aligns with the functions of the MHRA and, indeed, the boundaries of the regulatory requirements of the two organisations are very blurred and will become more so as human tissue becomes increasingly manipulated for therapeutic use. To have a seamless organisation with responsibilities across all materials for human application would possibly help control the standards of the sector to the benefit of the health providers, the producers of material for therapeutic applications and the welfare of patients. There is an opportunity to strengthen the functions of both regulators during any forthcoming change. However, the remit of the existing entities are very different and the two organisation are already co-operating to good effect in this respect.

Q5. If sense is to dominate, **very strongly agree.** The HTA currently functions extremely well at low cost to the taxpayer; “efficiency” has only recently been added as a real consideration. The HTA is lean-manned for its tasking, well organised, motivated and committed to fulfil their regulatory remit with an appropriate approach. The HFEA is effective in fulfilling its function, internally inefficient, but the problems could be best solved by improved management practices and not a major perturbation.

Q6. HTA – the organisation has always presented its regulating function as self-financing; an element of its tasking comes from statutory requirements (Grant-in-Aid) so it is unlikely that there could be a significant reduction to this relatively small element regardless of where the responsibility lies or what label is applied. Conversely, regardless of where the regulatory responsibility lies in the future, the element coming from the public purse will not change

unless the statutory element changes, in which case this saving could be made with the HTA in its present form.

Q7. The HTA clearly operates as a cohesive entity with responsibility for regulation under the Human Tissue Act and the EU Tissue Safety directives; it seems a retrograde move to a split responsibility and lose focussed experience for no real tangible overall gain.

Q8. The cost/benefit analysis has no evident supporting background to the assumptions made and is too coarse to draw any conclusions regarding its validity. However, true savings of somewhere between £3.9m and £8m over the period in view on an organisation costing the public purse largely only Grant-in-Aid seems very optimistic. If the median values are realised, the disruption and cost burden in the sector is simply not worth the level of savings forecast.

Q9. Covered in the preceding paragraphs.

Q10. Covered in the preceding paragraphs.

Q11. The true costs of these proposals will be borne by the licenced sector in terms of a less focussed service from the regulator. It would be better directly identified and covered by proportionate licence fee increase rather than hidden in “efficiencies” but ultimately the cost of the outcome of this consultation is will be paid for by the licenced establishments.

Q12. None.

If the merging of the CQC and the HTA is not a forgone conclusion, the proposals in Options 1 and 2 and their underlying assumptions in the consultative document are seriously flawed and should be abandoned. Merging with the MHRA, within the context of this response, is the “least worse” alternative.

In sum, as the HTA is not broken so should not be fixed. Any “efficiencies” suggested in alternate Options, perceived or actual, are simply outweighed by the loss of strategic, focussed direction in a very important and standard-leading sector.

Response 23 – Association of Biomedical Andrologists

R23 : Association of Biomedical Andrologists

Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

The ABA do not support the abolishment of the HFEA and the transfer of its functions to the CQC. We believe there is a distinct benefit in retaining the HFEA name and its experience as a specialist regulator in this complex field not only to ensure public confidence but to ensure effective and consistent regulation. The HFEA is a well established organisation and brand and the HFE Act holds national and international recognition. The HFEA has, since its establishment in 1991 dealt with ethical and policy issues, developed clear Code of Practices and improved the inspection process. It is not however without fault and has been open to criticism both publicly and privately which has prompted a more open culture and engagement with the sector. That said the model is respected in the UK and overseas and to lose that seems dangerous in a time where the regulatory and ethical challenges in the sector are on the increase. The HFEA is well established and has within its infrastructure a vast amount of experience which may be lacking of the CQC. Such experience includes;

- Composing, maintaining and updating a code of practice
- The collection of data and the maintenance of the HFEA register.
- Electronic submission of clinic performance data
- Direct experience in the inspection and regulation of the fertility sector
- Enforcement of the HFEA Act 1991(2008) and dealing with non-compliant and under performing clinics in the sector appropriately.
- Long forged relationships with professional bodies and learned societies representing nurses, clinicians and scientists working in the sector.

Whilst we believe there is an advantage for the HFEA to remain in something close to its current guise, we are aware of the cost saving element of amalgamating the HFEA into the CQC and the steps which have been taken already to achieve savings in relocating the HFEA to the CQC offices. The ABA believe that a situation where the HFEA works as a not for profit department of the CQC would work efficiently both to reduce the inspection burden to clinics and prevent the loss of the skills, knowledge and experience which make the HFEA a world respected fertility authority.

Furthermore, it is unclear if the CQC have the IT systems to support the databases and secure systems needed to maintain absolute confidentiality. This essential function should not pose a problem moving forwards were the HFEA to become a subsection of the CQC. The financial impact of creating new systems and their testing, training and implementation should be taken into account. Contracting system management out to an external provider

(one option) would result in additional unnecessary expense and may be of concern to clinics and patients regarding their confidentiality and may lead to difficulties for clinics, patients and researchers to be able to contact those maintaining the register and get access to data efficiently.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Clinics require a framework of guidance and regulation in which to operate. This is currently provided by the HFEA who are astute and experienced enough to recognise the part that professional bodies and their published guidelines for good practice and the clinics themselves as consultants can play in making service provision at a local level safe, consistent and in the best interests of public safety. Although many areas of medicine have their own guidance, fertility treatment is unique in the consequences of any never events. Whilst IVF treatment can now be regarded as routine medical practice and it is appropriate to prevent sensationalism to patients and the public, it is essential that a solid regulatory framework is maintained.

The HFEA is a recognised point of contact with patients, clinics and the media. Its removal would dilute this into the CQC, a much larger body. If the identity of the HFEA within the CQC infrastructure is protected this could to a big extent be avoided.

Without the HFEA, the burden of regulation, inspection and maintenance of the Code of Practice would fall into the hands of CQC. Without the experience of the HFEA behind them, we are concerned that the CQC would be less effective at ensuring best practice across the sector.

The ABA questions how the CQC can maintain the level of detail required for HFEA inspections. Can CQC, as a much larger organisation, maintain oversight of the relatively small functions of around 120 fertility clinics, continue to work with them closely and maintain the knowledge to perform detailed inspections? Is the CQC inspection process, which is designed for large organisations, appropriate for small independent fertility clinics? Would they be as in-depth or as stringent as required and would the result be an inadvertent relaxation of the inspection process?

As 90% of HFEA licensed centres are regulated and inspected by the CQC, Many of these will also now be inspected by the UKAS/CPA. A single licensing inspection would save considerable costs, and be less of a burden for both the inspectorate and the clinics.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Although the HFEA plays a part in the regulation of research work, this is only a small part of its function when compared to the clinical regulation and inspection burden. The establishment of the HRA is both a logical and progressive approach to research regulation which the ABA supports.

However, to ensure that the sector and its unique moral and ethical challenges are best represented moving forwards, it should be ensured that some of the existing expertise is transferred to the HRA. This will ensure that the uniqueness of the creation of human life and research into its many avenues is not underestimated, overlooked or progress seen to be unfairly limited. There are a number of key ground breaking proposals on the HFEA's agenda at the moment (e.g. mitochondrial transfer) which require careful public consultation, evaluation and cautious progress into clinical testing. We are not confident that an HRA working without the expertise of the HFEA would be able to effectively manage this process and the consequences could be disastrous.

The mechanism by which the HRA will access (or grant access) to the HFEA register for contact or non-contact researchers will need to be established and tested to ensure that data is not shared inappropriately or in a way that breaches the confidentiality of any individual or group of individuals.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

The ABA do not see a viable alternative to that described above within the current infrastructure. The MHRA and UKAS, as alternatives, would be viable in our view due to the nature of their practice and the existing burden of inspection. If a mechanism could be established to involve UKAS in a single inspection process for clinics moving forwards, the ABA would be highly supportive of this.

What is important is to minimise the inspection burden to clinics and to those carrying out inspection. If the HFEA were to sit as a functional unit of the CQC whilst maintaining its own brand and identity, it could perform an inspection that would cover the requirements of both. This would reduce the inspection burden both to the clinics and to the regulator. This would also result in financial and time-saving efficiencies for all parties involved.

This model would afford the HFEA the same remit as the CQC to close a poorly performing clinic. This would ensure that the inspection is taken seriously at the highest level within the institution being inspected. This in turn would increase the presence and leverage of a licensed fertility centre within a larger parent organisation which would without doubt be a positive change moving forwards.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

The HFEA need to adapt and have already made steps to do so. As professional bodies we are well aware that the HFEA have become more engaging and willing to listen to us in the previous two years. The paperwork burden for licensed centres is still too high; the amount of information

collected on individuals undertaking and born as a result of fertility treatment is too high; and the HFEA needs to continue to work closely with and consult with professional bodies to direct the future of the sector in a sustainable and progressive way. There is a feeling that the UK is over-regulated and measures should be taken to reduce this safely and realistically rather than to disband the regulator.

What is important is that there is the opportunity to completely review and overhaul the role, function and performance of the HFEA as part of this process. There are clear efficiency improvements that can and should be made.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

Amalgamation into the CQC will make clear savings both in infrastructure and, with careful planning, with the added advantage of a reduced inspection burden to clinics. Cooperative working with UKAS could lead to even further savings.

The HFEA should be seen as not-for-profit. For a regulator to announce profits of £3.5 million in times of recession, having accrued fees principally from patients, is both damning and inexcusable. Where possible, the cycle licence fee should be reduced or abolished.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The research function should be transferred to HRA in a manner that ensures that the expertise and experience the HFEA have gained in regulation of human embryo research is maintained.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

The cost saving with reducing salaries for the chairs and chief executives is substantial, but effective regulation has to be priority. Reducing overlap in inspections is a more practical and sensible way to reduce costs which can be achieved through more collaboration between the CQC and the HFEA without losing the identity of the HFEA and its presence in the sector. The most effective way to achieve this is to align the two and for the HFEA to become a department of the CQC. Cooperation with UKAS should also be encouraged.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

ABA has no comments on this matter
10. Do you have any other comments on the consultation proposals that you would like to share with us?
ABA do not believe any of the options detailed in the consultation documentation are the right and proper way forward. A fourth option, to retain a rationalised and efficient HFEA core and identity working within the CQC with a reduced inspection burden for the regulator and the clinics would confer a number of key benefits the other options cannot deliver .
11. Can you provide examples of costs and benefits of these proposals?
ABA cannot provide this information
12. Do you have any comments on the consultation Equality Analysis?
No Comments

**Response 24 - Human Fertilisation and Embryology
Authority**

Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

Response by the Human Fertilisation and Embryology Authority

September 2012

1 Executive summary

The **regulation of assisted reproduction and embryo research in the UK has been a success**. It has enabled thousands of women to have a long-wished for child in safe clinical surroundings. It has been flexible enough to respond to the development of new treatments and scientific research, within a widely accepted ethical framework. And it has maintained the confidence of Parliament and the public throughout.

The controversy which has surrounded assisted reproduction and embryo research in many other countries outside the UK shows how well the ‘bargain’ struck by Parliament between science and society has worked.

The Human Fertilisation and Embryology Act 1990 established a dedicated, specialist regulator to oversee the creation of life. Since then, the HFEA has developed a regulatory regime with three integrated functions at its core:

- It **sets standards** for the sector in respect of the procedures that need to be followed by a clinic or laboratory, the care that patients and donors can expect, and the information that they should receive in order to be able to give properly informed consent
- It **enforces those standards** in a way which is proportionate and risk based
- It **safeguards information** in a way which protects the interests of patients, donors and children born as a result of assisted reproduction, and also enables vital research to be undertaken using that same information.

At the heart of this regulatory regime is the embryo, the patient and the donor-conceived person. We track the embryo, in both treatment and research. We provide the patient with essential safeguards and accurate information to enable them to make informed choices about their treatment. And we provide a means by which donor-conceived adults can access information about their genetic origins –

information that we hold in trust, for all time. The integrated nature of the three functions enables us to do these things in a joined-up, consistent way.

The consultation issued by the Department of Health seeks views on three options:

1. That all of the functions of the HFEA are transferred to the Care Quality Commission (CQC), with the exception of those relating to embryo research which would transfer to the Health Research Authority (HRA)
2. That the functions of the HFEA are transferred to a range of bodies
3. That the HFEA should retain its existing functions but deliver further efficiencies.

It is argued that **Option 1**, by keeping most of the HFEA's functions together, delivers the best of both worlds: a dedicated expert resource, with the same legal framework, operating within a larger, and inherently more efficient and less burdensome, regulator. We disagree.

- Transferring a small dedicated, expert regulator like the HFEA into a large, general regulator like the CQC presents real operational risks. Staff may leave and corporate memory be lost. Complex issues relating to assisted reproduction might get insufficient senior attention in the CQC, with the result that mistakes are made; or they might take a disproportionate amount of the Board's time at the expense of the important issues the CQC already regulates. This could undermine the public's confidence in the regulatory system. Once lost, restoring confidence would be difficult and expensive.
- The law will remain the same, so the detailed regulatory requirements set out in the Act will still need to be administered by the CQC. Those who hoped that this consultation would usher in a different regulatory regime will be disappointed.
- And while we understand the need to release savings for the front-line, abolishing the HFEA will not make a real difference. In the context of the expenditure on the NHS, the costs savings that are claimed to result would be miniscule.

- The transfer of the HFEA embryo research functions to the HRA offers a simplified approval process for researchers. This is clearly an attractive prospect, but it carries risks and the benefits can be achieved by other means. We believe that there is one key argument against this proposal: it separates the oversight of the embryo between treatment and research and makes the regulatory regime more complex (and duplicates administrative cost), not less.
- In summary, we are of the view that **Option 1 would lead to a reduction in the quality of regulation, put at risk patient and public confidence, and deliver, at best, minimal efficiency savings.**

It is argued that **Option 2** also delivers efficiencies and it transfers functions to those bodies best placed to carry them out. We believe that **Option 2 has no merit and will only lead to greater inefficiencies:**

- The inter-linked nature of the existing regulatory regime will be lost and there is a real risk that the separation of functions will lead to mistakes which may, in turn, reduce public confidence.

It is argued that while **Option 3** would maintain continuity and quality, this option would not deliver the efficiencies sought, nor would it reduce the complexity of the regulatory landscape. Again, we disagree:

- We have already made substantial efficiencies over the past three years: our total expenditure is down by 25%, public subsidy down by 33%, staffing down by 20% and we have introduced a 28% reduction in the fees we charge to the sector. We can go further.
- We can also resolve the policy challenges set out in the consultation document. The modest regulatory overlap which exists between ourselves and the CQC can be resolved without a transfer of functions – that work is already underway and we set out in this response a proposal to make assisted reproduction clinics subject only to one regulatory regime.
- It is possible also to improve the experience of researchers by closer working between the HFEA and the HRA to provide a seamless research application process. We set out in this response a proposal which would see researchers

making a single application through the integrated research application service IRAS, with the HRA considering issues of ethics approval, patient consent and peer review; and the HFEA maintaining responsibility for licensing and inspection. Such a proposal would build on the expertise of the two bodies, reduce the administrative burden for researchers and, crucially, ensure the special status of the embryo continues to be safeguarded.

In arguing for Option 3 we are not simply arguing for the status quo. We recognise that this option assumes that an independent HFEA would be required to deliver further efficiencies and improvements, and we would be happy to be publicly accountable for their delivery. We have already delivered most of our share of the savings required by Government in the Spending Review period. And we can go further.

- Our support for option 3 is not because we believe that we are perfect. Further improvements can, and should, accompany further efficiencies. We have radically reformed the way we regulate over the past three years, and that work is not finished – for example, we are committed to improving the way in which we collect, validate and make available the information on our Register that we are required to hold.
- There are new models for the delivery of public services emerging in both local and central government, which offer radical savings through greater collaboration. We are willing to think through how such models might apply to the work we do, alongside other healthcare regulators.

In summary, we believe that **Option 3 delivers the highest quality regulation at the most efficient cost**. We say this because we believe that an expert dedicated regulator is best placed to maintain public trust and manage risk, in what is still a highly charged area of medicine.

2 How the Human Fertilisation & Embryology Authority (HFEA) regulates

Summary	
Our functions: We set and enforce standards, and safeguard people's information.	Main points to note: <ol style="list-style-type: none">1. These functions are fully integrated and each informs the other.2. This joined-up model is critical in such a fast-moving and highly charged area of science and ethics.3. Parliament was wise to set us up in this way. Anything else would be too slow to respond, and would have other risks attached too.4. This model has the public's confidence – because it works.

The HFEA was established in 1990 – one of the first statutory health regulators in the UK, reflecting the controversial nature of assisted reproduction and embryo research.

Twenty-two years on, it is clear that the regulation of assisted reproduction and embryo research in the UK has been a success. It has enabled thousands of women to have a long-wished for child in safe clinical surroundings. It has been flexible enough to respond to the development of new treatments and scientific research, within a widely accepted ethical framework. And it has maintained public confidence throughout.

Principally, the HFEA:

- **Licenses clinics:**

Providing IVF treatment and undertaking research using embryos. Such clinics must comply with our Code of Practice and with licence conditions, which we check on inspection, and report all serious incidents to us – which we investigate

- **Makes policies:**

For example on sperm and egg donation, where we recently increased the amount of compensation donors can receive

- **Makes decisions relating to the treatment of serious inherited conditions:**

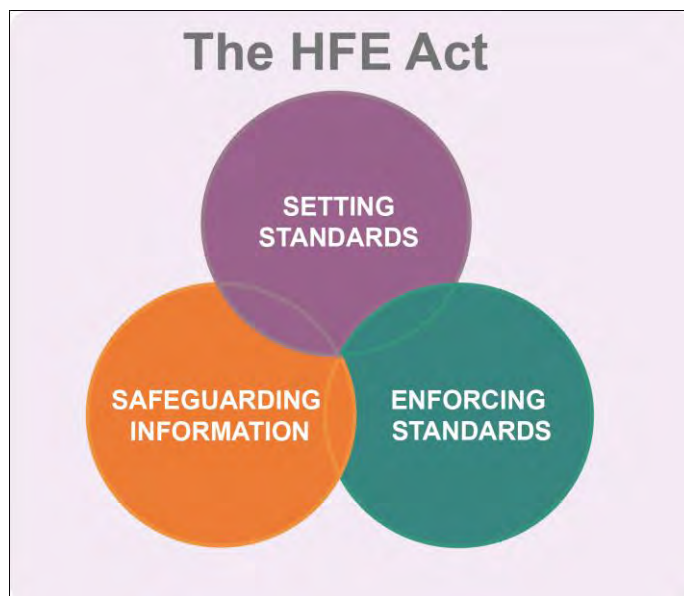
We authorise screening for specific and serious conditions that can be diagnosed in embryos prior to implantation in a woman

- **Keeps personal and identifiable information:**

About donor treatments and children born as a result of those treatments.

At the heart of this regulatory regime are the embryo, the patient and the donor-conceived person. We track the embryo, in both treatment and research. We provide the patient with essential safeguards and accurate information to enable them to make informed choices about their treatment. And we provide a means by which donor-conceived adults can access information about their genetic inheritance – information that we hold in trust, for all time.

The HFEA performs three main functions around which our staffing and other resources are organised:



The inter-related nature of these functions – with each informing and learning from the other – allows us to perform our statutory functions, as set out in the Human Fertilisation and Embryology Act 1990 (HFE Act), in as efficient and effective a manner as possible. Over our 22-year history, we have developed a regulatory model which takes advantage of Parliament having established a dedicated, specialist regulator presiding over a sensitive area of laboratory research and clinical care, about which the public regularly express concern.

Setting standards

Whilst the HFE Act establishes a clear legal framework within which assisted conception and embryo research could be provided, Parliament also wisely gave the HFEA the power to make policy and develop detailed guidance for practitioners. This allows regulation to adapt and respond to developments in clinical and laboratory practice, shifts in public attitudes and new demands upon services based on wider demographic and social changes – all without the need to return to Parliament to amend the legislation.

The Authority has a duty to maintain a Code of Practice, issue Directions and add conditions to licences, so licensed clinics and laboratories meet appropriate standards of care for patients and donors and those for facilities and equipment in clinics or laboratories. This covers, for example, the procedures and practices carried out in the clinical laboratory to ensure that gametes and embryos are

correctly collected, stored or transferred to the patient. It also covers the important information that we expect clinics to give to patients and donors before they give consent to treatment, storage, donation, parenthood or the disclosure of personal information.

We have developed robust practices for ensuring that the regulatory frameworks and tools set out above respond to the differing needs and views of the HFEA's key stakeholders (patients, donors, donor-conceived people; the nurses, scientists and doctors and other practitioners working in clinics and research units; and the wider public). These practices include careful research and consultation with external audiences, including the use of up-to-date methods of public engagement and dialogue.

Crucially, we also take advantage of the integration of our three functions by identifying gaps or problems with existing standards and evaluating new ones through feedback from Inspectors and Licence Committee members (Enforcing standards) and by analysis of data submission to and outcome data on the Register (Safeguarding information).

Enforcing standards

As we say above, licensed clinics and laboratories operate according to standards developed in consultation with professionals, patients and other key stakeholders. We ensure centres understand and comply with standards, and report our assessment of compliance to Licence Committees, which decide whether or not centres continue to be licensed.

As part of our modernisation of regulatory processes, our inspection team has developed a risk-based approach to compliance with standards, using live data from the Register to monitor activity in clinics and to make interventions where performance is slipping. This on-going monitoring, of multiple births for instance, allows us to measure the impact of our policies and refine them in a way which continues to drive improvements.

Inspectors have developed a close relationship with licensed centres, providing guidance and advice to help them comply with the law. The standards set out in the HFEA's Code of Practice have been developed with the involvement of inspectors, who can therefore convey the spirit and intention of policies to the centres in their inspection portfolio.

Safeguarding information

Reliable, accessible and transparent information is at the heart of 21st century regulation. Maintaining the world's largest Register of fertility treatments and outcomes (which includes details of the genetic origins of donor-conceived people), as well as running a joined up inspection and policy function puts us in the privileged position of holding high quality intelligence about clinic and sector-wide performance, trends and risks.

We provide information to patients about pregnancy outcomes, both across the wider IVF sector and in individual clinics. We do this by publishing *Choose a Fertility Clinic*, an online, freely searchable tool providing outcome data for the entire UK IVF sector

and updated every six months. This anticipated the now much more widely understood relevance of transparency for driving improvement and enabling patient choice.

More recently, following changes to the Act in 2008, we can make data held in the Register available to academic researchers. We have embraced this opportunity, and researchers have started to analyse data prepared by our staff, drawing conclusions about the health effects of IVF on children and women, for example.

The most important aspect of our information work is as guardian and provider of information to those born as a result of donor treatments, to their parents and to donors. Recent changes to the law have extended the access rights of donors and donor-conceived people, a move we welcomed. Responding to these enhanced access requests from a growing number of individuals (sometimes vulnerable) has been absorbed without additional resource by our highly skilled staff, trained in counselling techniques and equipped to have difficult conversations. This type of direct contact with people is unusual within comparable regulatory organisations.

Our unique role and responsibility is to provide assurance about the accuracy and accessibility of these highly sensitive pieces of information, which can be so intimately wound up with a person's sense of self, for many decades to come. Young donor-conceived adults are only now beginning to exercise their legal right to find out about their genetic origins and as a result our role is evolving and is set to increase as more donor-conceived people reach the age where they want to receive information. This crucial function needs to be fostered through encouraging good practice in the sector and ultimately guaranteed by the HFEA as a legally enshrined, not time limited entitlement.

Of all the responsibilities given to the HFEA, we are most acutely aware of the immediate impact we can have on a young person's life, depending on how their request for information is handled.

The accuracy of the information held is guaranteed by licensed centres' prompt and accurate data collection and return within our compliance framework (see our answer to Question 4 below). In turn, the information in the Register is the basis for enforcing standards and informs reviews of those standards to ensure that our regulation is targeted, proportionate and measurable.

In short, the model the HFEA has put in place to ensure the effective regulation of assisted reproduction and embryo research is built on many years' experience and, we believe, has been a success.

3 Response to the questions

This section sets out our response to the questions posed in the consultation document. Before continuing, we make two introductory remarks:

1. The consultation document is clear that the Government does not intend to change the legislation governing assisted reproduction and embryo research. Instead, the legislation and the responsibilities within it, would transfer to the receiving body essentially unchanged; or if the HFEA was retained it would continue to be responsible for the delivery of the law as it stands.
2. Ever since the proposals were first raised, the HFEA has said that what is important is the continued effective regulation of the assisted reproduction and embryo research sector. We have carefully considered the options and questions in the consultation in this light.

Q1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Summary	
<p>HFEA response: No.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. Many more risks than benefits. 2. The hoped-for benefits are few and optimistic, and any financial savings yielded would be tiny. 3. Too big a mis-match in terms of scale, nature, coverage and regulatory concerns. Our functions would either divert resources disproportionately or receive too little attention. 4. There are governance obstacles to overcome, owing to the HFEA’s legal duties – which will not change, whoever delivers them.

We do not believe this option will provide the expected benefits; and it has significant risks that will impact on public confidence in oversight of the controversial issues raised by assisted reproduction in the UK.

Transferring the functions we perform to another body neither guarantees a reduction in costs nor an increase in effectiveness. The opposite is likely to be true and it could bring more risks than benefits.

We have made big efficiencies over the past three years, and continue to do so – by modernising and engaging in ‘shared services’ developments. We do not believe that

another organisation taking our functions could go much further in making additional savings. We set out the costs and savings in some detail later in this document, in our answers to questions 5, 6 and 8 below. In summary, we have already reduced our total costs by 25%, our Government funding by 33%, our staffing headcount by around 20% and our treatment fees by 28%.

More importantly, our work is specialist and controversial, with specific and challenging legal obligations and we can see that the CQC would need to allocate a disproportionate amount of time and effort overseeing the HFEA's functions (and the accompanying publicity and controversy which are a day-to-day fact of life in this complex area), even though the HFEA itself is much smaller.

The consultation states that this option aims to 'reduce the burden of regulatory activity and associated cost on providers.' Our position on this is clear. It is misleading to view regulation as being inherently costly or burdensome. Rather, regulation is either effective or it is not. Our belief is that the work we do in regulating the assisted reproduction sector - whilst not always perfect – adds value. That is, it is efficient in terms of our running costs and we think that the impact on the regulated is usually proportionate to the benefits. We strive to do better, in further reducing our own costs and in maximising our impact and improving our effectiveness – and in reducing any unnecessary regulatory overlap of regulatory bodies, which is a burden. We deal with the overlap issue at question 2.

We understand that the Department of Health's position is that (following any decision to transfer) concerns will be worked through by the receiving bodies (CQC and HRA) and the transferring bodies (HFEA and HTA). If this option remains the preferred one we will work hard to make it work.

At the same time, working through all of these, in our view, risks both the HFEA and the CQC taking their eye off the ball and losing the crucial focus on improving patient outcomes and adding value for some time to come. This puts at risk the desired efficiencies that motivate this proposal. More fundamentally, a question arises about accountability and public trust and the confidence Parliament has in any new regulatory regime. The key test must be how confident Parliament could be in obtaining a good outcome from integrating the regulation of a small UK-wide specialist body dealing with highly sensitive, controversial issues into a larger body charged with the important task of regulating 30,000 health and social care organisations in England.

We identify here the main risks that would need to be managed in any transition: risks to delivery; and risks to governance. These are inter-dependent. (The issues relating to the proposed transfer of our research functions to the HRA are addressed later under question 3.)

Risks to delivery

We are a small, single-sector, expert regulator, with strong links to practitioners in the fertility fields and with well-developed lines of communication with people using or considering these services. At the same time as cutting costs and staff we have increased our focus on risks (through, for example, developing a sector monitoring tool and redesigning our regulatory processes) and our understanding of a wide

range of sources of evidence (surveys, workshops, mining our own data and so on). Examples include our recent work on reducing the incidence of multiple births (the single biggest risk of IVF) and in improving our processes for releasing information to donor-conceived people about their genetic origins.

This focus on adding value, analysing everything we do to see whether it improves the experience of fertility patients, practitioners and researchers, and those born as a result of treatments, is what makes our staff proud to work for us. Indeed, 98% of staff said that they were very proud, proud or somewhat proud to work for the HFEA in the most recent staff survey (November 2011). The HFEA has an engaged workforce and a high-performing, high-quality working culture. Change can be managed, but can also be disruptive due to the loss of expertise that can sometimes occur and which may have a disproportionate effect on the functions carried out by the HFEA.

In summary, the integration of a small, expert and experienced workforce into a much bigger organisation with a much wider remit, which brings its own and different challenges, risks undermining precisely what we have worked so hard to achieve: a focus on outcomes in the sector we regulate.

Risks to governance

The risks we outline here are more problematic still. Issues relating to governance go to the heart of the regulatory scheme that set up the HFEA as a publicly accountable, transparent regulatory body. The consultation document states that it would be for the recipient bodies to determine what arrangements ought to be put in place. We believe that the importance of governance issues mean we must raise these risks in advance of any decision on this option.

The governance structure that both set up and organises the HFEA was designed to handle the very specific challenges raised by the handling of human embryos outside a woman's body and the creation of families with the help of egg or sperm donors. This is why it was Parliament's will (first in 1990 and reaffirmed in 2008) that the Members of the Authority make both policy and quasi-judicial licensing decisions (the HFE Act 2008 gave scope for delegating some of these tasks, which we have done).

The law requires the Secretary of State to secure an Authority with an appropriate male/female balance, a majority of 'lay' members, and 'at least one-third but less than half of the Members with an appropriate expert background'. These rules bring about an Authority that, given the highly charged ethical issues and complex science the HFEA is tasked with regulating, has public credibility. In other words the Authority derives its authority with a small 'a' from the credibility and expertise of its Members, and it is this credibility that gives Parliament and the public confidence that assisted reproduction and embryo research are being regulated properly.

Transferring the Authority to the CQC creates real and tricky problems in maintaining a highly accountable, public-facing governance model.

- The proposal is that the functions would transfer unchanged – so the legal constraints (in the Act) apply, regardless of the body responsible for them. The consultation document suggests that a committee is set up to advise the CQC. Whether Members of sufficient calibre would be prepared to sit on a committee of the CQC is a real risk.
- The relationship of any such committee to the Board of CQC also carries risk. Decisions of the committee may need to be ratified by the Board and questions arise regarding not just expertise but the control that the Board must exercise as regards this committee.
- An alternative option, whereby the Chair of the committee might have a seat on the board of CQC, creates tensions as to the primary role – balancing advocating on behalf of the committee with full accountability as a member of the Board of the CQC; an awkward role to pull off.
- If the functions carried out by the HFEA instead became part of the general responsibilities of the Board of the CQC then further risks emerge. The volume of business relating to those functions may become so great that it would distract the Board from its important and wide-ranging work regulating health and social care generally. Conversely, if controversial matters relating to assisted conception and embryo research received too little time this would impact on public confidence.

Finally, we note the references to devolution and also that the CQC currently exercises functions in relation to England only. Extending the CQC's role to cover the UK for current HFEA functions is of course a matter for the Department of Health. A further set of governance risks arise, which are matters that the devolved administrations may wish to highlight.

To sum up, we believe this option risks a reduction in the quality of regulation (of assisted conception and embryo research as well as of health and social care) whilst bringing about few, if any, of the expected benefits.

Q2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Summary	
<p>HFEA response: Yes – in relation to proposals to reduce regulatory overlap.</p>	<p>Main points:</p> <ol style="list-style-type: none"> 1. There is some regulatory overlap between HFEA and CQC and this is keenly felt by some licensed centres, although we think the extent is overstated in the consultation document. 2. We have already proposed ways in which this can be tackled, now and in the longer term. 3. Within the healthcare system there are many organisations responsible for ensuring quality – each must recognise the others’ roles and co-operate productively.

Yes. In our response to question 1 we state that the anticipated benefits from transferring the functions of the HFEA are small and risk not being realised. The consultation in particular states that this option aims to ‘reduce the burden of regulatory activity and associated costs on providers.’ We agree that unnecessary regulatory overlap of regulatory bodies is a burden, and we also agree that some overlap does exist, but we know that this can easily be removed.

In answering this question we focus here primarily on one issue: the extent of the regulatory overlap between the CQC and the HFEA – and how this can be resolved by the Department of Health without recourse to transferring HFEA functions to the CQC. We also comment on the need for regulatory bodies to co-operate in the new health and social care system. We take each of these points in turn.

For licensed clinics and other registered establishments such as those undertaking research projects – and the doctors, nurses and researchers working in them - the clarity of regulatory arrangements is of critical importance. It also impacts directly on the people accessing the services provided by licensed centres – patients, family members, and donors – who expect high standards to be in place, maintained, and where not, enforced; good quality outcomes (a much hoped for healthy baby, or at least as good as possible an experience); and to be an active participant in the consent they give for treatment or for the embryos created during the course of treatment to be used for important research.

We appreciate that for a number of HFEA-licensed centres that is currently not the case and this is of concern for many. This is often perceived and experienced as an overlap between the HFEA and the CQC (and before it, the Healthcare Commission). To re-state the point: regulatory overlap is burdensome and ineffective for all concerned.

As such we have worked hard with CQC colleagues to understand this better, and we describe below the work we are doing together to tackle this.

However, it is also important to understand that the extent of regulatory duplication or overlap is often misunderstood and is, we believe, overstated in the consultation document. In fact the actual degree of formal regulatory overlap is small and derives in some instances from a failure to apply current exemptions in the CQC legislation. The picture on the ground is complex and is as follows.

Facilities currently licensed by the HFEA may carry out any of three activities that fall within the remit of CQC registration:

- *treatment of disease, disorder or injury (TDDI)* – this activity carries a specific exemption for facilities licensed by ourselves. This means that HFEA-licensed centres do not need to be registered with the CQC to carry out this activity and should not be inspected against this requirement
- *diagnostic and screening* – this activity was granted an exemption for HFEA licensed facilities in June 2012 after joint working between the HFEA and the CQC recognised that this requirement imposed an unnecessary regulatory overlap
- *surgical procedures* - any centre undertaking standard IVF involving ‘egg retrieval’ (which is currently classed as a surgical procedure) should be registered with the CQC either independently or under the auspices of a Trust registration. It has been the custom and practice of the HFEA not to review surgical procedure activities carried out in the course of providing fertility treatment in acknowledgement that this is within the remit of the CQC.

HFEA-licensed centres are impacted by regulatory overlap in three different ways:

1. *Around half of the 133 centres currently licensed by the HFEA are not subject to regulatory overlap* – this covers centres that are registered with the HFEA but not with the CQC, or those that are registered with the CQC but need not be. This group includes facilities based in Scotland, Northern Ireland or Wales (where the CQC has no remit); centres carrying out human embryo research (but providing no treatment); centres providing intrauterine insemination treatments; and centres storing gametes but providing no treatment.
2. *Around one third of HFEA licensed centres are subject to a likely regulatory overlap* – this includes 36 standalone independent centres and 2 NHS centres providing a full IVF service. A significant number of these are likely to be registered with the CQC for TDDI (see above) but should be exempted from registration. This regulatory overlap could be readily resolved without transferring the HFEA’s functions. All of these centres should be registered with the CQC for surgical procedures.
3. *The remaining 20% of HFEA licensed centres are only subject to a notional regulatory overlap* – this includes about 20 centres providing full IVF services that are registered with the CQC under the umbrella of the NHS trust registration. Where a CQC inspection of the hospital trust takes place, it is likely that the focus is not on the assisted reproduction centre – therefore assurances about the quality of care delivered in the course of provision of surgical procedures at that centre are at a general trust-wide level only.

It is clear then that, whilst there may be some 'overlap', its extent is variable and unclear.

The HFEA, CQC and HTA has been working together within a joint working group to understand better the policy and operational barriers to more effective regulation and removing duplication. This has been effective and there is more that we can do. We have a commitment with CQC to coordinate our activities better through greater partnership working to improve our regulation of organisations affected to drive improvement. In the long term, the aim must be to establish a single regulatory regime for assisted reproduction centres.

In observing the wider environment, we are aware that shortly following the close of this consultation the publication is expected of the report of the Public Inquiry into the role of commissioning, supervisory and regulatory bodies in the monitoring of Mid Staffordshire NHS Trust from 2005 to 2009. It is possible that one of its conclusions may relate to the number of regulatory bodies, and the extent to which they work well together to create an environment where a high quality of care experienced by patients at all times is an essential expectation.

Since 2010 (when the proposals to transfer our functions were first made) we observe that some health related arm's-length bodies have closed or have transferred functions, but equally several more have come into existence: the NHS Commissioning Board; the NHS Trust Development Authority; Health Education England; Healthwatch, amongst others. Ensuring high quality care is a collective endeavour, requiring collective effort and collaboration at every level of the system.

We welcome the proposal in the consultation for the CQC, HFEA, HRA and HTA to have a duty to co-operate. Our collective interest must be in creating a regulatory environment in which assisted reproduction centres can function, where they are clear about their regulatory responsibilities and to whom they must account. Regardless of the eventual number of bodies, the important thing is that they work together intelligently and co-operatively.

The current regulatory schemes in Scotland, Wales and Northern Ireland are variable, meaning that centres in these locations experience different regulatory regimes. In Scotland, private centres offering a full IVF service are only regulated by the HFEA: there is therefore no regulatory oversight of surgical procedures. If the HFEA were to expand its remit to this activity then these centres would experience a more comprehensive and consistent regulatory regime.

Q3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Summary	
<p>HFEA response: No.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. The regulation of embryo research is intimately bound up with the regulation of treatment. 2. We provide a tight/single oversight of the embryo from treatment to research. 3. There would be few if any savings and greater administrative burdens for some centres. 4. The application process for researchers can be streamlined by closer working between the HFEA and the HRA.

The HFEA regulates the creation and use of human embryos for research. We believe that the current model works well and that the proposal to transfer this function to the HRA carries risks and few benefits. However, we agree that from the perspective of the researcher the application process could be improved significantly and we have begun work to resolve this issue.

Before considering the question directly, it is necessary to set out briefly the moral, legislative and policy context that has governed embryo research in the UK.

Warnock

The principles of the regulatory regime were first outlined by the Warnock Committee (1984). It concluded that *“...the embryo of the human species ought to have a special status and that no one should undertake research on human embryos the purposes of which could be achieved by the use of other animals or in some other way. The status of the embryo is a matter of fundamental principle which should be enshrined in legislation. We recommend that the embryo of the human species should be afforded some protection in law.”*

The Warnock committee also concluded that: *“The protection of the public, which we see as the primary objective of regulation, demands the existence of an authority independent of Government, health authorities, or research institutions... If the public is to have confidence that this is an independent body, which is not to be unduly influenced by sectional interests, its membership must be wide-ranging and in particular the lay interests should be well represented.”* [our emphasis]

The statutory framework

The regulatory framework is set out in the HFE Act. In summary it:

- Enshrines the special status of an embryo - this justifies a special regulatory regime and any 'single research regulator' would need to ensure this special status is not lost
- Requires that the licensing of embryo research is subject to unique statutory tests and requirements - any organisation which took on this role would be bound by those tests. This includes requirements relating to *non-research-specific matters* (for example, ensuring the premises are suitable and that the centre has an appropriate person responsible)
- Requires that licensed projects of research must be inspected at least every two years – again, any organisation which took on this role would either have to inspect or delegate this task to another organisation.

The policy and decision-making framework

While the HFE Act provides the essential framework for the licensing of human embryos in research, our broader statutory and policy responsibilities ensure that such controversial work is carried out in a way which best commands public confidence. In particular:

- The Code of Practice provides advice to researchers on how they can meet legal requirements, for example the information to be provided to patients considering donating their embryos to research
- The outcome of research on human embryos provides evidence to the Authority's Scientific and Clinical Advances Advisory Committee (SCAAC) therefore allowing the committee to make informed decisions when providing advice on whether a process used in carrying out a licensed treatment service should be authorised or not. For example, the results of research on the activation of eggs was used, by SCAAC, to determine whether artificially activated eggs should be permitted in the provision of treatment to infertile patients
- The advice from SCAAC also plays an important role in informing the Authority's Research Licence Committee about whether it is necessary to use human embryos in research to derive embryonic stem cell lines
- Where appropriate, we develop policy, on, for example human admixed embryos, through large-scale public consultation exercises.

We provide independent oversight of embryo research by lay members and those with expertise but with no stake in the research.

The licensing regime established by the HFE Act requires the decision maker considering applications for research involving embryos to act in a quasi-judicial manner in respect of each and every proposed project of research. The regulatory processes and legislation that govern embryo research in the UK are necessarily dependent on those governing fertility treatment; as the majority of embryos used for research in the UK are donated by couples undergoing fertility treatment. (Around

4,000 embryos are donated to research each year.) As such, there is merit in having a single integrated licensing regime which governs the processes by which all gametes and embryos can be procured; the length of time for which they can be stored; and which ensures that appropriate information is provided to embryo donors and that all required consents are in place before embryos can be used in research.

Operational issues

The majority of our work relates to the regulation of treatment, but the same Members and staff also provide functions necessary for research regulation. We have a well-established and transparent administrative system for licensing for both treatment and research, which works well. The reduction in cost from removing our research regulation function would be negligible – since it is an activity that is intertwined with our other activities. For example, our inspectors have a portfolio of licensed centres that include both treatment and storage and research licensed centres.

By law, embryo research is licensed by project rather than by centre. This means that a centre may have more than one research licence. Some centres only conduct research, while others conduct both treatment and research. Some research projects involve more than one centre. We currently licence 27 research projects, of which only eight are conducted at research-only centres. For research-only centres the regulatory oversight under Option 1 or 2 would transfer from the HFEA to the HRA; there would in effect be no net change for those centres. For projects conducted at centres which undertake both treatment and research (the majority, currently, 19 out of 27), those centres would experience a net increase in the level of regulatory oversight under Options 1 or 2, since the HFEA (or the CQC) would be required to inspect treatment services and the HRA, research activities. It is difficult to see how such centres would see such an outcome as representing a more efficient regulatory regime.

The consequences of transfer

If our research regulation function were to be transferred to the HRA it is not clear that it would produce the benefits that the Government seeks. The HRA will have a strong skill set in research ethics approvals, but not experience in quasi-judicial licensing decisions, nor an inspection function. Moreover, such a transfer would result in a severing of the link between the regulator of the production of almost all embryos in the UK, through IVF treatment, and the regulator of any research carried out on those embryos. The integrated approach to regulation of treatment and research, which delivers significant resource and synergy benefits, would be lost.

This would create certain risks (for example, ensuring that patients donating embryos to research are offered counselling and given appropriate information) and overregulation (for example, two separate regulators will inspect research laboratories and treatment clinics which are next door to each other).

Improving the regulation of research

Equally, it is clear that from the perspective of the research community there is a perception that the various bodies involved in providing research approval (National Research Ethics Service (NRES); and now the HRA and the HFEA and the HTA) are not sufficiently sensitive to the administrative consequences placed on applicants. In short, the process is often considered unwieldy, time-consuming and costly. How can these issues be resolved?

We are committed to continuous improvement in the way we regulate applications for research involving embryos and the on-going regulation of licensed centres to ensure the Authority meets the requirements of better regulation. For example, we are working with other regulators like the HTA to move towards joint inspection visits. This will ensure that those research centres that are required to be licensed by both the HFEA and the HTA, because the researchers are using human embryos to derive embryonic stem cells for therapeutic purposes, are not inspected twice. Licensed research centres located within, or affiliated to, a licensed fertility centre have combined inspection visits where possible.

Looking ahead, an alternative model would be to retain the HFEA but increase efficiencies through closer working with the HRA.

The proposed process would see researchers applying for a HFEA research licence through the Integrated Research Application Service (IRAS). This system would also be used by the researchers to apply for ethics approval from the National Research Ethics Service (NRES). The HFEA would provide advice as required. Both IRAS and the NRES are now part of the Health Research Authority (HRA).

In the proposed model, the NRES would also take on full responsibility, if permitted and agreed, for approving the information given to patients considering donating embryos, created using their gametes, to research. NRES already has to approve this information but, at present, the HFEA is responsible for ensuring this information meets the statutory requirements as well as those set out in the Authority's Code of Practice. It is proposed that the NRES would take on responsibility for ensuring that the information meets these requirements.

The proposed model would also see the HRA taking on responsibility for seeking the views of scientific / medical experts on whether the proposed research meets the statutory requirements regarding whether the purpose of the research is necessary or desirable for one of the purposes set out in Schedule 2 to the HF&E Act 1990 (as amended) and that the use of human embryos is necessary for the purpose of the research. This information together with the information contained within the application would then be passed to the HFEA.

The HFEA would maintain responsibility for inspecting the research centre and for deciding whether the project of research should be licensed or not.

This proposed model would reduce the administrative burden for research whilst ensuring the special status of the embryo is maintained, as the model would utilise the expertise of the Members of the Authority and maintain the seamless oversight of the creation of embryos in treatment centres to their use in research.

Q4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Summary	
<p>HFEA response: No.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. Our Register information is about people’s lives and genetic origins. It is also highly inter-dependent with our regulatory methods. There are risks associated with moving it, and we do not view it as a good fit into the HSCIC. 2. Our information provision role is critical, and must reside in the same place as the Register. 3. Moving donor remuneration policy to the Department of Health risks undermining the principle that such decisions are taken at arm’s length from the Government of the day.

No. We do not see any merit at all in this proposal.

Option 2 proposes that certain functions of the HFEA (the Register of treatment cycles, patients, donors and donor-conceived people; the provision of information to donors and donor-conceived people; remuneration of gamete and embryo donors) could be transferred to bodies other than the CQC or HRA.

This offers no benefit to patients or centres. It would also be likely to result in greater costs and the introduction of new risks and inefficiencies.

Transferring our Register to the NHS Information Centre for Health and Social Care (HSCIC)

The superficial attraction here is that the HSCIC clearly has considerable expertise in handling national data collections. However, the proposal does not take into account how we use our Register data for regulatory purposes.

Through our inspection and licensing powers we can be certain the data we collect is substantially complete and correct. Removing the hosting of the Register from compliance functions leads to a real risk that centres will not comply with the extensive statutory reporting requirements. This risks undermining the information access guarantee given to people conceived from donor treatments. In practice, we often have to contact centres when we receive a request for information from a donor-conceived person (or from their parent or the donor themselves), in order to

clarify details that are of vital importance to the person requesting them. We also engage in data assurance processes, particularly focused on issues around donation. A major factor in achieving compliance is that we are also the licensing body.

We monitor centres' performance against the requirements of the Code of Practice. As such, we make performance information available to them through our risk tool, populated with information from our Register. This has been in place since April 2012, to assist centres to deliver continual improvement in outcomes and to allow us to monitor possible adverse events. We would be concerned that monitoring of risk in the sector would be less secure if the Register were at arm's length from our monitoring of risks.

This option would also require a change to the remit of the HSCIC. At present, the HSCIC only holds data relating to publicly funded healthcare in England. Our remit is UK wide, and the majority of ART treatments are privately funded by the patients themselves. Though such a transfer might be seen as a mere technicality, it would be a considerable change of remit for the HSCIC.

Transferring our information provision functions to the Department of Health

The proposal is to transfer our information provision functions in relation to donors and donor-conceived people to the Department of Health. It may then contract out the service to an external provider.

Leaving to one side issues about the suitability of such an external provider, the proposal fails to recognise critical inter-dependencies; in this case, between our information provision function (what we term Opening the Register or OTR) and the Register.

When an OTR request is received at the HFEA, a dedicated team interrogates the Register database, cross checking and referencing a woman's registration and treatment outcomes, and a donor's registration and use. This can also involve communications with the applicant and the clinic.

External organisations are not permitted to see these Register entries, since this form of disclosure is not envisaged in the current legislation. Moreover, considerable technical expertise is required to analyse the relevant reports from the database as it contains data for 20 years of treatments. Across this time period, there have been various changes to the amount and format of information going into the Register.

There is a strong risk that if the Register was located in another organisation, whether this was the CQC or the HSCIC, it would create an institutional barrier between those maintaining the Register and those trying to access it to respond to OTRs. It is difficult to see how this could be efficient, or lead to a quality service being delivered to OTR applicants.

It is vital that the information given to people who want to understand their genetic origins is accurate.

Transferring the setting of remuneration for donors to the Department of Health

The proposal to transfer policy responsibility for setting remuneration limits for gamete and embryo donors to the Department of Health raises many questions. We currently exercise policy responsibility for almost all aspects of donation, and we do not see the benefits of taking part of it away.

Policies on the donation of sperm, eggs and embryos were recently completed following a major public consultation in 2010 and 2011. That work encompassed not only compensation for donors, but also how many families a donor can help to create, and arrangements for donation between family members. That work showed that decisions relating to donation need to be considered carefully – in the round. Taking one aspect in isolation, like remuneration, is likely to lead to less effective policy-making.

The consultation document says there is some merit in the idea that Ministers would be accountable to Parliament and the public for setting donor remuneration levels. While this is true, it's also a common misconception that public bodies are not somehow accountable. We are indeed accountable to Parliament for both the policy decisions we make and the public money we spend. We do not believe there is an accountability gap to be addressed here.

Our policy-making is conducted in public. We put considerable effort into seeking the views of the sector, patients and the wider public in innovative ways. Decisions are made in public by publicly-appointed Members who are independent of the political pressures of government. This was a key feature of the Warnock report on assisted reproduction in the UK which resulted in the HFEA being set up. Transferring policy responsibility for donor remuneration would arguably be the first step in dismantling that consensus.

Q5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Summary	
<p>HFEA response: Yes. This is our preferred option.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. We have put in place an efficiency programme that has reduced our costs by 30% since 2009. We have plans to make further savings by working with the ‘shared service’ programme. 2. We have been responsive to the public debate on the HFEA’s future, and, where we can, we have made changes to the way we work – with more to come. 3. This is not a plea for the status quo. We accept and welcome the opportunity for a radical look at how we continue to improve and to deliver further efficiencies.

We believe the HFEA should retain existing functions; and that further efficiencies can and should be delivered. In our answer to question 1 we set out the key risks we see in the transfer of (most of) the HFEA’s functions to the CQC. We believe these risks can be mitigated in whole by retaining the HFEA as an independent body. In question 2 we demonstrate how some of the anticipated benefits of transferring functions can, in fact, be achieved without the disruption of formal transfer.

We go beyond this though. Our support for this option should not be interpreted simply as an argument for the status quo. All public bodies must continually ask themselves if the resources at their disposal are being used wisely, and we are no exception. The public sector drive for efficiency is an important one - and we have played our part. In addition we have listened, and responded, to other arguments – about the HFEA’s future - made by our stakeholders over the past two years.

In answering this question we begin with a summary of steps we have taken in recent years to reduce our costs, as part of a programme of efficiency, and the limits to going much further. We then detail the public debate on the HFEA’s work together with the key actions we have been able to take in response. Finally, we offer some brief thoughts on future possibilities.

HFEA programme of efficiency

The HFEA embarked on a modernisation programme in 2008 (called ‘Programme 2010’), initially to address the new requirements placed on the organisation by the revision of the HFE Act in 2008.

This provided us with an opportunity to make significant improvements to the way we work – at both governance and operational levels. At around the point of delivery of Programme 2010, and the final implementation of the new Act, the coalition

Government's ALB review was published, which set out the proposed abolition of the HFEA. This led immediately to a further period of transition and change for the organisation.

We had become a more agile organisation in the course of our preparations for the new Act, and we believe we were the first healthcare ALB to respond to the new 'direction of travel' on austerity. Our aim was to reduce our overall organisational size by about 30%, whilst still delivering core work, including the additional duties recently conferred on us by Parliament.

Over the past two years or so, we have maintained our capacity to deliver, taken on additional duties, and at the same time changed the way we work to be more effective (for example, improving online interaction with licensed centres on the way we collect data and so reduce the administrative effort involved).

In summary, we have made the following cost efficiencies since the ALB Review announcement (July 2010):

- Total expenditure down by 25% (from £8m to £6m)
- Grant-in-Aid, the annual funding provided to the HFEA by Government, down by 33% (£1.4m in 2012/13)
- Staffing headcount down by c. 20% by the end of 2012/13 (from 86 in 2010/11 to 70 staff now)
- Treatment fees (the amount paid by licensed centres for each cycle of treatment performed – this makes up most of the HFEA's income) reduced by 28% from 1 October 2011
- A further fee discount was introduced on 1 April 2012 to support the Authority's policy on reducing multiple births (where a frozen cycle follows an elective single embryo transfer, no fee is chargeable)
- A move to smaller and cheaper office accommodation, in the building occupied by the CQC, saving c.£400,000 per year.

Public debate on the future of the HFEA

In the two years since the publication of *Liberating the NHS: Report of the arm's-length bodies review*, there has been much debate amongst those working or involved in the assisted reproduction sector about their hopes for the future of the HFEA. This has included challenges and criticisms of the way the HFEA goes about its work, alongside warnings about the consequences of changing or abolishing the HFEA.

Changes in society's attitude to reproduction

Some have questioned the need for regulation of the sector '20 years on'. That is, since the introduction of the HFE Act, society is now more ready to accept research using embryos, that scientists uphold high ethical standards, and that there is now a range of treatment options for infertility that the majority of the public is familiar with. Furthermore, that other branches of health-care are not regulated to the same depth

and rigour as that relating to IVF treatment. Our view is that this is a matter for Government. The law was updated as recently as 2008 and, further, the Government has been clear since it first announced its consultation on the transfer of the HFEA's functions that the legislation will not be re-opened at this time. Our task, therefore, is to fulfil the requirements of the law. The way in which we do so is explained in section 2 above.

Efficiency in regulation

Some have argued that the way in which the HFEA interprets the legislation in carrying out its work leads to inefficiencies - notably the administrative consequences placed on centres and applications made by researchers; the volume of information we collect from licensed centres, and the way we collect it; and the overlap with other bodies. We are sensitive to these concerns and have made changes over time, usually in consultation with representatives from the sector. And we also recognise that we must continue to work hard on this – other parts of our response detail the work we are doing.

Costs

Some believe the HFEA is too expensive and inefficient. We have described our work to reduce our costs above. There has also been comment about the size of the HFEA's 'surplus.' A large proportion of the HFEA's running costs are generated from fees paid by patients linked to each cycle of their treatment. In the last few years our income has exceeded our costs leading to the generation of a surplus. Some have argued for this to be returned to patients – by funding more NHS-funded care, for example. This is a matter for the Department of Health, which sets the rules as regards our funding; and for Government, which sets the rules relating to public accounting more generally. We have long been keen that this money can be used in ways which will benefit patients and the sector. As noted above, in October 2011 the fee paid by patients was reduced by 28% and the amount of grant in aid provided by the Department of Health has reduced by a third.

The HFEA's 'brand'

Many welcome the role that the HFEA has played in working alongside new and established treatment and research centres in creating a reputable sector which upholds high ethical standards – which, in some quarters, is the envy of the world. The HFEA brand is an important guarantor to patients. As such the HFEA has a 'brand' value – which as a consequence reflects well on the UK internationally. One of the consequences of this has been that UK-based centres have been able to expand and market their services in a range of overseas locations promoting regulatory obligations from the UK as part of their offer, even where such regulatory frameworks are not required.

Concern about the location of transferred functions

Some anxiety has been expressed about the size of the CQC and its wide focus – covering acute hospital care, the care sector, general practice, mental health and incapacity and so on. This has led to concerns being expressed by many in the sector that the specialised oversight of assisted reproduction will be crowded out. Further, that the sector will lose access to a small, nimble regulator focused on a specific and complex sphere of activity.

Response and way forward

We welcome the range of views expressed and have reflected upon them, making changes where we have been able and where it has been sensible to do so. And we have put in train further changes that we would like to make and considered other options potentially open to us. Our aim is to be an even more effective regulator of the assisted reproduction sector now and over the next few years.

We recognise there are opportunities presented by this review for building on the changes that we have made over the past few years and involving as many of our stakeholders as possible in doing so.

Inspections

In the last three years we have transformed the way in which we inspect. This review was done in liaison with stakeholders and in consideration of the broader regulatory landscape. As a result of this work our inspections are more focused and risk based. We have moved beyond an episodic approach to compliance to a model that includes close to real time monitoring of performance, is more patient focused and provides patients and the public with assurance that we see clinics as they really are, by the increasing use of unannounced inspection.

We have also been working to reduce any duplication with other accreditation regimes like that provided by the CPA in respect of laboratory equipment and the quality management systems accredited by ISO. We take into account others' assessments when we make our own.

Looking ahead, we see real opportunities for a single regulatory regime for clinics in England (see the discussion of regulatory overlap under question 2). The aim must be to provide greater assurance on quality and safety, and also continue to build on the good ways of working developed with our regulatory partners in Scotland, Wales and Northern Ireland.

Data collection and validation

We moved to an on line system of information collection in 2005. In doing so we involved sector representatives in the development of the system. We know there are still frustrations with this system. At the same time we have to balance the wishes of people working in the sector who understandably want to keep administrative consequences to a minimum; the need to maintain a register of treatments such that the donor-conceived can receive information about their genetic origins; and the commitment to maintain our Choose a Fertility Clinic website on clinic performance. We are listening to sector concerns and are reviewing a number of policies and processes regarding our data collection. This involves:

- A better understanding of what we are required by law to collect and maintain
- A clearer focus on those parts of the data set that really matter to the donor-conceived and patients
- A review of how we could reduce the burden of verification and validation of the data in line with a clearer focus on those most relevant aspects of the data set.

Research licensing

As we set out under question 3 we are changing the way we license applications from researchers to carry out research using embryos by becoming a member of IRAS, so researchers will only make one application and the information will be shared between a number of agencies. In brief, we will:

- Work closely with the HRA
- Join IRAS.

Future possibilities

We have made significant savings over the past three years and believe that we can go further, especially in the area of shared services. But there is a limit to what more can be achieved in a public body the size of the HFEA. If the Government requires additional year-on-year savings for the foreseeable future, then we, like the majority of small public bodies, will reach a point where further significant savings are no longer possible, without a drop in the quality of the work we undertake.

We are also keen to discuss with the Department of Health how we might make more transparent the improvements and efficiency savings we are committed to delivering. We are content to be publicly held to account in this way.

We recognise that new models for the delivery of public services are emerging in both local and central Government. These have the potential to offer radical savings, through greater collaboration. We are willing to think through how such models might apply to the way we work with other regulators.

Q6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Summary	
<p>HFEA response: Yes.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. Since 2010 our expenditure has reduced from £8m to £6m, and the number of people who work for us has reduced from 86 to 70. 2. By the end of the year 2014/15 we will have reduced our expenditure to £5.8m and the number of people working for us to 67. 3. Taking into account our current functions, savings beyond those identified above could not realistically release <i>significant</i> sums of money, without directly impacting upon the delivery of core functions.

Yes. The package of savings and efficiencies described in our answer to question 5 largely meets our understanding of the expected requirements of Government or Department of Health public sector finance or efficiency initiatives. The savings have been achieved by a variety of means, including a reduction in the number of staff; not filling some vacancies; reducing in-house support services; and collaborative working with other ALBs sharing services and costs.

The reduction in staffing has, significantly, been weighted towards senior (more expensive) posts – over the last two years our senior management team has gone from 5 to 3 posts, and we have reduced other senior/middle managerial posts, though a combination of reorganisation and voluntary redundancies. Some routine administrative activities have been re-designed or are shared with other ALBs, notably the CQC. The organisation is ‘flatter’ and more focused on statutory delivery and less intensively resourced in corporate services.

Looking ahead, we expect our staffing numbers to continue to decrease, although more slowly than in the past two years, as we continue to make efficiencies and to share services, where feasible. We are carrying a number of vacancies, and we continue to consider carefully whether, when a vacancy arises, the role is business critical and/or can be reconfigured. The table below shows the headcount in the organisation at the end of each year over the transition planning period, and the corresponding annual budget.

Year	2010/11	2011/12	2012/13	2013/14	2014/15
Headcount	79 (86 at start)	73	70	69	67
£m	8.0	6.6	6.1	5.9	5.8
Of which Grant-In-Aid = £m	2.2	1.44	1.4	not known	not known
Non-payroll staff	3	2	0	0	0

The 'recurring' cost of the organisation will therefore continue to fall into 2012/13 and beyond. Our total estimated costs for the full current financial year will be £6.1m (compared to £6.6m in 2011/12). The full year effect of the 28% fee reduction and other fee reductions from October 2011 combine to lower the amount we receive from regulated centres from almost £6.0m in 2010/11 to £4.5m today. This benefits the sector as well as patients. It is also, in part, a further dividend from the investments made in Programme 2010 to modernise the HFEA, as reported to the Department of Health in January 2012.

The move to CQC premises in August 2011 saved in excess of £368,000 on accommodation costs (rent, rates and service charges) per year. The move also means that the existing estate of the CQC is used more efficiently, contributing to a net reduction in public sector occupancy of private sector London property.

We expect to make further savings as the Government's 'shared services' plans develop. Work is in progress relating to this and the HFEA is either further advanced than the proposals or is too small to be within their scope. We have made significant progress in sharing our services, particularly with HR shared services (including the permanent transfer of one member of staff to the CQC), facilities management, procurement, and estates. Further work is being done this year to prepare the HFEA to opt in to a finance shared service platform. This will reduce the size of the in-house finance function.

We take the need to reduce our expenditure very seriously and believe that our performance over the past three years demonstrates this. We will continue to bring down our costs where we can, but we do not believe that, taking into account our current functions, further savings beyond those identified above could realistically expect to release *significant* sums of money, without directly impacting upon the delivery of core statutory functions.

If the Government wishes to go further, this will require more radical thinking, as we set out under question 5.

Q7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Summary	
<p>HFEA response: No.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. It would damage effectiveness. The inter-linked nature of what we do is real and adds value. 2. Policy and operations benefit from being together; separation is known to be perilous.

We believe the HFEA is greater than the sum of its parts. And those parts are not conveniently discrete modules that lend themselves to dispersal without impacting on their effectiveness and thereby damaging public confidence.

As we make clear in section 2, our setting of standards through policy-making allows us to enforce those standards through our inspection and licensing functions. We believe that Parliament was wise to give us the two functions together; they are aligned and work well on the ground.

Similarly, the gathering of information to fulfil the statutory requirements for the Register enables that information to be analysed at both the level of an individual centre and the sector as a whole. This makes for more focused regulatory interventions and more nuanced policy-making.

The divide between policy and operations has bedevilled public policy in the UK; we believe that we are a rare example of this problem being avoided.

Q8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

Summary	
<p>HFEA response: We have a number of comments, and we consider this a limited exercise on which to base decisions on the transfer of functions.</p>	<p>Main reasons:</p> <ol style="list-style-type: none"> 1. The efficiencies expected from option 1 are far too small to meet the stated aim of contributing to reducing NHS costs by a third. 2. Less than £4m released in 10 years equates to about 3 minutes per year of NHS running time. 3. We believe there is overestimation of benefits and underestimation of costs of transfer. 4. We believe the assessment is based on a too narrow set of assumptions and variables; a small change in any of these can produce a very different outcome.

We have already set out, in our earlier responses, the efficiencies we have made and plan to make.

The impact assessment compares the preferred Option 1 against Option 3. In theory, transferring functions from a relatively small organisation (like us) to a much larger organisation (like the CQC) ought to result in some savings. The question is, are those savings significant enough to matter? And, importantly, do they come at too great a cost (a reduction in quality of the work currently carried out)?

These are our observations on the impact assessment:

- Option 1 is assessed as delivering a Net Present Value benefit after costs of £3.8m over ten years. This equates to average *annual* savings of c.£0.5m. This does not meet the stated aim of reducing NHS administrative costs by more than one-third; which would require a proportionate annual savings of c. £4m between the HFEA and HTA. Based on the current year’s NHS budget of just over £1bn, we calculate that the £0.5m per year saving would buy about 3 minutes per year of NHS expenditure. We question whether this is a worthwhile return from what would be a considerable effort, fraught with risks
- That said, we recognise that all public bodies including arm’s-length bodies have to ‘do their bit’, and we are no exception
- The estimate of benefits for Option 1 assumes that the functions of Chairs and CEOs for both the HFEA and the HTA can be completely absorbed by the receiving organisations. This is unlikely to be entirely true. We think the benefits would be closer to £1.9m than £2.8m

- We believe that costs of transfer are under-stated. The assumptions relating to redundancy of the CEOs do not take into account any prior ALB service. This is of marginal direct impact but is factored using 17% to estimate general average transition costs. A more realistic cost estimate would be £0.4m
- Certain things are always costly, for example the migration of websites and databases onto different platforms, and management of these systems. These are not included in the Impact Assessment
- A significant range of 'non-monetised' costs and benefits are missing. These include the costs of the legislative effort to enable the organisational changes required for Option 1; the costs of adjusting to the new regime; and the costs of setting up necessary arrangements with devolved administrations
- Option 2 is assessed financially as exactly the same as Option 1 despite the obvious differences. Option 2 would involve more fragmentation, more difficult transition(s) and much more complex information-sharing. We struggle to see how these two options have identical costs and benefits
- The assessment implies that the start point should be the financial year 2010/11. Since the proposals were introduced in April 2010, it could be argued that the year 2009/10 should be treated as 'year zero' for comparison purposes. We have delivered one-third savings in costs since then
- The assessment also states that future savings are uncertain under Option 3, but somehow certain under Option 1. Under either option, future savings are heavily dependent on the Department of Health's shared services initiatives. Under either option, savings will have to be agreed with the Department. Our track record in making efficiencies should be viewed as a predictive indicator in gauging our commitment and ability to deliver future savings.

In short we believe the assessment is based on too narrow a set of assumptions and variables; a small change in any of these can produce a very different outcome.

Q9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

Please see our response to question 5 where we set out our proposals for the continued effective regulation of the sector.

Q10. Do you have any other comments on the consultation proposals that you would like to share with us?

No.

Q11. Can you provide examples of costs and benefits of these proposals?

Please see our responses to questions 2, 3, 5 and 6.

Q12. Do you have any comments on the consultation Equality Analysis?

No.

Response 25 – Individual

CONSULTATION QUESTIONS Please note that we are answering in regard of the HTA as that is where our involvement and experience has been.

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Answer: We cannot agree with this option. The HTA has a unique, stand-alone ethos to fulfil. The impact assessment highlights the risks involved with this option – page 2 of the IA states ‘There is a risk that expertise may be lost in the transfer of functions from the HTA to the CQC.’ The Human Tissue Act addressed serious criminal activity and the HTA, as responsible to ensure compliance with the Act, has installed a sound moral system of protection which commands the respect and confidence of the public. There is no other Authority in this field that has such a unique remit which ensures the recognition of the conscience of the individual. The IA flags up further significant risks with this option, page 26, para.122 the potential risk that the CQC would become overstretched, para 123 again pointing out the risk that expertise might be lost and the resulting detriment for the services regulated and for public confidence. Perhaps the most poignant statement is in para.124 of the IA, which reads ‘An individual working at the HTA currently benefits from being one of a small number of staff working at an organisation that has a **well-recognised status in its area of regulation.**’

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Answer: Our conviction is that if the HTA is abolished, the ethical and moral support afforded, which gives the individual a sense of stability and assurance, would no longer exist. Para.125 of the IA stresses this very point by pointing out that currently the public know where to turn for public advice provided by the HTA. With the transfer of functions, this service may alter in a way that reduces its accessibility to the public.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Answer: HFEA, therefore we offer no comment.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Answer: As regards the HTA, No. We see the strength and effectiveness of the HTA remaining as it is at present, a self contained, stand-alone entity. Option 2 of this Consultation proposes separating the HTA’s functions. We see inherent dangers in these proposals, perhaps especially with those related to Research and Organ Donation, given the activities, already referred to in our answer to question 1, which lay behind the passing of the Human Tissue Act. As is universally acknowledged **proper consent** lies at the heart of the Human Tissue Act and this is rigorously insisted on by the HTA in all activities. There is a real threat that if the HTA’s functions are separated there would be a dilution of consent requirements.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Answer: It is our firm conviction that the HTA should continue as a separate organisation and retain its existing functions. Whether further efficiencies can be

delivered would be subject to clarification of what those efficiencies would be.
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
Answer: Yes. The HTA is already one of the ‘leanest’ Authorities. It is of note how they have kept overheads under tight control and to a minimum, including a remarkable performance in achieving 27% efficiency savings over the last 2 years . Additionally, surely the operation to transfer the activities and functions to another body would be a very costly exercise especially considering the knowledge, skill and experience that would have to be acquired to enable the quality of service to continue to be delivered. Furthermore, the willingness of the HTA to collaborate with other organisations in sharing information, can only result in delivering savings to the public purse. However, any cost cutting suggestions must always be subject to the HTA being totally comfortable that they can be implemented without there being any compromising whatever of the quality insisted on by the HTA in all its activities , as indeed the public both expect and demand
7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
Answer: As regards the HTA definitely No.
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
Answer: We feel our answers to Questions 5 and 6 cover this.
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
Answer: Whilst we feel that to date the HTA have performed very well in efficiently overseeing and regulating in areas that are very sensitive it would be common sense to acknowledge that there is always room for suggestions for improvement. However it is imperative that the final decision on implementing any such suggestion must always rest with the HTA to ensure that the excellence of their Regulating standards are maintained and not compromised in any way .
10. Do you have any other comments on the consultation proposals that you would like to share with us?
Answer: In answering the earlier questions we have sought to underline our deeply held conviction that the HTA must remain a self contained, stand-alone entity. Let us stand back for a moment and consider the reason that lies behind the HTA coming into existence. The terrible events at Alder Hey and Bristol and other locations demanded action from the Government. The Retained Organs Committee painstakingly scrutinised and analysed these events and out of their considerations the Human Tissue Bill emerged. Subjected to detailed Parliamentary scrutiny the Bill was enacted- The Human Tissue Act, 2004. The HTA was established to enforce and regulate practices to ensure that the awful events at Alder Hey and elsewhere could never recur . They – the HTA – have set themselves and enforced superb standards of regulation insisting on what Baroness Warwick described in a speech in a Debate on 1 st February 2011 as ‘a single set of core standards across all the sectors that we regulate’ with ‘consent as the golden thread through all our activities’ (Hansard 1 st Feb 2011 Column GC338). In a Debate a little later at Committee stage of the Public

Bodies Bill, she says that ‘A division of our functions into three or possibly four different parcels would, in my view, risk undermining the legislation that the HTA was set up to implement, increase the regulatory burden on the sectors we regulate and damage public confidence that has been so hard won’. (Hansard 28th March 2011 Col 1058).

Senior Consultant Surgeons writing in The Guardian in March 2011 said that moves to break up the HTA would undermine professional and public confidence in the area of medical consent and urged the Government to think again and stop trying to operate on things that aren’t broken. Case rested, the HTA **MUST** remain as it is, **a stand-alone organisation commanding public confidence and providing a clear benchmark for the professionals**. As Professor Margot Brazier wrote, last year, ‘Proposals to abolish the Authority and the divisions of its functions among larger non-specialist regulators risk confusion and error in the implementation of the Human Tissue Act, 2004, which, in turn, will erode public confidence.’

11. Can you provide examples of costs and benefits of these proposals?

Answer: We feel that we have answered regarding costs at Question 6. We have sought to provide examples of the benefits for Option 3, ie that the HTA should retain its functions as a stand-alone Authority in our responses to Questions 1, 2, 4 and 10.

12. Do you have any comments on the consultation Equality Analysis?

Answer: No.

Response 26 : Individual

“I am writing as an individual concerned for the welfare of donor-conceived children. I am unable to respond to the specific questions but feel it is important to state the belief that the needs and rights of these children should be the primary concern of any such proposals.

Maintenance of the donor register is therefore essential and would perhaps be best served by continuing with a separate organisation rather than being consumed under a bigger department and possibly diluting its function.

The independence and integrity of the HFEA as a regulator to facilitate ethical decision making is also paramount and feel that this can best be met by an independent body without competing priorities.

On balance therefore, I feel that the HFEA should remain as a separate independent body.”

Response 27 – British Transplantation Society

23rd September 2012

ALB transition team
218 Richmond House
79 Whitehall
London
SW1A 2NS

Dear Sir or Madam

Re: Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

I wish to state the position of the British Transplantation Society (BTS) with respect to the consultation on the future of the HTA and HFEA. The BTS has a membership of over 800 people in the multiple disciplines involved in transplantation in the UK, from surgeon and physician to pharmacist, specialist nurse and histocompatibility scientist. This response was drafted by members of the executive of the BTS and reviewed by the council before submission.

The BTS does not wish to comment on the future of the HFEA. Instead we will focus on the future of the Human Tissue Authority, and address the consultation questions in turn.

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this

We believe that the best option is to retain the Human Tissue Authority as a single entity as it is at present. The HTA has developed an expertise with respect to implementing and regulating the Human Tissue Act 2004, and has been in extensive consultation with the transplant community on the implementation of the European Organ Donation Directive EU2010/53/EU. It seems ill advised to change the competent authority for the EUODD at a time when it has just been transposed into UK law, and when the HTA have invested much time and effort into its introduction and method of regulation. The Transplant Community are currently going through the biggest regulatory change since the Human Tissue Act, and a change in regulators would add further to the regulatory burden which has recently been imposed. The transplant community has now had the opportunity to build what we believe is an effective relationship with the HTA and, while we have certainly not agreed on everything, we have come to understand each other's position. As a result we can effectively

advise on the level and manner of regulation required and how to best implement it. We are anxious that we may have to start from the ground up if the HTA is replaced by a new body. Transplantation is a complex and evolving specialty that has necessitated a dedicated team at the HTA to regulate. In addition there are occasions when advice is required at extremely short notice. The CQC would need a similar team if they adopted the HTA functions for transplantation, and as such no savings would take place.

2. Can you quantify what impact this could have at a local level?

It is difficult to quantify the effects of a change in regulator. The community has worked in collaboration with the HTA on the interpretation of the EUODD (and the HTAct before that). The level of "light touch" regulation deemed appropriate in the implementation of the EUODD may be at odds with the other areas regulated by the CQC. In addition, the CQC has understandably been the subject of significant controversy in recent times. Transplantation is hugely dependent on public confidence to optimise organ donation rates. We are concerned that the transfer of HTA's responsibilities to the CQC might jeopardise that level of public confidence .

The regulation of living donor transplantation has been one of the successes of the HTA, which has responded to a growth in living donor activity from 599 in 2005/6 to 1055 in 2011/12. Live donors are increasingly complex and require individual assessment by a team at the HTA. A similar level of attention will be required by the CQC if the successful living donor programme in the UK is to continue. If this is not forthcoming as a result of cost savings, the result will be that patients will die while awaiting transplants.

CQC inspections of transplant units would need individuals with dedicated transplant experience – such as the HTA do at present. It would be inappropriate for CQC individuals to inspect licensing arrangements pertinent to transplantation if they do not have the appropriate expertise.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA?

No comment

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

In implementing and regulating the Human Tissue Act and EUODD, the HTA relies on NHS Blood and Transplant (NHSBT) to collect data and to act as an interface between commissioners and regulators. NHSBT would be well placed to regulate the majority of transplant-related functions of the HTA, with the proviso that some of the NHSBT functions are regulated by the HTA at the moment. Elsewhere in Europe national transplant organisations act as competent authorities for the EUODD. However, that would leave the other non-transplant functions of the HTA to be taken on by another organisation, such as CQC.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

For the reasons outlined above we believe it would be appropriate for the HTA to remain as it is, maintaining its existing functions. It has already shown itself to be capable of making

efficiencies in its functions in the last two years. There is no reason to suppose this cannot be continued.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

The HTA have made savings to the public purse in recent years and are not an expensive organisation. We do not have the necessary knowledge to analyse budgets to determine where such savings may be made in future. However, we would make the observation that increases in licensing fees does not equate to a saving to the public purse, since license fees for transplantation come from the public purse in the vast majority of cases.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

If the HTA are to be kept as independent regulators then their functions should remain as they are. The new HRA may usefully play a role in research on deceased organ donors, an area where the UK Donation Ethics Committee is working to clarify aspects where uncertainty currently exists.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

The impact assessment predicts savings by amalgamating functions, but the history of mergers/incorporations is that they cost money, at least in the short term. The HTA have made efficiency savings over the last few years, and streamlined their interactions with the transplant community. The HTA is not perceived as being top heavy with managers, but rather staffed with appropriately informed individuals at all levels.

The consequences of loss of confidence in transplantation due to errors in regulation are an important consideration for the patients who remain on waiting lists for organs. Organ donation relies upon the good will of donor families. Several times in the past it has fallen foul of bad publicity, with consequent deaths of patients waiting for organs. It would be undesirable for this to happen as a consequence of change of regulatory body.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

No comment

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Paragraph 121, and others in the document, argues that moving regulation all under the CQC would simplify the interaction of healthcare establishments with regulators. This is a naïve comment. The CQC would need to expand to accommodate any responsibilities, and specific regulatory roles such as the specialised ones involved in transplantation will be regulated by a subgroup within CQC, while different departments within the CQC will oversee other aspects of the healthcare establishment. It is difficult to conceive of a single individual appropriately briefed on the many diverse regulatory functions of the CQC.

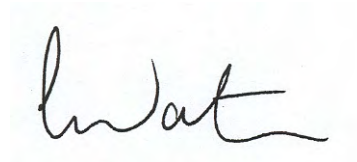
11. Can you provide examples of costs and benefits of these proposals?

No comment

12. Do you have any comments on the consultation Equality Analysis?

No comment

Yours sincerely

A handwritten signature in black ink, appearing to read 'Watson', is centered on a light blue rectangular background.

Professor Christopher Watson
President

Response 28 – University of Reading - Individual

“I have read with interest the three options put forward in the Consultation paper as to the future of the Human Fertilisation & Embryology Authority (HFEA) and the Human Tissue Authority (HTA). The synergies between the functions of these two bodies are clear and it is understandable that they are being considered at the same time. However, we should not forget that what is now the Human Fertilisation & Embryology Act 2008, was originally introduced with the aim of creating one body for the regulation of tissues and embryos (RATE) and that this was strongly rejected by various stakeholders.¹ Consequently, it is important that the Government look at both bodies independently, without assuming that a suitable response for one will necessarily be so for the other. In the light of the current distinction between the bodies and given that my expertise is in the area of assisted conception and embryology, the majority of my response relates only to the HFEA.

I have explored the regulatory functions and possible future developments for the HFEA in my article ‘Ensuring Operational Compliance and Ethical Responsibility in the Regulation of ART: The HFEA, Past, Present, and Future’ (2011) 3(1) *Law, Innovation and Technology* 85–111 and attach a copy herewith. (Of particular relevance are pp104-111).

Following an interesting public debate organised by Progress Educational Trust² on the future of the HFEA, it is apparent that a minimal level of consensus exists between different stakeholders. This common denominator accepts that some change is necessary because both the scientific and regulatory landscapes are very different today than they were in 1990, when the HFEA was set up. Whether one accepts that IVF treatment has become ‘routine’ medical practice or not, it has certainly become mainstream. Embryo research, although controversial, has also continued to advance as an acceptable avenue of research for the majority of the population.

In order to respond to the Consultation, it is necessary to address two questions: (i) what functions does the HFEA carry out? And (ii) how best can these functions be assured?

The functions can be categorised into three groups: (1) technical, quality control; (2) ethical evaluation and policy development; (3) Provider and guardian of public and private information respectively. Whilst all of these functions are important, it is crucial to maintain a certain level of realism in any analysis of future direction. The claim that the HFEA is widely admired both at home and abroad is often aired and there is no doubt, that at the time of its creation, it responded to a real need for regulation to be visible and trustworthy. Nevertheless, we should avoid the temptation of placing the HFEA upon a pedestal. Whilst public confidence is important, it is to be noted that the HFEA’s own Public Attitude Survey on its role revealed a very low awareness of it by the public.³

¹ See for example, *Human Reproductive Technologies and the Law*, House of Commons Science and Technology Committee, Fifth Report, session 2004–5, HC 7-1, vol I, para 385 and Joint Committee on the Human Tissue and Embryos (Draft) Bill, Session 2006–7, HL 169, HC 630, vols I (Report) and II (Evidence).

² Progress Educational Trust, ‘Quangoing, going gone: what should happen to the HFEA?’ held at University College London, 11th September 2012.

³ Results of the Public Attitude Survey were minuted in the Authority meeting of 8 September 2010. Available at www.hfea.gov.uk/docs/2010-10-13_approved_and_signed_Authority_Meeting.pdf.

With this in mind, let us turn to the functions and how they may be transferred or modified.

(1). A technical regulator for both treatment and research.

I would agree with the proposal in the CP that research licensing should be separated from treatment and I would support the transfer of research licensing activities to the Health Research Authority. Consequently, what follows relates to the provision of IVF treatment, with all research functions being transferred to the HRA.

The licensing of premises carrying out IVF treatment is central in the HFEA's role. One criticism of the HFEA at present is that it does not maintain sufficient distance from its regulates to ensure compliance and effective enforcement. The Hampton Implementation Review Report highlighted this risk of 'capture'.⁴ Transferring licensing and enforcement duties to the CQC would therefore address this issue. Moreover, there would be economies of scale in such a transfer, as the CQC already licenses many clinics for general activities. Although the CQC clearly has some operational difficulties with respect to adequate licensing and review procedures, the transfer of functions from the HFEA (and potentially the HTA) should provide the opportunity for review of the CQC itself to ensure that it is robustly prepared to take on such a role.

It is then feasible to suggest that the transfer of licensing and enforcement procedures to the CQC would negate the need for some backroom functions and notably for the existing Standing Committees of the Authority. At present, it boasts five: the Audit and Governance Committee, the Compliance Committee, the Remuneration Committee, the Ethics and Law Advisory Committee, and the Scientific and Clinical Advances Advisory Committee. On the current proposition, the Audit and Governance, Compliance and Remuneration Committees would no longer be required. Likewise, burdens on clinics would be reduced in the amount of paperwork and licence procedures would be reduced.

The elaboration of a Code of Practice for clinics carrying out IVF treatment and research is the backbone of the HFEA's work. The current edition clearly demarcates between the statutory requirements and the advice on good practice and it is obviously a mechanism which allows for policy imperatives to be incorporated by the clinics. Given the importance of the Code, it must be suggested that the Department of Health be responsible for its development, with the CQC being charged with its application and enforcement. Nevertheless, its detailed provisions require expert knowledge and experience in this field and it is imperative that a specialist arm of the CQC be created in order to respond to this need. This would require tapping into some of the existing expertise in the personnel of the HFEA who could be transferred to the CQC.

(2). Ethical evaluation and policy development – In order to ensure accountability, policy should be developed by the Department of Health and not by any ALB. Where policy may require a decision on principle, it is then up to the Government to consider whether a legislative response is needed. The questions of HLA tissue typing to save a so-called 'saviour sibling', or on the question of compensation payments to gamete donors are two examples where the HFEA has assumed a policy role, which I would

⁴ Sir Philip Hampton, *Reducing Administrative Burdens: Effective Inspection and Enforcement* (March 2005)

argue is best left to Government and ultimately to Parliament. Indeed, the HFEA itself recognised this by requesting legislative conformation of the policy it had developed on HLA tissue typing. If the functions of the HFEA are being transferred, the question of ethical oversight comes to the fore. The CP fails to acknowledge that both the HFEA and the HTA have internal ethics committees. Whilst this is an inadequate ethical structure, it nevertheless begs the question of where any ethical evaluation and discussion will take place once the bodies are abolished? I have argued that the UK needs an independent Ethics Commission⁵ and I attach a copy of this article herewith. Although Parliament must remain the final arbiter of ethical distinctions, there are many issues which require ethical evaluation through the provision of public debate. Once again, the abolition of the HFEA gives the ideal opportunity to review the provision of ethical debate in the UK and the Government should embrace this avenue ripe for development.

(3). Provision of information and guardian of personal data

In conjunction with the expertise required for the efficient development of the Code of Practice, the HFEA is currently mandated to advise Government on advances in assisted conception treatment and research—a role it is able to carry out effectively, in part due to its close relationship with the licensed clinics and the more recent creation of its Horizon Scanning Panel, which reports to the Scientific and Clinical Advances Advisory Committee (SCAAC). However, abolition of the HFEA does not mean a penury of expert advice. On the contrary, expertise should come from professional bodies and it is arguably more transparent for a system of reporting by them to the policy makers in the Department of Health.

It then follows, that the Department of Health should provide a hub for information on techniques, advances and clinics. Once again, realism is required in assessing the current impact of the HFEA's provision of information. Whilst it is without doubt a rich source of information and further contacts, anecdotal evidence suggests that the HFEA is not the first port of call for those embarking upon IVF treatment.⁶ Information on clinics would be available through the CQC as is the existing case for other healthcare providers presently regulated by the CQC.

It is perhaps the guardianship of personal information which is the most problematic in considering a transfer of functions from the HFEA. There are clearly concerns with the safeguarding and release of information on donor-conceived children and their donors and half-siblings, once the offspring reach majority. Yet this overhaul of the HFEA's functions could provide an opportunity for complex questions of information to be actively dealt with. Since the law removed donor anonymity, we have yet to see the consequences for the offspring when they reach the age of majority (at the earliest in 2023). This should not be ignored and the question not only of where the information is stored, but also how it is revealed needs to be grappled with. Clinics are in the front line here and there is scope for express recognition of the role of the clinic in this context.

[REDACTED]

There has been some suggestion that it may be appropriate for registers of donors and donor offspring to be kept by the General Registrar, as is currently the case with birth and adoption records.⁷ It is perhaps opportune to consider once again whether in fact any mention of donation should actually appear on a birth register (either on the birth certificate itself, or more probable, on a separate register linked to the birth certificate). But this would require that adequate provision be made for informing offspring and supporting parents in this role. What is clear is that there needs to be a central database coupled with central support mechanisms for individuals to gain access to the information stored within it. Beyond directly affected individuals, there is also the need for data to be available for research purposes. I would support the suggestion that the Information Centre for Health and Social Care could be an appropriate forum where this anonymous data could be held.

In conclusion, I respond as follows:

1. The majority of the current HFEA's technical, quality control, risk-based regulatory functions for IVF treatment could be transferred to the CQC. This would require some existing HFEA expertise to be brought into the CQC. The Health Research Agency should take responsibility for equivalent functions relating to embryology research.
There would be two main advantages : (i) administrative cost savings and a reduction in administrative burdens for clinics; (ii) potentially more effective compliance and enforcement because the CQC / HRA are not at the same risk of capture as the HFEA by its regulates.
2. The CQC should assume responsibility for respect of the Code of Practice. Amendments to the Code should be made by Department of Health, after consultation with professional bodies and clinic representatives.
3. Policy decisions should be taken by the Department of Health; principles decisions should be introduced through democratic expression in Parliament.
4. Professional bodies should provide advice and information to the Department of Health on scientific progress and developments. A central hub of information should be available.
5. Serious thought should be given to the development of an independent national ethics committee to encourage ethical evaluation and discussion. This Committee could also be the first evaluator of new technologies or applications. Public engagement and education should be at the centre of its functioning.
6. The information kept by the HFEA on its register of donors and offspring carries very important personal information as well as providing rich data for research purposes and potential follow-up. Reform of the HFEA provides the ideal opportunity to consider the use and transmission of the personal data, particularly for offspring. Whilst the Health and Social Care Information Centre may be the appropriate home for data used for research purposes, a more bespoke solution is required for the information kept for donor offspring. Consideration should be given to incorporating this information into the General Register of Births, but through a system which respects personal

⁷ Eric Blyth *et al*, 'Wither the HFEA and the Fate of Donor Registers?' *Bionews* 572, 23 August 2010, www.bionews.org.uk/page_69470.asp.

privacy. How and what information is given to donor offspring families should be the object of specific reflection.

7. All of the above may result in some financial savings, but we should not be duped: the amount of functions being transferred will require expertise to follow. The main advantage of transferring from the HFEA (and its ultimate abolition by statute) must be the provision of 'better regulation' – transparent, accessible and relevant to the health landscape of IVF treatment and research in the 21st Century.

Response 29 : Sheffield Teaching Hospitals NHS Foundation Trust, Centre for Reproductive Medicine and Fertility

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

As a stakeholder, we do not agree with abolishing the HFEA and moving functions to the CQC. We believe that there is a clear advantage in retaining a specialist regulator in this complex field, not only to ensure public confidence, but also to ensure effective regulation. The HFEA is well recognised and respected not only nationally but internationally and has the advantage of developing its regulatory systems over a 20 year period. Since 1991 the HFEA has dealt with ethical and policy issues, developed clear Codes of Practice and improved the inspection process. It was also able to become one of two competent authorities for the European Union Tissue and Cells Directive (2004/23/EC) which reduced the impact and burden of this legislation for UK centres. As a highly visible and respected organisation, patients have a trusted point of contact and the website provides invaluable information to patients embarking on fertility treatment. The HFEA also maintains a confidential register currently containing over 1 million records. Accuracy of this register is paramount as it holds details of every treatment carried out in the UK and information about the genetic identity of offspring. The HFEA is responsible, via this register, for the provision of certain non identifying information to parents and donors. It is also responsible for the provision of identifying information, about their donor, to donor conceived people when they reach the age of 18. All of this information is of a highly sensitive nature and requires expert handling by a dedicated and experienced body of people with access to professional counselling where needed. The HFEA already has such a team with the necessary knowledge and expertise. The CQC has no experience in maintaining such registers which raises considerable concern.

We believe that the primary aim of the government appears to be on saving money with no regard to the interests of patients, donors and donor conceived people. As stakeholders who represent clinic staff working with donors and potential parents of donor conceived offspring, it is vital that we have confidence in the services provided to these individuals now and in the future. The ethical recruitment of donors and treatment of patients using donor gametes and embryos is dependent on the maintenance of a secure and accurate register with a proper framework of information provision, counselling and support.

The HFEA also has functions in relation to the whole of the UK, the function of the CQC is currently limited to England only, which brings into question consistency between centres nationally in the future.

Whilst the HFEA has over 20 years of experience, the CQC is a relatively new organisation only having been in existence since 2009. We have concerns that the CQC is insufficiently experienced in regulating a complex and sensitive area of medicine. Since its founding, the CQC has been subject to much public criticism especially over its failures. The recent Winterbourne View Report highlighted many

failures in the CQC with respect to management and how information was handled and communicated. It also raised grave concerns over the fact that the CQC had previously rated the centre excellent and it was only the Panorama television programme which highlighted the mistreatment of patients.

Parliamentary MPs have also raised concerns over the CQC. A recent report by the National Audit Office concluded the organisation did not provide value for money; the NAO also raised concerns regarding training of inspectors and the number of inspectors who have a clinical background. The Mid Stafford scandal highlighted failings in several departments in the CQC and where reports by regulators had not always identified problems. Inspection teams need to be highly specialised and focused on their area of regulation to ensure effective inspections occur. The CQC does not have experience of developing codes of practice, collecting information, providing information, especially of a sensitive nature as in donor conception, and the CQC board is very different to the Authority board. The CQC is a large organisation which already seems overburdened. The HFEA has a dedicated small team of staff compared to approx 1900 in the CQC.

Whilst we believe there is an advantage for the HFEA to remain a single specialist regulator, we do believe that further improvements should be made to increase the effectiveness of the HFEA. As the HFEA is now located within the CQC, the HFEA can work more easily to identify the regulatory overlaps and move to joint inspections if appropriate. Joint working with the CQC could reduce regulatory burden and increase efficiencies if a single integrated inspection could take place. The HFEA is already working with the professional bodies to identify where further improvements could be made.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

As service providers we need effective regulation which promotes good practice in a defined framework. We believe that the current system delivers this. The HFEA is an initial point of call for many patients and centre staff. The web site is an excellent resource. The current expertise needs to be maintained and there is concern that in a large organisation like the CQC, this will be lost or diluted. The IVF sector is very specific and needs experts to deal with problems. If the HFEA were abolished and a change in the regulatory mechanism occurs, this may lead to an increased burden on the sector and a loss of confidence for the public. There is also the concern that there may be an increase in fees should this occur.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

There are very few currently licensed projects and the HFEA do not have a dedicated department to do this. The Health Research Authority is designed to protect and promote the interests of patients and the public in health research. It also works closely with other research organisations and will be able to deliver a consistent approach. It is therefore better placed than the HFEA to regulate research. The only concern is that there will be adequate expertise to meet the requirements of that HFE Act and a mechanism to protect information held on the register to which researchers can gain access to with patient consent. The public also needs to have confidence as there are many ethical issues surrounding the use of embryos in research.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

The functions of the HFEA would not sit better with any other organisations. The complex nature of IVF and the legislation surrounding it mean it is more advantageous for the functions to sit together.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

The HFEA should retain its existing functions but undertake a review to determine where efficiencies can be made. This process has actually already commenced and dialogue with professional bodies has promoted discussion as to where future improvements may lie. This includes more efficient data collection and mechanisms for policy formulation. The review mechanism could cover where regulation has 'crept' away from the core requirements and where focus can be reduced. Coherent joint working with the CQC will reduce time spent on inspections and prevent regulatory overlap. The HFEA provides a sound regulatory framework which is recognised internationally. The organisation has high public confidence in a sensitive area of practice. The same level of confidence in the CQC is questionable especially in the light of Mid Staffs and Winterborne View. The HFEA has a sound base to start with and has listened and changed practice to drive efficiencies. To start afresh with a new organisation could be counter productive and be more costly. The option of abolishing the HFEA and staff moving to the CQC to maintain expertise serves only to reduce an ALB in name and does not ensure cost efficiencies.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

The HFEA have already undergone changes to save money. Moving to the CQC office was an initial response to the challenge. Developing this relationship further to prevent regulatory overlap will produce savings. Engaging with the professional bodies has also enabled suggestions to be considered; reviewing regulatory 'creep' and the amount of data collected could not only be cost saving but also reduced regulatory burden on the sector. The HFEA could retain its autonomy and brand name, but sit underneath the umbrella of the CQC. Expertise would therefore not be lost and the organisation could continue to operate but with further improvements.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The research function should be transferred to HRA. This is appropriate as it will have more expertise than the HFEA.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

The cost saving with reducing salaries for the chairs and chief executives is substantial but effective regulation has to be the priority. Reducing overlap in inspections is a more practical and sensible way to reduce costs which can be achieved through more collaboration between the CQC and HFEA.

9. This consultation focuses specifically on where functions might sit and

implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

Whilst we support retention of the HFEA a review of how it functions should be carried out. The process of review should involve the professional bodies and stakeholders.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Option 3 is our preferred option, but this should include the option of research being transferred to the HRA. For this option to be successful further review will be required and involve more collaborative work between the CQC and HFEA. It is essential though that further improvements are made to the HFEA

11. Can you provide examples of costs and benefits of these proposals?

No

12. Do you have any comments on the consultation Equality Analysis?

No

Response 30 : Comment on Reproductive Ethics (CORE)

“23 September 2012

Re: Consultation on Proposals to Transfer Functions from the Human Fertilisation & Embryology Authority and the Human Tissue Authority

Thank you very much for the invitation to the workshop on 19 September, 2012.

The position of CORE, and of other colleagues who most frequently share our views, is that there should be no transfer of functions from the HFEA and that, whilst there is always room for improvement, we are not convinced that the Care Quality Commission could provide the same degree of responsibility (for example, in regard to the keeping of records) that the HFEA has developed over its years of experience.

That is not to say that there should not be a review of the remit of the HFEA which we would insist should not be extended beyond the provisions of the Human Fertilisation & Embryology Act 1990 (with the Amendments of 2008) in such a way as to cover for example debating controversial new technologies such as the current mitochondrial replacement proposals.

The special characteristic of the HFE Act is its focus on the human embryo, which we do not consider to be just another type of human tissue, and we feel therefore that it is appropriate for there to be a unique body in charge of legislation in this field.

We have no particular comments to make in relationship to the HTA except to note that gonadal tissues, and any human tissue that is potentially germline rather than somatic, should remain under the jurisdiction of the HFEA rather than the HTA.

At the workshop I attended there was discussion on the issue of policy making. It certainly appears to me that this is the most important aspect when the creation of human life is involved, and yet it seems to be the most neglected. The HFEA should not have any role in innovative policy making which should instead in our opinion be entrusted to a National Bioethics Committee, constructed along the lines of other countries such as France or Italy.

Some years ago a proposal was put together by Prof John Haldane mapping out such a committee and we attach this for your interest.

Thank you for your attention
Josephine Quintavalle
Director”

United Kingdom National Bioethics Committee
(June 2005)

Rationale

The case for the establishment of a UK national bioethics committee (UKNBC) can be summarised briefly.

- In Britain as in other societies we find ourselves in a situation in which those who make policy, those who implement it, and those whose lives are influenced by it are all challenged by hitherto barely imaginable medical and technological advances. There are enormous opportunities for good but there are also risks and threats to individual and social well-being.
- In recent decades we have become increasingly aware of the ethical dimensions of policy and practice. It is not enough to ask about what *has been* done in the past or what *could be* done in the future, we need also to address the question *what should* be done? This is in part a matter of prudence, effectiveness and efficiency; but it also has an important and ineliminable ethical aspect.
- Ethics comprises the identification of values and principles but also the determination of their appropriate application in particular fields and cases. This is no easy matter particularly given the diversity of moral, social and religious perspectives that characterises contemporary society. At the same time, however, there is widespread agreement on the importance of ethics; and among those who reflect upon such matters there is general agreement about the centrality of such values as welfare, autonomy and respect, and growing recognition that they cannot be reduced to a single value but must be maintained in some kind of balance.
- The field of bioethics brings together philosophy, science, medicine and healthcare but increasingly it recognises the need to have regard to broad social interests and well as the needs and concerns of specialists groups.
- The problems are pressing, the concerns are widespread and the issues are difficult, but there are also resources that can be brought to bear to provide policy makers and others with information, advice and guidance. Hitherto individuals, organisations and institutions have directed their attention to bioethical issues, but the time has arrived to establish a national resource responsive to UK needs, and which though independent of government is responsible to the nation through Parliament.

The existing situation

- The field of bioethics is well developed among academics, and for some years it has featured in medical and healthcare education. Patient and other service user-groups are also increasingly aware of the ethical aspect of their interest. In addition, religious faiths, denominations, and other value-based communities and organisations have focussed attention on bioethical issues, generally in response to developing, or prospective practices in which they have particular interests or concerns.
- Out of this background have emerged a number of academic journals, societies, and research groups, usually university based, as well as a growing cluster of voluntary organisations, large and small. Publications such as the *Journal of Medical Ethics*, or bodies such as the Nuffield Council represent high professional standards or research and dissemination, but good work has

also been done by small but committed groups. One such is CORE (Comment on Reproductive Ethics), which is prominent in the UK, often challenging decisions of bodies such as the HFEA (Human Fertilisation and Embryology Authority). Other groupings, such as PET (Progress Educational Trust) represent opposing ethical positions, and this diversity of independent parties has contributed much to the extent and level of current debates – in particular by drawing issues to the attention of the public and of politicians.

- In other parts of the world it has come to be recognised that the scale, importance and difficulty of bioethical issues calls for the establishment of national committees within which these can be analysed, reviewed and debated with the purpose of informing society and policy makers. In March 2005 the European Council of National Bioethics Committees (COMETH) produced a report on the functioning of the 42 national committees that comprise its membership. As this figure indicates, COMETH membership includes more than one committee per nation. These range from self-created voluntary associations to standing committees established by statute. There are two UK members: The Nuffield Council on Bioethics and the Scottish Council on Human Bioethics.
- In Austria, Belgium, Denmark, France, Germany, Italy, the Netherlands, Portugal, Sweden, and Switzerland, and in other countries, governments or ministers have established national bioethics committees. The constitutions, remits, operation and achievements of these bodies are relevant to the question of the establishment and responsibilities of a UK National Bioethics Committee. The Danish and German models are widely admired (see Appendix) but several others also have good features.

Proposal for a UK National Bioethics Committee

The idea of a UKNBC has arisen in the past, but in recent times it has re-emerged with greater urgency and definition in response to the growing number of difficult issues and decisions. One focus of these has been the review by the Commons Science and Technology Committee of the operations of the HFE Act and of the HFEA. In the course of that review members of the Committee and witnesses to it spoke favourably of the idea of an NBC, and in the same period Prof. John Haldane, Director of the Centre for Ethics, Philosophy and Public Affairs in the University of St Andrews (the leading UK philosophy and policy centre) has pressed the case in several contexts including in letters to the *Times* and *Telegraph*. Calls for the establishment by government of a UKNBC have also been made by the Archbishop of Westminster and by the Chief Rabbi.

- A UKNBC should have the authority and standing of an independent statutory body. Its membership should encompass relevant professional expertise, patients and other user-group interests, as well as major religious and ethical groupings.
- Membership must reflect the diversity of positions within society, and appointment procedures must be public and transparent.
- Though independent, the UKNBC should be responsible to Parliament through a government minister to whom it should deliver an annual report including recommendations for policy and such additional reports as may be commissioned or submitted.

- Its remit would be the entire range of bioethical issues, including but not confined to those concerning reproduction.

United Kingdom National Bioethics Committee

Appendix 1 Sample National Bioethic Committee Constitutions and Remits (1. Denmark and 2. Germany)

1. Denmark

The Act on The Danish Council of Ethics

Act No. 440 of 9 June 2004

Act on the Council of Ethics

WE MARGRETHE THE SECOND, by the Grace of God Queen of Denmark, do hereby make known: Folketinget has passed and We have provided the following Act with our Royal Assent:

Part 1

Purpose and sphere of activity

1. The Danish Council of Ethics is an independent council. The Council's operations and activities shall be based on respect for the integrity and dignity of the human being and future generations as well as respect for nature and the environment. Respect for the integrity and dignity of the human being also encompasses the early phases of human life, including fertilized human eggs and embryos. Respect for nature and the environment is conditional on nature and the environment having a value in their own right.

1. (2) The Council's sphere of activity is the ethical issues associated with the researching and application of biotechnologies and genetic engineering pertaining to human beings, nature, the environment and foodstuffs. The Council's sphere of activity also includes other ethical issues associated with health services and biomedical research relating to human beings.

1. (3) The ethical and animal welfare issues associated with the researching and application of biotechnologies and genetic engineering related to animals fall outside of the Council's sphere of activity.

2. The Council shall advise Folketinget, ministers and public authorities on the ethical issues mentioned in Section 1, subs. 2.

3. The Council shall follow developments and submit statements or reports on the general and fundamental ethical issues associated with the researching and application of biotechnologies and genetic engineering within one or more of the following fields:

- 1) Health, including reproductive technology, fetal diagnosis and the use of fertilized human eggs, embryos and fetuses.
- 2) Nature and the environment, including concerns about preserving biodiversity and sustainable development.
- 3) Food, including issues relating to food production.

3. (2) The Council shall further monitor developments and submit statements or reports on other general and fundamental ethical questions associated with health services and biomedical research relating to the human being, including the use of new forms of treatment and therapeutic procedures, new diagnostic techniques and new medical technology as well as questions concerning the registration, disclosure and use of data concerning hereditary diseases or attributes in individuals or groups of people.

4. The Council shall conduct information and debate-generating activities concerning the ethical problems and challenges faced by society. The Council shall make provisions to keep the Danish public continually informed about developments and about its work, ensuring that

such ethical issues are made the subject of public debate. The Council can make use of public enquiries and set up working parties etc. to report on particular issues.

4. (2) The Council shall submit an annual report to the Danish Minister for the Interior and Health, the Minister for the Environment, the Minister for Food, Agriculture and Fisheries, the Minister for Science, Technology and Innovation, and the Minister for Economic and Business Affairs, as well as Folketinget.

5. Within its sphere of activity the Council can deal with issues of a general and fundamental ethical nature on its own initiative. The Council shall itself assign priority to assignments within its sphere of activity

Part 2 Organisation

6. The Minister for the Interior and Health shall appoint the Council of Ethics.

7. At the beginning of each parliamentary year and after general elections, Folketinget shall appoint from its own number a committee of nine members elected by proportional representation. In the same manner, an alternate shall be appointed for each member.

7. (2) The committee shall constantly monitor the work of the Council of Ethics by means of joint meetings and similar arrangements. Furthermore, the Committee can ask the Council of Ethics to deal with specified subjects within the Council's terms of reference.

8. The Council of Ethics shall consist of 17 members, to be appointed by the Minister for the Interior and Health according to the following rules:

Nine members shall be appointed by the Committee referred to in Section 7. Said persons may not be a Member of Folketinget, a municipal council or a county council. Where the Committee cannot agree on an appointment, this shall be decided by a majority of the Committee.

Four members shall be appointed by the Minister for the Interior and Health.

One member shall be appointed by the Minister for the Environment.

One member shall be appointed by the Minister for Food, Agriculture and Fisheries

One member shall be appointed by the Minister for Science, Technology and Innovation.

One member shall be appointed by the Minister for Economic and Business Affairs.

8. (2) Those members to be appointed in accordance with subs. 1, subparagraphs 2-6, shall have insight into the ethical, cultural, social and other professional issues of importance to the Council's work.

8. (3) In nominating and appointing members, it shall be ensured that both laypersons and professionals are represented on the Council.

8. (4) In nominating and appointing members, it shall be ensured that the Council has equal numbers of both sexes with the addition of only one more person of either.

8. (5) The chairperson shall be appointed from among the designated members by the Minister for the Interior and Health on the recommendation of the Committee mentioned in Section 7.

8. (6) The members and chairperson shall be appointed for a term of three years. Reappointment may take place once.

8. (7) The Council shall lay down its own rules of procedure

9. The Council of Ethics shall operate in collaboration with the Central Scientific Ethical Committee, the Ethical Council for Animals, the Board of Technology and relevant authorities etc.

9. (2) The Council of Ethics can create fora for dialogue with representatives of relevant research environments, commercial enterprises and special-interest organisations with a view to promoting the flow of information and ensuring interdisciplinary dialogue, cf. Section 4.

10. Attached to the Council shall be a secretariat whose staff are employed and dismissed by the Minister for the Interior and Health on the recommendation of the chairperson of the Council.

*Part 3
Commencement etc.*

11. This Act shall come into force on 1 January 2005, cf. however subs. 3.

11. (2) The Act on the Formation of a Council of Ethics shall simultaneously be repealed, cf. [Danish Consolidation Act No. 220 of 4 March 1997](#).

11. (3). The committee referred to in Section 7 shall be set up for the first time at the beginning of the 2004-5 parliamentary year.

12. The Danish Act on Environment and Genetic Engineering, cf. Consolidation Act No. 981 of 3 December 2002, shall be amended as follows:

1. Section 9a, subs. 3, shall be repealed.
Subs. 4 will then become subs. 3.

13. Danish Act No. 402 of 28 May 2003 on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects shall be amended as follows:

1. Section 24, subs. 1, subparagraph 2, shall be worded thus:
"2) to monitor research developments in the field of health and to work towards an understanding of the ethical problems to which such developments may lead in terms of health services and biomedical research environments, and"

Section 14. The Danish Board of Technology Act No. 375 of 14 June 1995, as amended by Section 26 of Act No. 388 of 30 May 2000 and Section 2 of Act No. 396 of 6 June 2002, shall be amended as follows:

1. By way of a new subsection after subs. 1, the following shall be inserted in Section 4:
"4. (2) The Danish Board of Technology shall collaborate with other boards and councils and shall be involved in ongoing discussions with them as to the demarcation and distribution of their remit."
Subs. 2 will then become subs. 3.

15. This Act does not extend to the Faroe Islands and Greenland, but can be extended by Royal Decree to the Faroe Islands subject to such departures as may be required by circumstances peculiar to those parts

*Given at Christiansborg Palace on 9 June 2004
Under Our Royal Hand and Seal*

Margrethe R.
/ Lars Løkke Rasmussen

2. Germany

Decree of 2 May 2001

Establishment of a National Ethics Council

§ 1

A National Ethics Council shall be established as a national forum for dialogue on ethical issues in the life sciences.

§ 2

(1) The National Ethics Council shall be the central organ for interdisciplinary discourse between the natural sciences, medicine, theology and philosophy, and the social and legal sciences. It shall organize the social and political debate and ensure that all the relevant groups are involved. It shall provide citizens with information and material for discussion (e.g. exhibitions, publications, Internet forums, etc.). Every year the National Ethics Council shall hold at least one public conference on ethical issues.

(2) The National Ethics Council shall express views on ethical issues relating to new developments in the field of the life sciences and on their consequences for the individual and society.

The National Ethics Council shall also draw up Opinions at the request of the Federal Government or of the Lower House of the Federal Parliament (the Bundestag).

(3) The National Ethics Council shall submit recommendations for political and legislative action.

(4) The National Ethics Council shall work together with the national ethics committees and comparable institutions of other States, in particular European States, and of international organisations.

(5) The National Ethics Council shall report to the Federal Chancellor at least once a year, on 1 October, on the situation of the social debate.

§ 3

(1) The National Ethics Council shall be composed of up to 25 members, who shall be prominent representatives of the scientific, medical, theological, philosophical, social, legal, ecological and economic worlds.

(2) The members of the National Ethics Council shall belong neither to the Federal or a Land government nor to a Federal or Land legislative body.

(3) The members of the National Ethics Council shall be appointed by the Federal Chancellor for a term of four years. They shall be eligible for reappointment once.

(4) Members may resign from the National Ethics Council at any time by giving notice in writing to the Federal Chancellor.

(5) If a member resigns before the end of his or her term, a new member shall be appointed for the duration of the period of office of the resigning member.

(6) The National Ethics Council shall elect a chair and a deputy chair from among its members by secret ballot for a period of four years. The chair and the deputy chair shall be eligible for re-election once.

(7) The National Ethics Council shall provide itself with Rules of Procedure.

§ 4

The National Ethics Council shall be bound solely by the function laid down in this decree and its activity shall be independent.

Its Opinions, recommendations and reports shall be published.

If a minority takes a dissenting view in the drafting of Opinions, recommendations and reports, it shall have an opportunity of expressing that view.

§ 5

The National Ethics Council shall be assisted in the conduct of its work by a General Secretariat, which shall be located in the premises of the Berlin-Brandenburg Academy of Sciences.

§ 6

Upon request the members of the National Ethics Council shall be reimbursed with their expenses, including travel expenses in accordance with the provisions of the Federal Travel Expenses Law.

§ 7

The costs of the National Ethics Council and of its General Secretariat shall be borne by the Federal Government.

Appendix

Rules of procedure

In accordance with § 3(7) of the Decree establishing a National Ethics Council dated 2 May 2001 (Decision of the Federal Cabinet), the Council provided itself with the following Rules of Procedure at its meeting of 6 July 2001:

§ 1

Independence of members. Conflict of interest. Duty of secrecy

(1) The members of the Council shall not be bound by external instructions. They shall represent their personal convictions and shall be subject to their conscience alone.

(2) In the event of concern about a possible conflict of interest in relation to a specific issue, the relevant member shall declare this to the chair and discuss it with him or her. Should agreement not be reached in this discussion as to whether a conflict of interest exists, the Council shall rule in the absence of the relevant member on whether he or she shall participate in the deliberations and in the taking of a decision on the issue in question.

(3) The members shall observe secrecy with regard to the deliberations and to documents stated to be confidential. The same requirement shall apply to experts and to other persons summoned by the Council to attend its meetings or to work with it in any other way.

§ 2

Taking of decisions

The Council shall have a quorum for taking decisions if not less than 13 members are present. Except where different majorities are provided for in these Rules of Procedure, the Council shall take decisions by a majority of the votes of the members present. In the event of a tie the chair shall have the casting vote.

§ 3

Office of chair

(1) The chair and his or her deputies shall be elected by absolute majority of votes of the members of the Council. If this majority is not obtained in a first ballot, a second ballot shall be held and the decision shall be taken by relative majority. In the event of a tie the result shall be decided by lot.

(2) The chair shall be in charge of meetings and shall be responsible for preparing their agenda. He or she shall represent the Council to outside bodies and individuals. If he or she is prevented from exercising his or her functions, his or her deputies shall assume these functions in the order determined by the Council. With the consent of the Council he or she may assign individual functions to the deputies.

§ 4

Work programme

The Council shall provide itself with a work programme on the basis of the Decree of 2 May 2001 by which the Council was established. This programme shall as a rule be updated annually.

§ 5

Meetings

(1) Meetings shall as a rule be held monthly in Berlin. They shall not be public unless the Council so decides.

(2) The dates of each meeting shall be set for a fairly long period in advance by the Council. An extraordinary meeting shall be held within ten days if so requested by not less than seven members.

(3) The agenda of each meeting shall be fixed provisionally at the preceding meeting. The chair may add further items to the agenda if the need arises subsequently. He or she shall do this if so requested by three members. A final decision on the agenda shall be taken at the beginning of the relevant meeting.

(4) Notices convening meetings shall be despatched not less than ten days in advance and shall be accompanied by the agenda and by the necessary documents. In the case of extraordinary meetings the period of notice shall be three days.

§ 5 a

Public meetings

(1) Meetings of the Council shall be open to the public in so far as they serve the preparation and discussion of Council opinions and recommendations; the Council may deviate from this arrangement in exceptional cases. Meetings of the working parties shall not be open to the public.

(2) Agenda items which are to be discussed at a public meeting in accordance with paragraph (1) shall be so identified on the agenda. The agenda shall be made public on the Internet.

(3) Admission to public meetings shall be subject to the availability of seating. The Council may allow meetings to be filmed or recorded in individual cases.

§ 6

Minutes

Minutes recording the results of meetings shall be drawn up. The minutes shall be forwarded to all members within two weeks of the relevant meeting. Any objections shall be raised within ten days of forwarding. If an objection is not accepted, a decision on it shall be taken at the next meeting.

§ 7

Expert reports, experts and guests

The Council may commission studies or expert reports and invite experts to its meetings. In addition, representatives of the constitutional bodies entitled to submit issues for consideration, of authorities and institutions, of organisations and associations, as well as other guests, may be invited to attend meetings on specific topics.

§ 8

Rapporteurs. Working parties

(1) The Council may appoint members, subject to their consent, to act as rapporteurs on specific topics.

(2) In addition, the Council may appoint working parties from among its members to prepare individual topics, as well as to discuss entire fields of related topics. The working parties shall appoint their spokesperson and, if required, their rapporteurs to present the results of their work to the Council.

§ 9

Expression of views. Publications

(1) Opinions, recommendations and annual reports shall be adopted after oral discussion on the basis of the draft presented by the rapporteur. If this cannot be done immediately after the relevant deliberations, the taking of a decision may be postponed until the next meeting. For this purpose a version of the draft revised by the rapporteur on the basis of the results of the proceedings shall be forwarded to the members sufficiently in advance of that meeting. At the request of members who disagree with the version adopted, the relevant dissenting views shall be attached to the decision.

(2) The Council shall decide in each individual case as to the timing and manner of publication of Opinions, recommendations and reports.

§ 10

Provision of information and material for discussion. Public conferences

The Council shall draw up information and discussion material to be addressed to interested groups and shall prepare public conferences. For this purpose too, rapporteurs may be appointed and working parties set up.

§ 11

General Secretariat. Budget

(1) The Council shall be assisted in its work by a General Secretariat. The staff of the General Secretariat shall carry out the instructions of the Council in matters relating to the Council's function and, where the day-to-day business of the Council is concerned, the instructions of its chair.

(2) On the basis of proposals submitted by the chair, the Council shall decide on the organisation of the General Secretariat and on its executive-grade staffing as well as on the appropriation of the overall budget at its disposal.

(3) The staff of the General Secretariat shall attend meetings as determined by the Council.

§ 12

Amendments to the Rules of Procedure

Amendments to the Rules of Procedure shall be adopted by a two-thirds majority of the members of the Council.

Response 31 – Loughborough University

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

As long as all the functions of the HTA remain as before, then transferring is not a problem. As such, it doesn't matter where the regulation sits, as long as the regulation still occurs. That being said, the HTA has been an efficient and effective regulator.

The research sector of the HTA is a smaller part of the HTA's work, but should not be neglected. It is also the area of work that is potentially least familiar to the CQC, and therefore there is the potential of a change of approach which may negatively impact on the research activity. Also, there is a concern that, as a governing body taking on a new role, the CQC would feel that it needed to assure itself of standards and repeat inspections already undertaken by HTA.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

If a change is to be made, it should have no or minimal impact on the service providers and the patients. As an institution, it would be preferred that the only impact would be that the annual licence fee and all correspondence goes to a different address. It would be much better for the institution if all the systems were already in place, the staff had been well trained and it was an extremely smooth transition between the two organisations. If it was felt that there would be a significant impact then it would be better that the HFEA and HTA are allowed to remain as they are.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

We do not agree that it is suitable for HFEA's research functions to be moved to the HRA, if the HTA's research function does not. There is acknowledged concern that breaking up the HTA's functions will impact on the implementation of the Act, then breaking up the HFEA functions will potentially do the same?

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Moving the research component of the HTA's functions to the HRA could be advantageous as it would mean that all research functions are under the HRA, so providing a 'one-stop shop' for all things research. This would be

under the proviso, however, that the integrity of the work done by the HTA so far in terms of the public's perception of research and the reputation of the HTA was not lost.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes, we do believe this. The HTA has proven to be an extremely useful organisation, for both the public and those who need to contact them on a regular basis. They have already made efficiency savings, and there is no reason to doubt that they will continue to do so. The HTA has also restored public faith in a system after it was severely damaged.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Yes, we do believe this as we feel that the HTA has already proven that they have made efficiency savings, and will continue to do so in the future.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The HTA should be kept whole if it is to be retained. There is no advantage to keeping the HTA as an independent regulator and then splitting it up.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

A £3.8 million saving over 10 years for what will be a large amount of restructuring must be weighed against any confusion with the public.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

No comments.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

None

11. Can you provide examples of costs and benefits of these proposals?

None

12. Do you have any comments on the consultation Equality Analysis?

None

Response 32 : Project Group on Assisted Reproduction (PROGAR)

PROGAR (Project Group on Assisted Reproduction) was set up originally at the time of the Warnock Inquiry in the 1980s, taking forward work done by a predecessor group which had submitted evidence to that Inquiry on behalf of the British Association of Social Workers. PROGAR continues to be administered by the British Association of Social Workers, the largest professional association for social workers in the UK with more than 14,000 members employed in frontline, management, academic and research positions in all social care settings

PROGAR draws on the knowledge and expertise of social workers in the fields of infertility counselling, donor linking, adoption and fostering, child care, family work and health care as well as that of other groups of professionals, academics and people directly affected by donor conception. We work in partnership with:

- British Association for Adoption and Fostering
- British Infertility Counselling Association
- Cafcass (Child and Family Court Advisory and Support Service)
- DC Network
- NAGALRO (National Association of Guardian *ad litem*s and Reporting Officers)
- UK DonorLink
- Individual academics

PROGAR has contributed to policy discussions and policy formation in assisted conception on many occasions. The principles underlying PROGAR's work have always been that those conceived as a result of donor procedures and their families, donors of gametes and embryos and their families, those undergoing fertility investigations and treatment and those involved in surrogacy arrangements should receive the best care possible, including access to professional support. We firmly believe in the importance of early disclosure of origins to donor- conceived individuals and those born as a result of surrogacy arrangements, their right of access to identifying information about their donor(s) or surrogate and that policies and services should take full account of the lifelong implications of donor conception or surrogacy.

CONSULTATION RESPONSE

1. *Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.*

We are commenting solely on matters to do with the HFEA; those concerning the HTA fall outside of our area of core interest and expertise, namely the family building and well-being aspects of those directly affected by donor conception: donor conceived people; their families; donors and their families including their non donor-conceived offspring; and the well-being of those affected by surrogacy. While there are similarities with family building using other forms of assisted reproduction, we strongly believe that there are unique aspects where there is third party involvement in family building. Where donor conception is involved, the family that is formed (and the individual offspring) have to manage the implications of genetic difference over their lifetimes, including the potential and as yet unknown implications of donor mitochondrial use, not only over their own lifetimes, but also for their own descendants.

We are not opposed to the transfer of functions relating to research to the HRA (and see our response at Q2).

We are not opposed to the transfer of regulatory functions per se to the CQC (subject to it being delivered through a specialist arm as indicated in your consultation document as a possibility) but have grave concerns about the transfer to the CQC of those HFEA functions to do with:

- (i) maintaining donor conception related information for the central Register and Donor Sibling Link
- (ii) policy development and evaluation matters

There are a number of reasons for our opposition to the transfer to the CQC of (i) and (ii) and these are as follows:

- CQC is a regulatory body and hence has no skill or experience in dealing with the release of information from the Register to those seeking information from it because of being directly affected. This work would sit much better with or in an organisation that has skill and expertise in **the release of** personal information and associated intermediary work between those seeking personal information and those about whom personal information is sought.
- CQC is a regulatory body and hence has no skill or experience in policy development and associated consultation with the general public or with professional and personal stakeholders. This work would sit much better with or in an organisation that has skill and expertise in such work.
- We are aware that the Government will seek to extend the powers of the CQC to cover all 4 nations of the UK. This will bring new demands for the CQC at an organisational level as it seeks for the first time to manage the

necessary liaison with service providers, policy makers and so on in all 4 nations and to acquaint itself to an appropriate level with the relevant new systems, procedures and statutes. Demanding though this will be, it will at least be extending its remit within its core business (presuming those currently employed in this role by the HFEA will be transferred into the CQC, bringing their existing knowledge with them). Asking it to take on wholly new functions would, in our view, not be workable.

We make suggestions in our response at Q4 as to where these functions might be better placed.

With regard to inspection and regulation per se, we strongly believe that donor conception treatment services should continue to be regulated and inspected and welcome recognition of that by the Government, acknowledging the importance of ensuring minimum standards in this area of family building through the use of outside assistance. If this work were to be transferred to the CQC then it would need to:

- be carried out through a specialist arm that is well informed about family building and about lifelong donor conception matters
- have a title that reflects its work rather than using the CQC generic 'brand'
- take full account of the information arising from the work of our proposed national information release and intermediary service (see below) as well as that from medical and scientific services and research
- develop close and effective liaison with associated relevant services.

2. *Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?*

We understand that this question is asking for views about the impacts that we could perceive from transferring all HFEA functions except research to the CQC.

In relation to regulation and inspection, we believe that there could be some advantages to service providers. Existing overlaps between current non-HFEA inspection regimes involved in inspecting non-HFEA licensed aspects of service provision and that of the HFEA have arguably an improved likelihood of being removed through the transfer (we are aware that some work is also ongoing currently between the HFEA and CQC on this). However there would almost inevitably be hiccups in any transition period, perhaps especially in those parts of the UK where the CQC does not operate currently. Additionally we base our comments on the assumption that there would be a transfer of some of the HFEA staff to the CQC into a specialist arm.

We also believe that many patients and donors value the fact that services are licensed and inspected. It will therefore be important that this retains a high profile, including a name that reflects its work, as stated above.

3. *Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.*

This does not fall within our area of knowledge or expertise as this proposal relates to the current HFEA functions in relation to research licences for medical and scientific research only.

4. *Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?*

Given PROGAR's interests and expertise in child and family welfare matters (including those relating to information release and intermediary services) in relation to donor conception, surrogacy and adoption, our response deals solely with HFEA matters associated with donor conception and surrogacy, not the HTA. We use a lifespan and family building perspective to do so.

Our belief is that there are core functions (in addition to inspection and regulation) that need to be delivered safely and ethically, putting the needs of those directly affected at the centre. These are:

1. The accurate and appropriate collection of full information, including biographical information, by services that recruit gamete(s) donors and/or provide donor conception treatments (including where surrogacy is involved and potentially donated mitochondria).
2. The timely and safe transfer of such information, fully validated, onto what is currently called the HFEA Register of Information no later than at the birth of a donor-conceived child.
3. The safe and accurate updates to such information as and when it becomes available.
4. The safe and accurate recording of information, including updates, onto what is currently called Donor Sibling Link.
5. The release of information and provision of professional support and intermediary services as necessary to those seeking information and/or contact with those genetically related through donor conception.
6. The review and/or development of policy with regard to donor conception matters that attends to medical and scientific matters *within* a family building model in recognition that the core purpose of the use of donor conception treatments is to bring about a family. Putting long term child and family welfare at the core of all policy and service developments is crucial.
7. The regular review of evidence from psycho-social practice, research and theory and from user feedback (including from those throughout the life cycle not simply from patients and donors at around the time of treatment/donation). Such evidence to include that from related fields of child and family welfare.

The underlying principles as enacted in the 1990 and 2008 Acts lead us to conclude that policies and services to do with donor conception should be developed and delivered to a standard that meets the desired outcomes of:

- (i) enabling parents to raise their children with openness from an early age about their donor conception and in a happy, healthy and supportive environment;
- (ii) enabling those seeking information about and/or contact with those genetically related through donor conception to have confidence that it is robust and respectful in terms of accuracy and sufficiency and to receive appropriate levels of professional support in doing so in recognition of the potential complexity of the lifelong implications of third party conception.

It is our view that such standards have not been met adequately to date by the HFEA or the fertility treatment sector generally.

PROGAR has maintained a regular informal dialogue with the HFEA since the HFEA's establishment in 1991. Until recently, HFEA staff attended PROGAR's meetings as observers (although this presence was withdrawn as part of the HFEA's review and implementation of their professional stakeholder engagement policy). PROGAR has also held formal meetings with HFEA staff over many years: initially this was in conjunction with the British Infertility Counselling Association and, more recently, as part of the Professional Stakeholders Group. Some of our members have in their individual capacities acted as Inspectors, External Advisers and as an HFEA Member. PROGAR has also regularly responded to HFEA consultations. It is therefore with considerable depth of knowledge and experience that we make our comments.

Our experience is that the HFEA has traditionally worked hard to improve its inspection regime through seeking feedback and keeping abreast of broader developments in the field of regulation. Sadly, its record in relation to the inspection of counselling services is poor, despite this being raised with it on many occasions by PROGAR and BICA. The HFEA has also traditionally sought to have regular contact with professional stakeholders and with patients. At times, it has approached consultations and policy development creatively and openly. However our experience is that, especially in recent years in relation to third party conception family building, the HFEA culture has become increasingly defensive, risk averse and adversarial. It appears to struggle with engagement with stakeholders and other interested parties in a 'listening' way and instead is more likely to use such contacts in 'top-down' fashion to cascade information that they wish to impart. Most importantly in our view is that recent years have seen far too little progress towards putting the family that is formed at the core of its thinking and the HFEA's approach to information release from the Registers falls far short of what is acceptable good practice. This has contributed to its highly selective use of research, theory and practice evidence from both the field of donor conception and the broader fields of child and family welfare in its decision-making.

Recent examples to illustrate our concerns about policy development are the conduct of the recent Donation Review, the associated HFEA decisions in relation to payment to donors for which no support from the research evidence can be found, see for example ESHRA 2012⁸) in particular and the subsequent appointment of a National Donation Strategy Group where the focus is firmly on improving donor recruitment (incidentally not, in our view, the job of a regulator). In addition we have grave concerns about the HFEA's failure to date – more than 20 years since its launch - to develop and implement policies to ensure that all clinics collect good quality biographical information on donors.

In relation to the release of information from the Register and from Donor Sibling Link, PROGAR believes that the HFEA is not meeting its own policy as agreed at the Authority meeting on 20th January 2009 in response to the report from the multi-disciplinary Steering Group chaired by the British Infertility Counselling Association (BICA) and funded by the Department of Health (DH), the Scottish Executive and the Bruce Trust (BICA, 2003⁹) to look at the needs of those applying for information from the Register. In particular we believe that it is not meeting the following decisions that it made:

- The HFEA should ensure that donor-conceived people receive information on counselling before they make an application to the HFEA. This information should include *adequate* signposting to counselling services. Once an application has been lodged, the applicant must be told that they are free to change their mind at any point before the information is released.
- Currently there are a limited amount of people with the specialist counselling skills to address the emerging needs of donor-conceived people. *The HFEA has a role in engaging with the sector to ensure there is adequate provision of appropriate counselling expertise available to donor-conceived applicants.*
- *Front-line Register staff should have adequate training and skills to enable them to deal sensitively with applicants.*

(our italics)

HFEA Minutes, item 10 [HFEA (21/01/09) 485]

http://www.hfea.gov.uk/docs/2009-01-21_Authority_Meeting_minutes.pdf¹⁰

Currently, the HFEA only provides details of a generic counselling database (British Association for Counselling and Psychotherapy) and the British Infertility Counselling

⁸ http://humrep.oxfordjournals.org/content/27/suppl_2.toc?etoc

⁹ BICA (2003) 'Opening the Record - Planning the provision of Counselling to People applying for information from the HFEA Register – Report of the HFEA Register Counselling Project Steering Group' BICA Publications available at: <http://www.bica.net/downloadable/opening-record>

¹⁰ The paper that was taken to the Authority at this meeting can be found as follows: HFEA (2008) 'Opening the Register – a principled approach' TRIM reference 2008/07083 http://www.hfea.gov.uk/docs/AM_Item_9_Jan09.pdf accessed 29.8.2012

Association and advises enquirers that they can seek referral to GP counsellors. This does not, in our view, fulfil its role in ‘engaging with the sector to ensure adequate provision of *appropriate* counselling expertise to donor conceived registrants’ in respect of information release. It also provides details of the Donor Conception Network (the peer support group, primarily for families) and UK DonorLink (the voluntary register service for those conceived prior to the implementation of the 1990 Act) and website information about the implications of seeking information from the Registers. It does not make any provision either for those who wish to avail themselves of a counselling or intermediary service specialising in this work for those affected by donor conception or for those unable to afford private counselling or intermediary services. The HFEA has enabled a small number of its front line staff who deal with Register enquiries as a part of their core post to receive basic counselling skills training¹¹ but we have been unable to establish whether this is now part of their role specification, whether they receive supervision from a qualified counselling supervisor, or whether there is any ongoing user evaluation of the quality of their service.

We believe that functions (1) to (4) should be met as follows:

- The collection of the data on donors, treatment with donor gametes and live birth outcomes should continue to be a statutory obligation. These should be held on a single dedicated Donor Conception Register run by a body competent in handling large data sets and able to do so for the whole of the UK. Such a body should also maintain Donor Sibling Link. National minimum standards for clinics and the Registers should be in place to ensure the quality, safety and sufficiency of the information collected, including:
 - A (newly developed) Donor Information form that includes a *requirement* for biographical information. The categories for information collection should be kept under review in the light of emerging research and practice evidence and user feedback.
 - Donor gamete(s) to be released for use only after donor information is provided in full.
 - Clinics to be responsible for preparing a ‘child’s file’ comprising the Donor Information form(s), details of treatment cycle and legal parentage to be passed to the central Register following the notification of the child’s birth and validated at that stage. Clinics to retain a copy for their own records but all requests for information from those affected to be dealt with centrally.
 - Robust systems for collecting and updating information from the parties concerned (including family members in the case of mental incapacity or

¹¹ Progar would like to point out an apparent inaccuracy in the DH Consultation document at paragraph 132 page 61. Our understanding from the HFEA is that its staff have undergone counselling *skills* training but not counselling training – there is an important difference. We further understand that *one* of the staff has completed a Diploma in Counselling because of personal interest but we understand she is not a practising counsellor.

death) and supplying updated information to existing enquirers where appropriate.

- Central Register services to be responsible for updating such files to include non identifying information about any other children conceived using the same donor(s) and any other new information as it becomes available.
- Central Register services to be responsible for releasing information as required to a national information release and intermediary service (see below)

We believe that function (5) should be met as follows:

- There should be a centrally funded dedicated UK wide information release and intermediary service through which all enquiries to the Register and Donor Sibling Link are routed. Given that numbers seeking information are, as yet, quite low (though rising), that professional expertise in DC information release and intermediary services is currently held predominantly by the voluntary register, UK DonorLink, for those affected pre August 1991, and that the 2008 Act allows for the HFEA (and hence presumably its equivalent) to take power of authority to run a voluntary register (Section 31ZF) the national service should include those affected pre and post August 1991.

In addition, we have grave concerns about the position of those born through surrogacy arrangements (not currently a statutory responsibility of the HFEA unless the surrogacy involved donated gametes) and seeking information from the Parental Order Register at the age of majority. There are currently no plans to provide services to this group of people and we believe this to be wrong. Their needs could therefore be met through the proposed UK information release and intermediary service.

Consideration should be given to the UK service employing staff (appropriately qualified and with specific additional training to manage the unique features of donor conception) based in post adoption support services with a small number of centrally based staff to support them, thus enabling the exchange of experiences across services with shared interests as well as being potentially cost effective. Such services should be subject to a regulation system that applies across the UK, perhaps through the Ofsted system that currently inspects English post adoption services.

National minimum standards should be in place to ensure its quality, safety and sufficiency, including:

- A 'triage' system that assesses the support needs of those seeking information.
- Staffing requirements that reflect the need for professional qualifications and experience in sensitive areas of information release and intermediary work.

We believe that functions (6) and (7) should be met as follows:

Should the HFEA be abolished, the setting of the national minimum standards and development of policy in relation to donor conception should be undertaken by the relevant government department, currently the Department of Health for the 4 nations, with the support of advisers seconded for the purpose and chosen for their knowledge and experience in sensitive matters of information collection and release, intermediary work and family work. Given *current* legislative requirements under the HFE Act 1990, the body that is currently constituted as the HFEA could become an Expert Advisory Board to the government department. Such a Board must, in our view, have members selected for their expertise in child and family policy and practice and members with direct experience of donor conception, including donor offspring, together with a smaller number of those with appropriate medical, scientific and other experience.

As a reflection of the core purpose of donor conception treatment as family building, close collaboration with those government departments across the UK concerned with family policy, currently for example primarily the Department for Education for England, should be a requirement.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Our view is that, should the HFEA be retained, there is a need for significant improvements to its practice. The Authority membership is, we believe, too large. Its work is also adversely affected by the lack of representation to date from those directly affected, in particular donor conceived adults; this runs counter to government policy elsewhere that states the need to put those directly affected at the centre of policy and practice developments. In addition, the membership has to date been dominated by medical, scientific and ethical professional interests and has not adequately represented those with psycho-social interests in family building using third party assistance.

The HFEA's history of being an effective regulator has also been a checkered one. We are not qualified to comment on its robustness in relation to medical and scientific matters but its attention to the inspection of counselling and donor conception services, donor conception services is poor. In addition we believe that the HFEA has been too cautious in its interpretation of its responsibilities with regard to the inspection of satellite units and of links between UK clinics and those overseas. In similar vein, there appears to be a growing underground 'market' for the buying of gamete(s) and a growing use of surrogacy arrangements and we are not confident that the HFEA is sufficiently proactive in trying to keep one step ahead of such developments rather than being merely reactive.

These comments are in addition to those responses supplied above.

6. *Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.*

These are difficult questions for bodies such as ours to answer. We are professionals offering our considered views as to the best way to deliver good quality services that are 'fit for purpose' and hence are not focussed on the relative costs of services – neither is this within our sphere of expertise. However we would point out that we believe that savings can be made in the longer term when treatment services pay proactive attention in these early stages to the lifelong implications of donor conception or surrogacy.

7. *Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?*

Whatever the outcome with regard to the HFEA, we strongly believe there is a need for:

- (i) A dedicated Donor Conception Register
- (ii) A national service to provide a professionally led UK wide information release and intermediary services to those approaching the HFEA Register, Donor Sibling Link, the pre 1991 Voluntary register and the Parental Order Register.

See our detailed response at Q4 above

8. *Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?*

We have serious concerns about the paucity of information in relation to costings of the different options. Although this is not our area of expertise, there is little to indicate any realistic costs associated with the actual transfer of functions and personnel and establishment of new services (which can prove very costly); the costs associated with new liaison responsibilities for both the new service(s) and the services to whom it/they will be required to relate and so on. Without such information, the request for comments on proposed efficiencies is meaningless.

9. *This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.*

In addition to the Recommendations made earlier, we also believe that the following should be in place to inform the development and regulation of treatment services and information release and support services:

In relation to donors and surrogates

1. Counselling should be mandatory for donors and surrogates (with a minimum of two sessions available) in order to provide for informed consent to be assured through the time for reflection between sessions, if required.
2. Where the donor or surrogate has a partner, s/he should not be accepted as a donor without their consent.
3. Guidance should be made available to clinic staff and to donors on the importance of providing good biographical information and how to go about doing so.
4. Professional support should be available to prospective and past donors, surrogates and their families in relation to disclosing the donor's (or surrogate's) role in donation/surrogacy and in relation to any difficulties that they face from the impact of donor conception and/or surrogacy.

In relation to recipient parents

1. Counselling should be mandatory for all who wish to undergo treatment using donated gametes/embryos and/or surrogacy (with a minimum of two sessions available) in order to provide for informed consent to be assured through having time for reflection between sessions.
2. The current requirements for parents to agree 'consent to disclosure' should be removed, bringing this area of medical intervention into line with good healthcare practice insofar as treating specialists inform patients' family doctor (and others as relevant, for example, ante-natal services) of the facts of their treatment and outcomes.
3. Recipient parents should be involved in donor (or surrogacy) selection and provided with relevant non-identifying information both at this stage and once a child is born to promote a beginning relationship with the donor (or surrogate) and her/his background to aid them in their parenting role.
4. Professional support in conjunction with peer support from DC Network (where appropriate) should be available to existing parents of donor conceived offspring for their ongoing task of talking with child(ren) of all ages about donor conception and in relation to any difficulties that they face from the impact of donor conception. The same should be available for those using surrogacy.

In relation to donor conceived people

1. Professional support should be available to donor conceived people and their families when seeking information about their origins and when seeking contact with the other party(parties).
2. Professional support, in conjunction with peer support (where appropriate) should be available to donor conceived people in relation to any difficulties that they face from the impact of donor conception. Such support should also

be available to assist them in talking with their own child(ren) (if they have any) about donor conception.

In relation to those born through surrogacy arrangements

1. Professional support should be available to those born through surrogacy and their families when seeking information about their origins and when seeking contact with the other party(parties).
2. Professional support, in conjunction with peer support (where appropriate) should be available to those born through surrogacy and their families and to surrogates and their families in relation to any difficulties that they face from the impact of surrogacy. Such support should also be available to assist them in talking with their child(ren) about surrogacy.

In addition:

1. *Birth registration review* - In the adoption context, adopted children are issued with a new birth certificate and this together with their original birth certificate is held by the Registrars General of the 4 nations. A similar system applies where children are born following surrogacy arrangements and commissioning parents are granted a Parental Order. We would like to see detailed consideration of donor-conceived people having their details recorded by the Registrars General in such a way that enables them too to retrieve details of their biological parents at the age of majority. This in turn will enable them to learn (as do adopted people) that other records are held on them elsewhere which might contain information of value to them. In addition changes are required to the birth registration/Parental Order process for those conceived through surrogacy arrangements. At present those applying for their original birth certificate have no way of knowing whether donor gamete(s) were used in their conception and hence that there may be additional information available to them on the HFEA Register. This needs addressing.
2. *Voluntary register for DC post 1991* Evidence from the US-based Donor Sibling Register and developments in Australia and New Zealand suggest that there is a need for a voluntary register open to donors and parents of donor conceived minors who wish to exchange information and/or make contact while the child is growing up (including between families with children who share a donor). There are informal moves in the UK to develop such services on a 'do it yourself' basis. We would like to see this option being explored for the UK along similar lines to those currently eligible through statute to apply for information release.
3. *Opening registers to donors' 'own' children* - Some of the voluntary registers around the world, and that based in the UK (UK DonorLink) are open to non-donor-conceived offspring of donors to register. We would like to see such developments happening for those affected post 1991; we can see no logical

reason to exclude them from being able voluntarily to seek information about and/or contact with their half-siblings.

4. *Register for those affected by surrogacy* – there is an urgent need for a debate about register services for those affected by surrogacy, including whether to include them in the donor conception registers, regardless of whether donated gamete(s) have been involved. The issues relating to the UK consequences of surrogacy overseas, must also be addressed.
5. *Preparation for parenthood sessions* - DC Network has been running some very successful Preparation for Parenthood workshops since 2008. We would like to see further work done to develop such workshops to be run around the country and to be made available to all those considering DC treatment.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

We welcomed the opportunity to take part on the workshop organised by yourselves on 19th September. These are complex matters to consider and opportunities for cross fertilisation of ideas are important. It would have been helpful if such initiatives could also have been extended to members of the public across the 4 nations.

Matters to do with donor conception, surrogacy and assisted reproduction are of major importance. Although they clearly can involve highly technical procedures during the fertility ‘treatment’ stages, those affected will only be well served if all involved at each stage recognise their lifelong implications see it as a family-building matter rather than a treatment choice **and** put the welfare of those affected - especially the child/adult that is conceived – centre stage.

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

We found the Equality Analysis to be rather bland and repetitive. Such documents have become a requirement in many settings but we have rarely been convinced of their usefulness in attending to equality and diversity matters in any meaningful way and that is the case here too.

<p>NOTE: WE HAVE NOT SUPPLIED A COMPREHENSIVE LIST OF THE UNDERPINNING EVIDENCE FOR OUR RESPONSE, ONLY THOSE THAT ARE CITED SPECIFICALLY BUT ONE IS AVAILABLE ON REQUEST.</p>
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Response 33 : National Childbirth Trust (NCT)

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	No - these two organisations should remain separate. We have particularly good experience of working with HTA: they seemed to be focused and effective, and willing and able to listen to stakeholders.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	The specific expertise and remit of the HTA and HFEA will get lost in the far broader scope of work of the CQC, which itself has stated it is over-burdened with a heavy work programme. In particular there are dangers that commercial stem cell collection companies may succeed in conveying misleading information to pregnant women at a vulnerable time.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	We have no comment on the research activities aspect
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	'Back-room' functions - for example finance, IT, HR - could be combined or carried out on contract by other organisations, but the core functioning of the HTA and HFEA need to be separate.
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	There are key functions that are better carried out by those with specific and detailed knowledge and experience, as set out above. Further efficiencies could perhaps be achieved by a head office outside central London, for instance?
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	It is about quality - we need to make sure short-term cost-savings don't lead to longer-term inefficiencies: 'small but perfectly formed' seems to work here. Larger is not always cheaper or more efficient (cf large NHS Trusts) as there may in due course be more waste and less flexibility. The crucial and unique nature of the task of setting and maintaining standards to ensure (for example) eggs are not fertilised by the wrong sperm or in the wrong woman is unlikely to be enhanced by embedding it within a larger organisation. Getting this and other aspects of the HFEA work right will save a huge amount in money and distress, if processes go wrong.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	Currently no. Though another comparable activity needing urgent attention is human milk banking - it needs to have the testing done by the state and become a UK-wide service. All premature babies thrive better on breastmilk and, if their mothers cannot provide it, there are hundreds and thousands of women who are willing to. However it

needs to be co-ordinated under a properly regulated state provided service
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
No comment.
10. Do you have any other comments on the consultation proposals that you would like to share with us?
If it is working don't mess with it. This is not broken so leave as is - let's get CQC fixed and then think again when it is.
11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?

Response 34 : Independent Cancer Patients Voice

Please find attached the response of Independent Cancer Patients Voice to the Public Consultation on the future of the HTA.

ICPV is a patient led independent group of people who have been treated for cancer and are actively, and effectively, involved in research.

This response is based on collated views which have been gathered from members though google-group discussion and meetings – including a session on this topic at a recent workshop with input from researchers, biobanks, medical ethicist, HTA rep, PhD students and ICPV members.

Our opinion is based on considerable experience - Several ICPV members sit on Boards of tissue banks –eg UKCCB, Breast Cancer Campaign, Brainstrust, Newcastle. Members are in also in working groups for the UKCCB and the HRA.

We have visited several pathology depts and tissue banks and have heard from staff about their experience of HTA inspection. ICPV has produced a patient to patient information sheet about PPI, participating in trials and donating tissue for research. This was approved by CRUK and adapted for use by Breast Cancer Campaign specifically for use with breast tissue bank.

We are appreciative of the need for proper use of public money but very concerned that cost should be properly assessed and that specialist interest and expertise is protected.

We are more and more aware of the vital role of pathology in cancer treatment and that increasing research knowledge and technology is leading to a greater number of more defined cancer diagnoses. This also requires an increase in tissue donation, storage and use for research. We recognise the need for proper regulation but, as potential donors of tissue and beneficiaries of the research, we think our needs are best met by the HTA remaining as a separate body. We are keen to promote public interest in donating organs and tissue but, to be comfortable doing this, need to be confident of effective regulation which is transparent and open to public scrutiny – we would like to work with the HTA in the future.

www.independentcancerpatientsvoice.org.uk

CONSULTATION QUESTIONS
This response is from Independent Cancer Patients Voice and is therefore commenting on proposals affecting the HTA
We do have public interest in HFEA (some members having had IVF)
1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
This option will transfer the research function of HFEA to HRA but the whole of HTA to CQC – including the research function?

We do not believe the CQC has the right expertise, experience, skills nor public confidence to encompass the work of the HTA despite a common function of inspection and licensing.

The inspection, regulation & licensing of tissue banks and research/pathology laboratories is very different from that of centres providing care. Many are based in universities with no direct patient care function and staff in those based in hospitals do not usually have any patient care responsibility..

The use of human tissue in research is expanding and vital to improved diagnosis and treatment and needs reliable monitoring by a specialist body.

ICPV is very aware of the importance of pathology and research using tissue to improve outcomes for cancer patients and feel very strongly that this is best regulated by the HTA

There has been considerable public disquiet about retention and storage of body parts and tissue – especially after Alder Hey and Bristol. This has gradually reduced since the HTA act in 2004 and the establishment of the HTA. Our impression is that it has taken time for the HTA to develop an efficient inspection & regulatory process whilst gaining acceptance, respect & compliance from those inspected. It now appears to be viewed in a similar way to Peer Review – it causes extra work/stress in preparation for an inspection but the effort is very worthwhile and helps maintain and improve practice.

At the same time the HTA has greatly increased public confidence in the proper collection, storage and use of human organs & tissue for public benefit.

ICPV members do not think it appropriate to de-rail this regulatory process by re-organisation or resiting the functions of the HTA. We are very concerned that the high level of acceptance to researchers will be undermined and public confidence eroded if the process was managed by the CQC in which public confidence is very low.

We do recommend increased collaboration with the HRA on ethical issues but do not approve splitting of research from other functions.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

There is already increasing communication between local and national bodies using human tissue in research and the development of national guidelines
Eg UKCCB , BCCampaign Tissue Bank As patient advocates we would wish further collaboration between researchers, units, banks, the HTA and the public.

ICPV does not consider that the CQC has the necessary expertise nor the public respect necessary – The HTA has developed that expertise and earned that respect over the past 6 years.

The impact of change to CQC risks losing public confidence and reducing the donation of organs and tissue at a time when exciting research with great potential for patient benefit is needing such tissue.

It is of interest that half the enquiries made to the HTA are from members of the public.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

ICPV not commenting on HFEA

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

ICPV does not believe that splitting of research from other functions of HTA is appropriate. We greatly respect the HRA and members have worked with the NRES

<p>for some time and would welcome continued collaboration between the HTA and the HRA also MRC, Coroners, Researches and the Public. We understand that the HTA already has a Memorandum of Understanding with the HRA to avoid duplication and is working with the MHRA and MRC.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>We believe that any organisation has to audit its activities and justify its costs but we do not wish to see any reduction in costs which dilutes the quality of the work done by the HTA and reduces our confidence in the governance of use of human tissue and reduces interest in donating.. This is such an important service and the need for the public to retain and increase trust is so great that it would be a tragedy if the service was compromised by too great a reduction in funding.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>We consider that the HTA has already reduced costs and some efficiencies date from before the review and involved rebate of some licence fee monies –However, we note that there was a previous reversion of a cost saving after a proposed merger was not confirmed.This could be addressed without a reorganisation and we have serious concerns about too great a reduction in costs</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>We would prefer to see increased collaboration to reduce duplication and achieve efficiencies. An example would be in the provision & funding of joint training for both staff and PPI.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>We question the success of the CQC in “maintaining oversight of, and focus on, specialist areas of regulation” We accept that it is unnecessary duplication to have any inspection and regulation conducted by both HTA and CQC. However, we would consider it more cost effective, as well as more patient benefit effective , to retain the specialist service provided by the HTA. Any necessary data could be forwarded to the CQC. The claim that a disproportionate amount is spent currently on senior personel at the HFEA & HTA in comparison with CQC – maybe this is a validated spend in view of the difference in achievement and level of public & professional confidence Costs are continually measured in financial terms -this is highly important but costs also need to be considered in terms of quality, loss or gain in terms of expertise/relationships/trust as well as good collaboration with both researchers and public. The morale of staff in the HTA and in the units they licence is a major factor in an efficient regulatory service but is difficult to quantify.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>ICPV has concerns at the level of PPI in these bodies and the quality of such PPI where it is said to be in place. It varies from excellent to tokenism and organisations</p>

should be required to illustrate clearly what PPI involves in their structure and operation. This needs monitoring to ensure that it is effective and we recognise that it is not easy to achieve and maintain. To attract people with interest & skills, provide any necessary training/support and then use and retain their input requires real interest, considerable effort and adequate funding.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

The HTA is an organisation which is still developing and recognises the need for further improvement but which is proving very effective and so has won the respect of most researchers and the confidence of the public. ICPV considers that it would undermine both, and the morale of staff, to impose a reorganisation which would in itself, not be without cost and could decrease efficiency.

The public interest in donating organs for treatment and tissue for research is growing and the HTA website is user-friendly – people are using it to find out about donation and related issues.

If the HTA has to be merged into another body we would much prefer this to be with the HRA because we consider this to be much more relevant with better expertise and it already has the benefit of an excellent track record from NRES and is establishing a strategy for effective PPI.

11. Can you provide examples of costs and benefits of these proposals?

No. However, in terms of the effective PPI which we suggest, ICPV does provide PPI for the Breast Tissue Bank run by Breast Cancer Campaign which is one of the most cost effective charities and we know that they consider that collaboration to be very effective in both cost and benefit.

12. Do you have any comments on the consultation Equality Analysis?

We would challenge the statement that this will have no impact on the public and would hope that the impact on staff would be mitigated as much as possible and subject to best practice.

Response 35 – UK Donor Link

UK DonorLink is the voluntary Register for donor conceived adults and donors prior to August 1991 who wish to trace genetic relatives.

It was established in 2004 with funding from the Department of Health. It is a unique organisation covering the whole of the UK and is the only body providing a service for pre-1991 donors and donor conceived.

In our response we will be confining our comments solely to matters relating to the HFEA. We are an organisation whose remit is to work with donor conceived people and their families and donors and their families including their non-donor conceived offspring. The functions of the HTA therefore fall outside our area of expertise. However, we do understand that the HTA is a well-respected organisation which enjoys public confidence in its regulation of human tissue and organs.

Consultation Response

1. *Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.*

We have a number of concerns relating to the transfer of HFEA functions to the CQC, specifically:

- i) The Central Register on donor conception related information and Donor Sibling Link
- ii) Policy Development Matters

The CQC is a regulatory body. It has no experience or skills in dealing with the release of information from the Register to those seeking information. Our experience at UK DonorLink has informed us that this can be complex and sensitive work and should be carried out by, or in, an organisation that has expertise in information release and intermediary work.

The CQC currently only covers England. Whilst we understand the Government will extend its powers to cover the whole of the UK this will, of course, put extra demands on the CQC at an organisational level as it familiarises itself with service provision, policies and even separate legislation in Scotland, Wales and Northern Ireland.

The CQC is a regulatory body and unlike the HFEA it has no skill or expertise in policy development and carrying out public and professional consultation.

We are not opposed to the transfer of functions relating to research to the HRA.

2. *Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?*

There may be some advantages in having a single regulatory authority. However, we would not wish to see a loss of expertise.

We assume that some HFEA staff would have to be transferred to the CQC although there is always a loss of personnel in such circumstances.

It is clear to the public and patients what are the functions of the HFEA and for those seeking advice it could be confusing to transfer those functions to the CQC.

3. *Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.*

We do not feel that we can comment on this as the HFEA's research matters fall outside of our areas of expertise.

4. *Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?*

We believe there should be a UK-wide dedicated Donor Conception Register run by a body capable of handling large amounts of data.

There should be National Minimum Standards in place to ensure the quality of the information collected.

Improvements should include:

- a) A new donor information form which should be developed after seeking the views of donor conceived people on the information they would like to receive. Donor gametes should be only used after the donor information is provided in full.
- b) Clinics to be responsible for preparing a file relating to the child / children born of donor conception to be passed to the Central Register following the notification of the child's birth. Clinics to retain a copy for their own records but all requests for information from those affected should be dealt with centrally.
- c) The Central Register to be responsible for files and updating files to include non-identifying information about any other children conceived using the same donor; updating information from the parties concerned (including family members in the event of mental incapacity of death).
- d) The Central Register to be responsible for releasing this information as

required to a UK-wide information release and intermediary service.

We believe that there should be set up, and centrally funded, a national information release and intermediary service which would need to be run by those with expertise in information release and intermediary services.

This national service should hold the Registers for those affected both pre and post-August 1991.

This service could be based in post-adoption support services with appropriately qualified staff who have received additional training in the specific issues of donor conception.

This service should also be subject to a regulation system (currently Ofsted inspects English post-adoption services).

Currently, we do not believe that the HFEA is offering an adequate service to those affected by donor conception post-August 1991. In fact, it is not even meeting its own policy as agreed at the Authority meeting on 20 January 2009 in response to a report from the multi-disciplinary steering group.

The HFEA does not provide any services for those who wish for counselling or an intermediary service. Instead, details are provided of the British Association of Counselling and Psychotherapy, the British Infertility Counselling Association or enquirers are advised that they can seek a referral to a counsellor through their GP.

They also provide details on DC network and UK DonorLink. In fact, UK DonorLink often receives enquiries from post-August 1991 donor conceived people or their parents enquiring what support services may be available for them.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

If the HFEA is retained we would like to see some changes to the Authority's membership. It is a very large body but has no representation from a donor conceived adult. This is out of step with Government policy that states that those directly affected need to be at the centre of policy and practice developments.

In fact, the HFEA seems particularly averse to listening to the voice of the donor conceived as their recently convened National Donation Strategy Group also does not include a donor conceived adult (and this is despite the fact that one of our Registrants offered her services).

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

This is a difficult question for us to answer. However, we gather the HFEA

has already saved £2m since July 2010.

7. *Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?*

With reference to our answer to a previous question we would like to reiterate our view that we believe there should be:

- i) A dedicated Donor Conception Register.
- ii) A National Information Release and Intermediary Service for those who wish to access the HFEA Register, Donor Sibling Link and the pre-1991 Voluntary Register.

8. *Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?*

This is not our area of expertise. However, we feel the fairly modest savings of £3.7m to £3.8m over 10 years would need to be weighed against the risk involved in the transfer of functions.

9. *This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.*

In addition to the comments we have already made regarding donor conception issues we would like to add the following (again drawing on the experience of adoption services):

1. Counselling should be mandatory for donors and for all those who wish to undergo treatment using donated gametes / embryos.
2. Potential parents should be offered the opportunity to attend a training day to look at the specific issues relating to parenting a child conceived through donated gametes or embryos.
3. Recipient parents should be supplied with information on the donor at the time of treatment and once the child is born there should also be professional support and peer support from DC Network available.
4. There should be on-going professional support available to donor conceived people and their families, particularly when seeking information regarding their origins and intermediary support if they progress to contact with genetic relatives.

The recommendations have been informed by our work at UK DonorLink

We would like to add:

5. Birth Registration Review

Many donor conceived people have been pressing for a change in their birth registration. Adopted children are issued with a new birth certificate and this is held with their original birth certificate at the General Register Office (GRO). For children born following surrogacy arrangements commissioning parents are granted a Parental Order.

We would like to see consideration being given for donor conceived people having their details recorded and held by the GRO which they can access at the age of majority. This would give them details of their biological parents and inform them that other records are held on them in relation to their genetic origins.

6. Evidence from the US, Australia and New Zealand indicate there is a need for a voluntary Register open to the parents of donor conceived minors, donors and the families with children who share a donor and who wish to exchange information and/or make contact whilst the child is growing up.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

UK DonorLink believes that matters associated with assisted reproduction and donor conception are of major importance.

We find it hard to comprehend why more recognition is not given to the needs of donor conceived people, their parents and donors whilst Governments have understood and legislated for the rights of adopted people.

The same recognition of rights of the donor conceived has been lamentably slow.

We were pleased to have the opportunity to take part in the consultation workshop held on 19 September 2012 and to note that many of the professionals involved were concerned about the future of the HFEA Register. UK DonorLink encouraged their Registrants to respond to the Consultation and we posted information on our website. However, we are unsure as to how far the consultation was extended to the general public.

11. Can you provide examples of costs and benefits of these proposals?

No comment at this stage.

12. Do you have any comments on the consultation Equality Analysis?

Standard document – no specific comments.

Response 36 : Scottish Transplant Group

Please note – this consultation response is from the Scottish Transplant Group (STG) and therefore relates only to the proposed transfer of functions of the Human Tissue Authority (HTA)

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No – This is not our preferred option although we recognise that it would keep the majority of the current functions undertaken by the HTA, together, a factor the STG considers to be essential. The Care Quality Commission (CQC) is an English body which has no locus in Scotland. Our main concern is that, assuming the functions did indeed transfer to the CQC, the Commission would need to be instructed not to stray into other matters of the type that it is responsible for in England but which are devolved to Scotland.

The STG would like to acknowledge the HTA's significant expertise and knowledge in the field of organ and tissue donation and transplantation and has concerns as to whether the CQC has the necessary expertise in this area. Transfer of the specialist team from the HTA to the CQC would resolve this issue but would no doubt reduce the cost savings anticipated as a result of the transfer of functions. Organ and tissue donation and transplantation are highly specialised areas, and any loss of public or patient confidence could have a significantly adverse effect on organ donation and transplantation rates.

In recognition of the substantial extension of the HTA's role in Scotland following the introduction of the EU Organ Directive, the relevant Regulations contain a provision amending the Human Tissue Act 2004 to empower the Scottish Ministers to nominate a member of the HTA board who will be able to make representations, at board level, about the way in which the HTA discharges its functions in Scotland. In the event of the functions of the HTA transferring to the CQC, discussions would need to be held prior to the transfer of functions about the way in which this provision would then be expected to operate in practice.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The position regarding the HTA's functions in Scotland is complicated. It undertakes the following options:

- **It scrutinises applications for living organ donation in Scotland, but is only able to do so by virtue of its formal contract with the Scottish Government. Advice and guidance to referring units requires to be undertaken in a professional and timely fashion. As the HTA has demonstrated its ability to undertake these responsibilities very efficiently, it has gained the confidence of the transplant community. There would be concerns as to whether the CQC could match this standard.**

<ul style="list-style-type: none"> • It is the Competent Authority for Scotland in terms of the EU Directive on the Safety of Tissues and Cells, and that role is enshrined in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 as well as being included in the contract with the Scottish Government. Again, the HTA has won the confidence of those responsible for therapeutic tissue banking in Scotland. • It acts as the Competent Authority for Scotland in terms of the EU Organ Directive and that role is reflected in the Regulations that transpose the provisions of that Directive into law in the UK. This is also reflected in the contract between the Scottish Government and the HTA. The STG is content with the manner in which the licensing process was introduced, as it was done in such a way to retain the confidence of the transplant units in Scotland. This standard of service would have to continue and the inspection process required under the EUODD would most likely have to be delivered by a team of specialists rather than the existing CQC inspection teams whose experience relates to undertaking inspections of more generic standards across a wide variety of institutions in England.
<p>3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.</p>
<p>N/A</p>
<p>4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?</p>
<p>The STG agrees with the consultation document that it would not be appropriate for NHSBT, as the UK-wide organ donation organisation, to self regulate living donor transplantation. In order to ensure a high level of confidence of patients and healthcare professionals it is essential that there is an independent regulator who works effectively with NHSBT. The Group cannot think of any other body that is currently positioned to assume this responsibility.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>This would be the STG's preferred option. As indicated in the answer to Question 2, the HTA has an established track record in undertaking functions in Scotland in a professional and expert manner. It has a strong awareness of the provisions of the Human Tissue (Scotland) Act 2006 and has built up relationships and confidence with patients, the public and the professionals working in the field of organ and tissue donation and transplantation.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>Yes. In terms of value for money for the services the HTA undertakes in Scotland we are content. Further cost savings may be possible however we are aware that the HTA has already made significant savings (27%) over the last 2 years. Further efficiencies should become possible as the HTA develops experience of regulating both tissues and cells and organ donation.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>No opinion</p>

8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	No
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
	No opinion
10.	Do you have any other comments on the consultation proposals that you would like to share with us?
	No
11.	Can you provide examples of costs and benefits of these proposals?
	N/A
12.	Do you have any comments on the consultation Equality Analysis?
	No

Response 37 – Royal College of Nursing



Royal College of Nursing's Response to the Department of Health Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority

Introduction

With a membership of over 410,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

The RCN expressed concern regarding the Government's proposals for the future of the HFEA throughout the passage of the Public Bodies Act through Parliament. Working jointly with the key organisations concerned with the provision of fertility treatment in the UK, we called for an independent review of the HFEA before any functions were transferred. This is because we have seen no evidence or analysis to show that abolishing the HFEA and transferring its functions would provide any benefit over the status quo. We therefore welcome the opportunity to submit a response to this consultation.

Our submission will refer to the future of the Human Fertilisation and Embryology Authority (HFEA) only.

- 1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.**

Since the proposal to transfer the functions of the HFEA was first made in *Liberating the NHS: Report of the arm's length bodies review (July 2010)*¹², the RCN has considered all the options carefully and consistently concluded that the HFEA should not be abolished. We therefore support option 3 as set out in this consultation - we would like to see the HFEA retain its functions but seek to deliver further efficiency savings, where possible.

12

Although we recognise the need for changes that make the HFEA a more efficient, cost-effective and less bureaucratic specialist regulator, we have been unable to identify any practical benefit in abolishing the HFEA and handing its functions to the CQC. There is no evidence to suggest that this would lead to any real financial savings or improved efficiencies over and above those that could be made by under the current regime. Furthermore the CQC, Health Research Authority and the Health and Social Care Information Centre all cover England only. Extending their remit and establishing processes to work with the devolved administrations will incur cost financially and lead to extra administrative burden.

We have grave concerns about the ability of the CQC to retain the achievements of the HFEA in giving “the public and healthcare professionals confidence in areas that are complex, requiring significant ethical considerations, and where the public has made clear its wish to see effective controls on the use of human material.”¹³ The HFEA has been crucial in gaining public confidence in the sensitive area it regulates and we are very concerned that regulation by the CQC will not instil the same confidence. We believe that there is merit in retaining a single specialist regulator, with a recognised brand, in this area so that patients have a single, trusted point of contact.

The RCN is also concerned that the CQC may struggle to take on the functions of the HFEA. The remit of the CQC has expanded in a short space of time, and it has been acknowledged that the organisation has struggled to cope with the increasing demands placed upon it. We question whether it is the right time to add to its responsibilities, particularly when CQC does not have expertise in the areas the HFEA regulates. This could lead to the CQC lacking credibility and the confidence of those who are regulated, as well as the public and parliamentarians.

In addition, both National Audit Office and Public Accounts Committee have warned of the serious risks of transferring the functions of the HFEA to the CQC. In a report on the CQC published December 2011, the National Audit Office concluded that:

*“There is a risk that extending the Commission’s role will distract it from its core work of regulating health and adult social care. Before making decisions, the Department should assess the costs and impact of giving the Commission additional responsibilities and determine whether the Commission has the capacity to take on an extended role”.*¹⁴

This was followed, in March 2012, by the Public Accounts Committee’s report on the CQC which concluded that:

- *“To date [the CQC] has failed to fulfil (its role in providing assurance, ensuring appropriate quality standards and deterring poor quality and unsafe care] effectively.”*
- *“We have serious concerns about the Commission’s governance, leadership and culture”*

¹³ <http://www.dh.gov.uk/health/files/2012/06/Consultation-on-proposals-to-transfer-functions-from-the-Human-Fertilisation-and-Embryology-Authority-and-the-Human-Tissue-A.pdf> (Executive Summary, p10)

¹⁴ http://www.nao.org.uk/publications/1012/care_quality_commission.aspx

- “... the public are unclear what the Commission’s role is and lack confidence that it is an effective regulator.”
- “The Commission has a long way to go to become an effective regulator. It is not ready to take on the functions of other organisations, such as the Human Fertilisation and Embryology Authority, as the Department has proposed.”

It recommended that:

*“The Commission should not take on the functions of the Human Fertilisation and Embryology Authority at this time. The Department is proposing to transfer to the Commission the functions of other organisations, including the Human Fertilisation and Embryology Authority, which regulates IVF services. In our view, the Commission does not have the capacity to take on oversight of such a complex area, and the change would undermine its ability to focus on the improvements it needs to make in relation to its existing regulatory functions”.*¹⁵

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

If the functions of the HFEA were transferred to the CQC, the immediate impact would be the loss of an established, nationally and internationally recognised organisation which gives confidence in the regulation of the sector to patients, professionals and the public. It would also lead to the loss of an easily identifiable and reliable resource for up to date impartial information and advice for patients, donors and donor conceived individuals. The HFEA is widely respected and highly regarded for taking into account the broad spectrum of views on ethically complex scientific and clinical matters ensuring that the lay perspective is included through the consultation process in addition to lay representation on the Authority itself. This would almost certainly be lost.

We are aware of discussions within the sector about the potential effect on the fees paid by licensed centres if the HFEA’s functions were transferred to the CQC. There is an assumption that the fees may be reduced, however, we believe that this is mistaken as the same degree of diligence and expertise will be required for regulation. The impact assessment not only supports this view but predicts a possible increase in the fees as well.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

The RCN welcomes the establishment of the Health Research Agency (HRA) in general. We believe that it should be effective in unifying and streamlining the health research processes overall. However, we believe at this time that embryo research should continue under the auspices of the HFEA for the following reasons:

- Embryo research is intrinsically linked with HFEA’s functions and is one of the principle reasons for specialist regulation of IVF centres, where embryos are created whether for treatment or research. The consent procedures are complex

¹⁵ <http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1779/177902.htm>

and the transfer of embryos from IVF centres and research establishments requires meticulous audit and monitoring, of which the HFEA has extensive experience.

- The HRA would need to set up an inspection and licensing procedure for premises and individual research projects, some of which would be in clinical settings that the HFEA inspect. This would make eradicating duplication difficult. It is highly unlikely that there would be financial savings and in fact may incur greater expense.
- The HRA would have to establish an appeals process to comply with the Human Fertilisation and Embryology Act which it would not need in any other aspects of its remit.
- The HRA will be a new, unproven organisation with a wide remit. The HFEA has been successful in maintaining and promoting public confidence in embryo research, including in new areas. An example of the effectiveness of the HFEA was when cell nuclear transfer (cloning) was successful in an animal model and the HFEA announced an immediate moratorium on similar research with human embryos allowing a public consultation and the passing of legislation in a timely way.

Once the HRA is established, the HFEA should work in collaboration to simplify aspects of the research approval process and where appropriate delegate powers as allowed in the 2008 amendments to the Human Fertilisation and Embryology Act.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

We think that the functions of the HFEA should be retained and consider that there are potential risks regarding less effective regulation, loss of public confidence and risks to public safety if they are transferred.

Data collection

The HFEA register is one of our main concerns and we think that it should remain with the HFEA. The CQC does not have experience of collecting such data, which is unique in its sensitivity and relevance to patients, donors, recipients of donated gametes and donor conceived people. It is also an invaluable source for research and epidemiological studies.

The Health and Social Care Information Centre (HSCIC) has experience of data collection on this scale. However, the use of this data for the regulatory activities to comply with the Human Fertilisation and Embryology Act are complex. Separating the data collection from the licensing and inspection process would present a very real risk that centres may not comply with the statutory reporting requirements and impose a greater administrative burden with the monitoring and audit of data collection for all the organisations involved including the licensed centres. .

It would require considerable change at the HSCIC, which at present has a remit covering England and not the rest of the UK as required by the Human Fertilisation and Embryology Act. It also currently only holds data relating to publicly funded health care. The majority of Assisted Reproductive Technologies treatments are funded by the patients themselves. The use of the data to ensure that the public

receives complete, accurate consistent information about live birth rates and other outcomes from each licensed centre and to allow for monitoring of multiple births are essential tasks for the regulator.

The RCN is one of the professional bodies, which have been meeting with the HFEA Executive to discuss the amount and method of data collection to seek to identify whether it is possible to refine the present system. The HFEA has taken on board all concerns raised during these meetings. It is also actively addressing them by taking external advice about the legal requirements and seeking an external view on how to improve the data collection process through working with an expert from the HSCIC.

Information to donors

We welcome the acknowledgement that there is no room for error in the information provided to donor conceived people and that this function is still developing.

The HFEA has already made progress in this area but much more needs to be done. The newly established HFEA National Donation Strategy Group could provide invaluable support with this vital work. In our view, forming links with an external provider is a sensible way to deliver the service and the already well established adoption services seem ideal. A network of regional staff, with the training and expertise to deliver the sensitive information and support recipients and their families, is an option we would favour pursuing.

The HFEA and other providers will need financial support. We do not consider that it would be appropriate for Ministers to have responsibility for this service as it would be another tier between the regulator and service provider. This would add to the bureaucracy and risk poor communication, which could have disastrous consequences.

Remuneration of gamete and embryo donors

One example of the how effective the HFEA has been in co-ordinating policy and practice, is the very successful collaboration with stakeholders that resulted in a significant change in practice to reduce iatrogenic multiple births. The RCN is represented on the Multiple Births Stakeholder Group and has firsthand experience of how well this has been managed.

The suggestion that the policy functions of the HFEA could be transferred to the Department of Health is one of the greatest concerns to the RCN. We do not consider that it would be appropriate to transfer decision making to Ministers. Ministers would not, and could not, be expected to have the depth of knowledge and expertise to make such decisions and impartiality would immediately be brought into question. In addition, the separation of policy making and licensing would be difficult as the two are frequently linked. Not only would decision making be questioned but the bureaucracy would be likely to prolong the time taken to make licensing decisions, which is a loudly voiced criticism already.

A well planned arrangement with the new HRA would address the current criticisms. However, if a third party were introduced, the time taken to make policy decisions and then process research or treatment licensing applications would be extended even further.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

The RCN believes that the HFEA should retain existing functions for the following reasons:

- The Human Fertilisation and Embryology Act requires a Board to oversee the implementation of the legislation, as it was recognised that the policy, licensing, regulation and maintaining the register are intrinsically linked. The RCN wholeheartedly recognises that reviewing the effectiveness of regulation in the context of scientific advances, changes in society and cost efficiency is essential. However, we are not persuaded that there would be any advantages in moving the HFEA functions to any other organisation at this time. We believe that the administrative burden can be reduced through closer working with organisations.
- We are very concerned that the body of knowledge and expertise the HFEA has gained in the complex and ethically sensitive area could be lost to the detriment of the patients, service providers and society. Uncertainty about the future is highly likely to lead to the loss of key members of staff with vital experience and knowledge which could not be replaced.
- The National Audit Office and Public Accounts Committee have both recently raised concerns regarding the CQC's ability to carry out its current functions effectively. Transferring the functions of the HFEA to the CQC would incur the risk of inadequate, poorly managed regulation of the creation and use of embryos, the loss of an authoritative specialist source of information for patients and the overall loss of public confidence.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

The RCN's view is that further savings could be made should the HFEA retain its functions. The HFEA has already made savings since 2010; total expenditure is down by 25 per cent (from £8 million to £6 million); Grant in Aid has been reduced by 33 per cent; and the number of staff has been reduced. The HFEA has achieved this while also reducing treatment fees by 28 per cent in 2011.

We believe that further savings and efficiencies could be made through collaboration with other organisations to reduce the regulatory overlap and duplication in inspections. The HFEA has already demonstrated a commitment to making savings and is currently working with the CQC and Human Tissue Authority (HTA) to produce joint working and inspection protocols.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

We do not think that any of the functions of the HFEA should be transferred.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

We believe that the anticipated actual saving of £3.8 million over 10 years is extremely low.

The HFEA has functions in relation to the whole UK and the CQC is the regulator for England only. The consultation refers to the need for the CQC and HRA to work closely with the existing regulators in the devolved administrations if the functions were transferred from the HFEA. However, there is little detail about how this would work in practice and the costs both in financial terms and administrative upheaval would be significant.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

The RCN is very pleased to see that the HFEA is already working with the Health and Social Care Information Centre to identify ways in which the process for data collection could be improved and simplified. We believe that this could also result in financial savings in the longer term.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

N/A

11. Can you provide examples of costs and benefits of these proposals?

N/A

12. Do you have any comments on the consultation Equality Analysis?

N/A

Response 38 – Individual

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No. I am in favour of Option 3.

I believe that the field of assisted reproductive technology is a unique and particular area of medical care that demands a unique and particular regulatory framework to meet the expectations of:

- a) the public;**
- b) the personnel involved in delivery of clinical and laboratory services;**
- c) Society at large looking in to a fast moving and often controversial and contentious area of medical practice.**

These elements of regulatory need have been successfully addressed for the most part in the construct of the HFEA and I am not convinced that the expertise within the CQC exists to meet the particular demands required in this sector.

There are particular concerns in my view in relation to the handling of sensitive data relating to the birth of individuals conceived with the use of donated gametes as well as the data relating to those who have provided donations of sperm, eggs or embryos. The competence of the designated authority is hugely important in this sensitive area and I am not at all sure that the transfer of such functions from the HFEA to the CQC would be safely achieved. The ongoing rigour required in database maintenance might not be appreciated within an organisation which has responsibilities in many areas of medicine with much less sensitivities.

I would agree that data demands of the HFEA are inevitably burdensome for clinics. However, dialogue with the sector has improved the way in which this is gone about and I am sure further efficiencies within the HFEA can be achieved.

I agree that research procedures as administered by the HFEA do not easily facilitate scientific enquiry and further complicate an already burdensome research ethics bureaucracy to little advantage – streamlining this element of activity by merging with the new HRA seems progressively useful and should be supported.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The burden of demand on clinics for data submission, preparing for inspection, quality management delivery etc will not be eased by a transfer of regulatory responsibility to the CQC. Patients will not notice a difference with a change unless problems arose with data management. The main issue will be whether a new regulator will be up to speed with the clinical science and ethics within the sector. The CQC would be required to absorb the experience of the HFEA in adopting this role.

I am not convinced that significant financial savings would be achieved within the new construct – those mentioned within the consultation (£3-4M over a 10 year period) strike me as being rather small and not substantive enough to justify the risk of investing in a new framework.

The consultation emphasises how important it is that certainty exists that all the organisations to which responsibility for regulation would be assigned have the capability and capacity to cope with this. The case is not convincingly made in my view that this is in place.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

I agree with this proposal for the reasons outlined above.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Policy development has been an area of controversy within the sector. Some have argued that the present arrangements whereby the HFEA holds a policy role represents a conflict of interest given that is also the deliverer of the regulation within the sector influenced by policy change. The place for an independent Bioethics commission has been debated and there is some merit perhaps in further exploration of this as a possibility. That said I do not believe that the HFEA involvement in policy development has, in practice, posed a significant problem for the vast majority of clinics and patients receiving treatment. The relationship of executive and authority seems to me to have been mutually beneficial and I would not be in favour of that being altered.

The devolved administrations have different mechanisms of licensing premises for the delivery of healthcare. The consultation does not make it clear how the DH in Scotland for example might liaise with the CQC. Sub-contracting licensing to the CQC could be considered. Presumably this would entail cost which will erode the projected savings forecast though the abolition of the HFEA. However I have again major doubts about the ability of the CQC to meet the need.

Data management it is suggested might be taken over by the Health and Social Care Information Centre (HSCIC) rather than be held within the CQC. The fragmentation of sources of information in this particularly sensitive area of medical practice would not be advantageous. Quality assurance of these data is vital particularly where elements relating to genetic identity and origins etc need to be faultless. The HFEA is already sensitive to this issue and acknowledges the need for rigour and security.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

I think this is achievable and desirable. Those within the sector will acknowledge that in respect of licensing, data management and inspection significant progress has been made within the last 2-3 years.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

The transfer of activity to other bodies will not be cost neutral. The savings suggested within the consultation document, over a 10 year period amount to

<p>relatively small sum. The retention of existing structures will perhaps be slightly more costly than might otherwise be the case but the savings are not defensible when one considers the potential risks.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>Research components of ART based enquiry could and should be in line with a new HRA construct for research regulation.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>Para 155/156: the financial savings are relatively insignificant Para 157: Duplication of effort savings for clinics are overstated.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<ul style="list-style-type: none"> • Is there robust evidence that the CQC is delivering effectively on its existing responsibilities for robust inspection of healthcare facilities? • The particular sensitivities of the management of information relating to donors, recipients and donor conceived people are not adequately considered. Are those involved at HSCIC aware of these issues?
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>
<p>The consideration of the issues in respect of the devolved administrations is given scant attention in the consultation. There will be costs involved in the establishment of links/dialogue/interaction with the CQC which do not seem to have been quantified.</p> <p>What will the impact of the proposed changes on clinics' fees? A rise will be passed on to patients and lead to an extension of NHS waiting lists.</p>
<p>11. Can you provide examples of costs and benefits of these proposals?</p>
<p>12. Do you have any comments on the consultation Equality Analysis?</p>
<p>The consultation is timely and welcome – in my view the case is not convincing that changes will provide benefits to the key stakeholders who are likely to be influenced by any changes in the regulatory framework – namely:</p> <ul style="list-style-type: none"> • clinics (engagement with a body with no experience within a complex clinical field, engagement with a potentially over-extended regulator with wide responsibilities and lack of sensitivity/insight in to the unique nature of ART); • patients (no particular advantage in dealing with the CQC but perhaps an anxiety that the regulator will be unfamiliar with the field, concerns re data security and quality assurance, and no cost savings to them with respect to treatment costs); • society (cost savings unconvincing, the sensitive nature of assisted reproduction, while arguably more common now than ever before, still has a profile that demands particular and unique consideration for public reassurance)

Response 39 - ESRC Genomics Policy and Research Forum

Response prepared September 2012 on behalf of the ESRC Genomics Policy and Research Forum

Our comments fall under Question 10: Do you have any other comments on the consultation proposals that you would like to share with us?

The Genomics Policy and Research Forum is a novel ESRC-funded initiative dedicated to the development of links between social scientists and scientists working in the contemporary life sciences, and the connection of research in this area to policymakers, business, the media and civil society. The Genomics Forum is based at the University of Edinburgh and is part of the ESRC Genomics Network (EGN), a major ESRC investment spanning five of the UK's leading universities examining the development and use of the science and technologies of genomics. We welcome the opportunity to comment on the proposal to transfer functions from the HFEA and HTA.

The nature of our subject area means that over the 8 years since our inception in 2004, we have worked with both the HFEA and HTA on a wide range of topics relating to their respective remits – assisted reproduction and embryo research, and the removal, storage and use of human tissue. Our relationships with the two authorities have been informative and fruitful with respect to the Forum's public and stakeholder engagement work. We have been impressed and pleased with the willingness of both authorities to engage with academic research in the social sciences and humanities.

Having worked most recently with the HFEA, we would like to highlight the reflective and horizon-scanning role of the HFEA in relation to ethical and social aspects of assisted reproduction and embryo research. Research ethics may be understood as a practical issue of balancing the risks of harm and potential benefits of research. However, ethics may also be approached more broadly. In relation to assisted reproduction and embryology, the HFEA has provided an official space for reflection on the many, varied and vexed ethical questions these areas of science and technology raise, and will continue to raise given their rapidly evolving nature. This reflective ethical role is different from, and broader than, the formal process of research ethics consideration and approval conducted by the Human Research Authority (HRA), but equally essential. The HFEA's committees, notably the Ethics & Law Advisory Committee, Horizon Scanning Panel and Scientific & Clinical Advances Advisory Committee, have played a crucial role in scanning for and considering ethical and social dilemmas that may arise from scientific and technological developments in assisted reproduction and embryology, as well as social and legal developments that may impact on these areas of science and technology. We hope that these vital functions will continue in future, no matter where they may be located.

The HFEA itself may be best placed to comment on what factors have enabled its reflective approach and engagement with social sciences and humanities research. We believe these factors include:

- _ its specialist remit as a public body dedicated to these issues, including a remit in public and stakeholder engagement and ethical deliberation;
- _ its governance structure – in particular, the requirement that members of the authority come from a range of backgrounds, in practice including prominent humanities scholars in history, philosophy and academic law, as well as scientists, clinicians, legal practitioners and former fertility treatment patients; and
- _ a staff experienced in public and stakeholder engagement on scientific and technological issues, and with high levels of expertise and academic training in social aspects of science.

Regardless of whether and how the HFEA's functions are redistributed, we urge the government to retain these features that enable a reflective, thoughtful and participatory approach to clinical treatment and research involving the creation and use of human embryos. We have every confidence in the ability of the Care Quality Commission and Health Research Authority to deal effectively with the now-routine aspects of the HFEA's work. However, we believe that retaining capacity for the reflective, engaged approach described above is vital to meet the as-yet-unknown future challenges that will inevitably arise in this new, evolving, and ethically complex area.

**Response 40 – King’s College Hospital NHS
Foundation Trust**

26 September 2012

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Dear Sir/Madam,

Consultation on Proposals to Transfer Functions from the Human Fertilisation & Embryology Authority and the Human Tissue Authority

In my capacity as Vice-Chair of this Trust's Human Tissue Act Committee, I have set out below the Trust's responses to the abovementioned Consultation. I have used the "Table of Questions" template you provided, with our responses following each question in italics.

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

We do not agree with this proposal. In our view both the HFEA and HTA have been effective regulators of highly complex, specialist areas.

HFEA

The HFEA has been successful in its role of licensing and monitoring clinics and has been successful in driving up standards, particularly and more recently, in reducing the multiple birthrate.

We are concerned that a new organisation responsible for licensing and monitoring clinics without the highly specialised experience that has been built up within the HFEA may be less effective in carrying out this important role.

Additionally, the HFEA has played an important role in educating and informing the profession and the public in an objective and unbiased way. We have concerns that the CQC would not be in a position to devote appropriate resources and expertise to this end, given its broad remit, and this would be contrary to the public interest.

It would also be a major disadvantage if the research in this field was regulated by a separate body that is not informed by the experience gained from regulating the clinical service.

HTA

The HTA has been a successful and effective regulator. It has adopted a practical and reasoned approach to regulation and it has developed a highly specialised advisory role that has ensured a consistent understanding of complex regulatory requirements. Additionally, the HTA has developed a highly professional and constructive inspectorate that has expert knowledge of the highly complicated and diverse activities that are regulated.

The CQC does not have the benefit of the years of specialist knowledge and expertise that has been accumulated by the HTA and as such we are concerned that it would not be in a position to fulfil the crucial advisory role delivered so successfully by the HTA. Moreover, the existing CQC regulatory approach is not well suited to the highly technical Blood/Tissue/Organ industry in the following respects:

1. CQC inspectors currently exercise a high degree of individual interpretation of their regulatory standards, whereas within the sectors regulated by the HTA it is more appropriate for standards to be clearly expressed, well publicised and consistently interpreted;
2. The CQC's risk-based approach to inspection is not well developed and does not seem to be wholly effective.

As with the comments we have made above with respect to the HFEA, we are concerned that the broad remit of the CQC would mean that it would not have sufficient resources (in terms of both quantity and quality) to effectively regulate the highly technical sectors regulated under the Human Tissue Act 2004 and associated regulations, which have recently expanded (e.g., the recent Organ Donation Directive).

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

We understand that the rationale behind the proposal to transfer functions and abolish the existing regulators is to achieve efficiency savings, however in our view this is a short-sighted strategy. The efficiency savings will be comparatively small, even on your estimates, but in any event you have not taken into account the impact that these changes will have upon the numerous organisations that operate within the regulated sectors. Taking the HTA, for example, there will be no financial advantage to our organisation as

we will still require the five (5) licences that we currently hold – the proposed changes will not alter the licensing regime – such that our expenditure on licensing fees will remain the same.

However, there is the potential for increased costs in that the CQC could bring about fundamental changes to the approach to regulation and inspections, which could result in expensive operational changes, e.g., redesign of manufacturing facilities, IT systems, education and training systems. For example, if each regulated establishment (300 NHS organisations, taking your figures) had to employ the equivalent of one (1) additional member of staff to manage the changes necessary to achieve compliance under the CQC (at a cost per organisation of approximately £50,000), the cost to the NHS would be £15M. Clearly this is a conservative projection as it does not take account of the cost of equipment/software or the opportunity cost of diverted resources.

In recent years the HTA has been working closely with the MHRA to achieve consistency of approach, including interpretation of legislation and guidance, and also joint inspections, which has been very effective at achieving cost savings for regulated organisations. The proposal in question would risk losing these costs savings whilst at the same time potentially actively increasing costs.

In addition, these increased costs, combined with any dilution or diminution of the expertise of the HTA, could have a substantially negative impact on various regulated industries, including particularly the UK Stem Cell Industry, which is at a critical stage of its development.

In summary, consideration should be given to the impact of the potential for increased costs across regulated sectors and the NHS as a whole. In our view, it is very likely that the total cost to the NHS would far outweigh any minor efficiency savings achieved via the proposal.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No. As stated above, we believe that the highly complex and specialised nature of the work of the HFEA requires that it should retain existing functions.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No – the organisations should remain as they are for the reasons stated above.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes – they should remain as they are for the reasons expressed above. There may be the potential for the organisations to achieve further efficiencies although in our view this should not be a pre-condition to their continued existence.

There could be further benefits and costs-savings achieved by a continuation of the joint working between the HTA and the MHRA and we see more potential for a merger of the functions of these organisations.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

For the reasons expressed in response to question 2 above, we believe that the proposed changes would result in increased costs to the NHS and thus the public purse. Retaining the functions with the HFEA and HTA would thus avoid this additional expense. As stated in response to question 5 above, these could be an opportunity for further efficiencies and as such savings to the public purse, particularly if the MHRA's functions are more closely aligned with those of the HTA.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No, for the reasons expressed above.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

Please refer to our response to question 2 above.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

Please see above.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Please see above.

11. Can you provide examples of costs and benefits of these proposals?

Please see above and our response to question 2 particularly.

12. Do you have any comments on the consultation Equality Analysis?

No.

If you have any further queries with respect to the Trust's responses please do not hesitate to contact me on the telephone number set out in the header, above.

Yours sincerely,



Brady Pohle
Senior Trust Solicitor
Legal Services

Response 41 – Northern Institute for Cancer Research

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	No- Researchers have established a good working relationship with the HTA which has led to the raising of standards in the sector based on sensible dialogue between the research community and the regulators. Similar support has been given to staff in the university working in other sectors. Splitting up the HTA in the way proposed will threaten progress in improving standards with little benefit in terms of cost.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	There will be a significant opportunity cost to the research sector, with time spent building up new relationships with different organisations. During the period of transition there may be threats to the continuity of service provision for advice and the approval of new licences
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	No specific comment
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	Please see answer to Q1
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	Please see answer to Q1
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	With regard to the HTA further savings could be made by continuing the programme of “risk-based” on-site inspection. Inspection in the research sector should be limited to a few sites undertaking particularly high risk activity. Exemption could be granted to sites with other forms of accreditation.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	No specific comment
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	No specific comment
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
	No specific comments
10.	Do you have any other comments on the consultation proposals that you

would like to share with us?

The savings that this upheaval will produce are very small, even if realised, and threaten the smooth running of a sector of great value both in academic terms, and, through commercial collaboration- of monetary value as well

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Response 42 - Association of Clinical Embryologists

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

As a stakeholder we are not happy with the current situation with the HFEA, and believe this is the time for streamlining and improvement. We don't agree that all the functions of the HFEA should transfer to the CQC. There is a clear advantage in retaining a specialist regulator in this complex field not only to ensure public confidence but to ensure effective regulation. The HFEA is a well known brand which is respected not only nationally but internationally and has the advantage of developing its regulatory systems over a 20 year period. We believe that the HFEA could exist within the CQC umbrella, perhaps as a Fertility branch of the CQC. It is of absolute paramount importance that the expertise of the HFEA is transferred.

The HFEA has since 1991 dealt with ethical and policy issues, developed clear Code of Practices and improved the inspection process. It was also able to become one of two competent authorities for the European Union Tissue and Cells Directive (2004/23/EC) which reduced the impact and burden for UK centres.

There are real concerns that should the CQC become solely responsible for inspections, unnecessary demands will be made on clinics to comply with regulations that are not relevant. A situation that already exists in Ireland; Up until the implementation of the European Union Tissue and Cells Directive, (EUTCD) in 2007, Ireland had no national regulatory or advisory body. The practice of ART was under the guidance of the Medical Council Code of Ethics, pertaining only to medical practitioners.

The Irish Medicines Board (IMB) were nominated by the Department of Health as the competent authority for the implementation of the directive and for the Irish clinics, this meant an inspection every two years to ensure that clinics were compliant. The EUTCD was primarily designed to promote the health and safety of tissues and cells in clinical use and while the directive is easier to apply to blood, organ or tissue donation, it had to be adapted in some respects to cover reproductive tissue and cells. There has, and continues to be been considerable debate over the relevance of applying certain aspects of the directive, such as air quality in the IVF laboratory or timing and frequency of biological screening to couples undergoing IVF treatment with evidence showing that there is no need for the level of screening originally prescribed by the directive. HFEA with the experience and knowledge accumulated as the UK ART regulatory authority were able to retain autonomy and practicality in relation to the implementation of the directive.

To date, the Irish Medicines Board only serves as a regulatory body and offers no policy or guidance in relation to assisted reproduction. This is a position which is often envied by our Irish Counterparts and most Irish clinics refer to the HFEA Act and Code of Practice while developing clinic policies.

The HFEA also maintains a register currently containing over 1 million records where

accuracy is paramount as it holds details of every treatment carried out in the UK and information about genetic identity of offspring. The CQC has no experience in maintaining such registers which raises concerns.

The HFEA also has functions in relation to the whole of the UK, the CQC is currently limited to England only which brings into question consistency.

Whilst the HFEA has over 20 years of experience the CQC is a young organisation being only in existence since 2009. Since its founding it has been subjected to much public criticism especially over its failures in the recent Winterbourne View review. The report highlighted many failures with respect to management and how information was handled and communicated. It also raises grave concerns that the CQC had previously rated the centre excellent and it was only the Panorama programme which highlighted the mistreatment. Parliamentary MPs have also raised concerns over the CQC and a report by the National Audit Office concluded the organisation did not provide value for money. It also raises concerns regarding training of inspectors and the number of inspectors who have a clinical background. The Mid Stafford scandal highlighted failings in several departments and where reports by regulators do not always reveal problems. Inspection teams need to be highly specialised and focused on their area of regulation to ensure effective inspections occur. The CQC does not have experience of developing codes of practice, collecting information, providing information and the CQC board is very different to the Authority board. The CQC is a large organisation which already seems overburdened. The HFEA has a dedicated small team of staff compared to approx 1900 in the CQC. The above are concerns regarding the CQC as a whole and highlight the need even further that should the HFEA should retain its expertise within the CQC. Going forward the regulation of the fertility sector should benefit from the current HFEA expertise, along with relevant input from the CQC.

We can see advantages to the HFEA existing within the CQC, which include making it easier to identify the regulatory overlaps and move to joint inspections if appropriate. Joint working with the CQC could reduce regulatory burden and increase efficiencies if a single integrated inspection could take place. The HFEA inspections of clinics have come a long way and at the moment are working well from both sides, it would be disastrous if this knowledge were lost. We recommend that a joint 'Fertility Inspection' should be developed between the CQC and the HFEA. In addition the HFEA is already working with the professional bodies to identify where further improvements could be made.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

As service providers we need effective regulation which promotes good practice in a defined framework. The HFEA is an initial point of call for many patients and centre staff. The current expertise needs to be maintained and there is a concern in a large organisation like the CQC that this will be lost or diluted. With adequate mechanisms being put in place prior to changes being made the CQC and the HFEA could improve on existing practises, but this would require the CQC to work in an alternative manner to how they regulate other healthcare practises. It will not work by simply conferring the role of the HFEA to the CQC, and the CQC applying their existing practises to

fertility clinics. The IVF sector is very specific and needs experts to deal with problems. If the HFEA were abolished completely, and a change in the regulatory mechanism occurs this may lead to increased burden on the sector and a loss of confidence for the public.

Advantages at the local level from the HFEA and the CQC working together could include the likelihood that hospital trusts will be more willing to listen to a combined group. As the fertility sector is so specialised it is sometimes poorly understood by hospital officials, grouping the HFEA with an already revered group such as the CQC could mean more gravitas being put on inspections or non-conformances. The current situation can often result in the person responsible coming under fire, rather than the trust as a whole.

Certain situations exist where the HFEA needs to be stronger at enforcing regulation, this needs very careful management and it is vital that this includes input from the relevant professional bodies. With transfer of some functions of the HFEA, alongside integration into the CQC this could be better managed.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

There are very few currently licensed projects and the HFEA do not have a dedicated department to do this. The Health Research Authority is designed to protect and promote the interests of patients and the public in health research. It also works closely with other research organisations and will be able to deliver a consistent approach. It is therefore better placed than the HFEA to regulate research. The only concern is that there will be adequate expertise to meet the requirements of that HFE Act and a mechanism to protect information held on the register to which researchers can gain access to with patient consent

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

There are certain functions of the HFEA which will sit better with other bodies, these include the functions relating to research as mentioned above. Other areas include the donor register and register of children resulting from donor conception. Expertise should be drawn from agencies such as the adoption register, but it is vital that this is treated as a separate sector. There should be an expert group of people to include counsellors, which are recruited to ensure that adequate support is given to a vulnerable group of people.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

A review to determine where efficiencies should be made is needed. It is essential that professional bodies be involved to drive efficiencies in the following areas: data collection, regulation and inspection and policies. This process has actually already commenced and dialogue with professional bodies has promoted discussion to where

future improvements may lie. This includes more efficient data collection and mechanisms for policy formulation. The review mechanism could cover where regulation has ‘crept’ away from the core requirements and where focus can be reduced. Coherent joint working with the CQC will reduce time spent for inspections and prevent regulatory overlap. The HFEA provides a sound regulatory framework which is recognised internationally. The organisation has high public confidence in a sensitive area of practice. The HFEA has a sound base to start with and has listened and changed practice to drive efficiencies.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

The HFEA have already undergone changes to save money. Moving to the CQC office was an initial response to the challenge. Developing this relationship further to prevent regulatory overlap will produce savings. Engaging with the professional bodies has also enabled suggestions to be considered and reviewing regulatory ‘creep’ and the amount of data collected could not only be cost saving but also reduced regulatory burden on the sector. The HFEA could retain its autonomy and brand name but sit underneath the umbrella of the CQC. Expertise would therefore not be lost and the organisation could continue to operate but with further improvements.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The research function should be transferred to HRA. This is appropriate as it will have more expertise than the HFEA. There is a possibility that the donor register could also be transferred, although this would require careful coordination. Recognition will need to be given to the fact that this is separate from the adoption register, it will come across different problems and need to function in a different manner. Knowledge will need to be drawn from the existing HFEA on how this new group will function.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

The cost saving with reducing salaries for the chairs and chief executives is substantial but effective regulation has to be priority. Reducing overlap in inspections is a more practical and sensible way to reduce costs which can be achieved through more collaboration between the CQC and HFEA. Concerns include the fact that the word ‘efficiencies’ is used without mention of improvements, indicating it is just a matter of saving money.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

The process of review should involve the professional bodies and stakeholders.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Of the 3 options given there is none that fit our view exactly. We feel that the expertise of the HFEA should be retained (option 3), however there is a need for serious improvement and streamlining (incorporation of option 1).

11. Can you provide examples of costs and benefits of these proposals?

No

12. Do you have any comments on the consultation Equality Analysis?

No

Response 43 - National Gamete Donor Trust

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	No. The HFEA has functions that cannot be managed by the CQC and the HRA alone. See question 10.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	We expect service providers to be pleased that they would only need to be inspected by one body (the CQC) rather than needing the two inspections (by the CQC and the HFEA) that they need at the moment. However, as at the moment the role of the CQC is to ensure good working practice only, we have some concern that patients and donors would be anxious that the inspectors sent out by the CQC might not be fully cognisant with their issues.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	No. See question 10
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	See question 10
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	Yes. See question 10
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	Yes. See question 10
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	Inspections of licensed centres could be carried out by the CQC, thus avoiding duplication
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	The financial efficiencies are based only on a reduction of senior personnel. It is difficult to compare the options because accurate figures for the budget of the CQC are not available. Neither is there set out the number and cost of new junior staff that might need to be employed. There is an assumption that the CQC could carry out all the functions of the HFEA, which we dispute. See response to question 10.
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
	See question 10
10.	Do you have any other comments on the consultation proposals that you

would like to share with us?

This is the view of the National Gamete Donation Trust (NGDT).

We are a charity with the aim of increasing awareness of the need for egg, sperm and embryo donation for the purpose of treatment to conceive. As such, we have regular contact with the HFEA as well as other organisations involved in fertility treatment. Our board of Trustees includes donors, parents of donor conceived offspring and a clinician who has run an NHS donor sperm bank and been an inspector for the HFEA. The NGDT is currently considering whether to apply to run the service for providing links between donors and offspring born before the HFEAct. We are therefore very aware of the functioning of the HFEA and are particularly concerned about the safe care of the donor Register.

We understand the need to review practice and look for efficiencies both financial and logistic. We understand that, although it is not our preferred option, Option 1 is the preferred option of this government. We wish to make it clear that we will support whatever option is chosen with a view to creating the best possible environment for donors, recipients and the donor conceived.

A starting point might be to ask why this area of patient care should be dealt with in a way that is different from other areas of health care, such as, for example, cancer care. Management of cancer care, for instance, involves patient care, research and collection of statistics and one could argue that this has to be as rigorous as the care of centres delivering fertility treatment.

In terms of patient care, we appreciate that one of the functions of the HFEA is duplicated by the inspections carried out by the Care Quality Commission (CQC). We know it is a burden for clinics to have to prepare for two very similar inspections. We would in theory be happy for the CQC to take over this role. We note that this would require the CQC to take on additional staff and thus become a more expensive service. We also note that changes would have to be made to allow the CQC the right to inspect clinics in Scotland and Northern Ireland – areas over which the HFEA currently has legal jurisdiction.

As far as the research aspect goes, one could argue that an organisation such as the Health Research Authority would be well placed to monitor research in this field. We note however, that this organisation is not yet functional and that no costing is given for this proposed Non-Departmental Public Body (NDPB).

We would however, argue that the “statistical” data collected by the HFEA does not just consist of quantitative details of various treatments and their success and is hence very different from the data collected in, say, cancer care. In the case of the HFEA there is also the data that records the names of patients treated using donor gametes and allows links between the names of the donors and recipients. The issues of confidentiality are also different. Because this data will allow the donor-conceived to find details, both personal and medical, of their donor it is vital that this data is maintained and regulated very carefully. Furthermore, the giving of the linking information needs to be done in a sensitive manner- a requirement not usually necessary for people dealing with recording statistics. This means that the management of the HFEA register cannot be maintained just by a data collection

organisation, such as the Health and Social Care Centre (HSCIC).

We are being asked to consider the option of the CQC taking over the roles of the HFEA with very little explanation as to how this would be done: no idea of the number of new inspectors required, funding given, etc. We are unhappy about giving our support to a “broad brush” option with so little detail of the proposed structure. If the intention is to incorporate the HFEA without any change in the practice and funding we cannot see all the functions of the HFEA being successfully dealt with just by the CQC.

However, if the proposal is that the HFEA be subsumed within the CQC but remain in many ways intact, we would be agreeable to this arrangement.

In the alternative proposal Option 2, it would seem that the inspection aspect could be carried out by the CQC, the research aspect covered by the HRA and, if somewhat unsatisfactorily, data collection managed by the HSCIC. We are concerned that the option of splitting up the various functions of the HFEA between several different agencies will lead to lack of cohesion and do not favour this option.

One of the remits of the HFEA is to explore society’s opinion on new treatments. We are not aware that this is part of the provision of the CQC. With treatments that make fundamental changes to the structures of families and change the social landscape, we recognise the value of the consultations that have taken place in the past. A consultation on the use of mitochondrial donation is currently underway. This is a treatment with immense social significance and these issues are of great importance to the NGDT. We are pleased that society currently has the possibility to engage in these consultations and would regret their demise.

In relation to this, we seek reassurance that the CQC under Option 1 will have some structure for drawing on the informed advice on new treatment possibilities that is an integral element of the HFEA.

We need to be convinced that the proposed changes will save any money. Currently the bulk of the HFEA’s income is levied through the clinics. It is acknowledged that the CQC would need extra staffing and resources to take over the functions of the HFEA. We think all the functions of the HFEA could not be carried out by the CQC alone as it currently stands and is funded. Changing the structures would in themselves require financing. We find it difficult to see where the efficiencies in finance would come from.

We are aware too that changes required to legislation would be costly both in time and money.

The HFEAct has been a benchmark for the development of legislation around the world. It has been the cornerstone for the European legislation. We know there is room for change at the HFEA and we acknowledge that there might be the need for some efficiencies but would be in favour of maintaining the HFEA.

The view of the NGDT is that the most “fit for purpose” option is Option 3 – to retain the HFEA with efficiencies. Our main concern is for the safety and well-being of

donors. We would work positively and actively within whatever framework is chosen.

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

The equality analysis does not consider the loss of the consultative process used by the HFEA. That is to say, transfer of the functions of the HFEA to the CQC would be the end of the consultations that inform new treatments, such as mitochondrial transfer, and which we feel the general public has a right to consider because they change the nature of society.

Response 44 : Donor Conception Network

About us:

This response is made by the trustees and steering group of the Donor Conception Network, a registered charity. The Network aims to support those contemplating or undergoing donor conception, families with donor conceived children, and donor conceived individuals. We have been in existence for just under twenty years, and are the leading organisation focussing on the interests of donor conception families in the world, and as a result have a unique repository of knowledge and experience about donor conception, donor families and their feelings. We are a mutual support organisation with over 1,500 families in membership. We are contacted by phone and email by hundreds of enquirers each month. Our guidance materials are sold all around the world. While this response cannot be entirely reflective of the views of all our members, we believe that it substantially reflects their interests.

Our strongly held principle is that donor conceived children should be told by their parents about their origins from an early age. Twenty years ago this was not the received wisdom; in fact most clinicians advised patients to keep the information a secret. We have contributed significantly to a change of climate, to the point where the HFE Act now requires that patients now be informed that their children should be told the facts about their origins at an early age and where to access support materials. In 2004 we supported the proposal to end anonymity of gamete and embryo donors. We have received grants from the Department of Health to produce materials and run courses to prepare those contemplating treatment for donor conception parenthood, and to support parents in “telling and talking” to their children.

We therefore have maintained a very close interest in and knowledge of the work of the HFEA and in particular the Register of treatments, donors, recipients and donor conceived individuals. The Network’s chair, Walter Merricks, was a member of the HFEA for six years and was interim chair for six months in 2007-08.

Our response is confined to the proposal to transfer functions of and to abolish the HFEA.

Discussion

Our serious and strong objection to the break-up of the HFEA’s functions is the risk that the interests of donor conception will be lost amid the huge range of CQC’s responsibilities; that information that should be compiled on the Register will be less accurate as a result of the downgrading and lack of senior management focus; that those requesting information from the Register might be given inaccurate information, or less information than they would or could be entitled to; and that the disclosure of information would be handled poorly.

The HFEA is not merely a regulator of fertility clinics. It has an important policy-making function in a wide range of highly sensitive and controversial issues. These must be underpinned by two important principles - a respect for the special status of human embryos, and a concern for the welfare of children to be born as a result of assisted conception. These have included – in relation to donor conception – the payment of donors, the number to be permitted of children conceived from the donations of one donor, the

rights of donors and their access to information on the Register, particular considerations in relation to egg sharing, and many others.

We believe that none of the Options proposed will serve the interests of donor conception families, and any combination of them will be detrimental. The consultation starts from false premises about the supposed benefits of “streamlining the regulatory landscape”.

Option 1

It is abundantly clear that the CQC does not wish to take on the responsibilities of the HFEA and the HTA, and it must be doubtful whether it would have the capacity to do so. It cannot be wise to force a public body to take on extra responsibilities for which it believes it is ill-equipped and cannot carry out effectively. This would not only threaten the carrying out of HFEA responsibilities, but also the existing functions of the CQC itself, a body that has already been shown to suffer from serious inadequacies in its performance.

The consultation paper ignores the disruptive effect of institutional change on people, processes, systems and services. It assumes that savings can be made while the level of service and performance can remain untouched; there is abundant evidence to the contrary – not least in the formation and performance of the CQC itself.

The CQC has a huge range of responsibilities, among which the special needs of the assisted conception and donor conception sectors would be in danger of being lost to view by its board and senior management. These sectors would become insignificant pin-pricks on its risk-map. The interests and concerns of donor conception families would rarely rate a mention on a CQC board agenda. Former HFEA functions would be delegated to the a low level in the organisation. The managers given responsibility for these areas would have less of a focus on stake-holder interests than in attempting to manoeuvre their way through the bureaucratic hierarchy of the organisation. External voices and input would count for less for a large multi-focus regulator than for an organisation whose objectives are more narrowly targeted. The current HFEA staff with their accumulated expertise would find themselves significantly outnumbered; their focus might inevitably be on how to survive in a new climate. The sense of corporate memory and institutional pride in the HFEA’s values and objectives could be lost. The commitment to serving families and individuals will be diminished.

Option 2

This option explores two possible functions of interest to us that might not be transferred to CQC if the main proposal in Option 1 was adopted.

The first is concerns responsibility for the HFEA Register of treatments, donors, recipients and births. This is of vital interest to donor conception families. The CQC has no experience of or capacity for running such an important register that has to be maintained in existence almost certainly in perpetuity. So the consultation paper suggests that this responsibility might be severed and given to the NHS Information Centre. The HFEA has described some aspects of its work in this area:

In a nutshell, it is through its powers of inspection and licensing, which includes audits and management reviews, that the HFEA is in a position to be reasonably certain that the data it collects is complete and correct. Splitting off the hosting of the Register from the wider compliance functions poses a real risk that clinics

won't comply with the extensive statutory reporting requirements and that this will undermine, for example, the information access guarantee that is given to those people conceived from donor treatments. In practice, we often have to go back to clinics when we receive a request for information from a donor conceived person, their parent or the donor themselves in order to clarify issues with the data. We are also routinely engaged in data assurance processes, particularly focused on issues around donation. We feel a major factor in achieving compliance from (parts of) the sector with this is that we are also the licensing body.

When a request for information about the outcomes of donor treatments is received (Opening the Register - OTR), a dedicated team at the HFEA interrogate the Register data base, cross checking and referencing a woman's registration and treatment outcomes, and a donor's registration and use. [...], this can also involve communications with the applicant and the clinic.

External organisations would not currently be allowed to see these Register entries, since this form of disclosure is not envisaged in the current legislation. Furthermore, considerable technical expertise in the Register team is required to analyse the relevant reports from the database that contains data for 20 years of treatments, during which time various form changes regarding the amount and format of information on donors were introduced. Frequently, staff dealing with OTRs also contact centres regarding historic patient data, sometimes from centres which have now closed.

HFEA staff handling these requests have had at least basic training in counselling and handling difficult conversations. This does not mean that the HFEA does not recognise that at least some of the people asking for information would like access to further support or counselling services. The need to consider whether counselling would be helpful is flagged up in our correspondence with those requesting information. But we are aware that there is no direct and dedicated support we can signpost people to. In order to address this issue, we held a meeting with sector representatives in 2009. Here it was agreed that the British Association for Counselling and Psychotherapy would, together with representatives of the fertility sector, address the need to increase expertise and knowledge of the relevant issues for interested counsellors. To our knowledge, this has not happened. We are keen to find ways of signposting donor conceived people and other OTR applicants to more accessible and relevant sources of support.

We feel that accessing the actual information contained in the HFEA Register is intrinsically linked to our expertise in how the Register was built, how forms have changed over the years and how rules and processes have to be adapted to make sure that as accurate as possible information is given to people who want to understand better their genetic family ties. [Letter to BMA]

We oppose the transfer to the HFEA's functions to the CQC which we think would be little short of disastrous. However the consultation also canvasses another possibility that might be even worse. That would involve splitting the functions and severing responsibility for the compiling, maintaining and manipulating the information on the Register and entrusting this to yet another body unfamiliar with the work and separate from the regulator.

It is therefore extremely worrying that the handling of requests might be transferred to a body (NHS-IC) that would not have regulatory and licensing oversight of the body from which the data had originally been obtained when as appears to be the case, the source data frequently needs to be checked with the clinic concerned. While some of the requests relate to relatively recent events/data entries, (e.g. from a recent parent: how many other children have been conceived from the same donor's sperm) many and probably an increasing number will relate to conceptions in the 1990's when record-keeping and data transfer by clinics was far less accurate than it is today. Because of the poor state of that data, in the early 2000's it was necessary for the HFEA to carry out a historic audit of birth data going back to 1991. Even after that lengthy and expensive exercise, it was clear that many deficiencies in the data remained. As the HFEA point out, the way that information was recorded has changed over the years, and a consistent team with a good corporate memory familiar with the history of the Register both from a technological and a regulatory point of view is vital to the effective carrying out of this function. NHS-IC would not have the authority to obtain cooperation in seeking answers to such requests, while failure or delay in responding might suggest that the clinic merited regulatory attention; a quick word with a regulatory colleague might easily resolve such an issue, while a formal reference to a separate regulator might be seen as cumbersome and time-consuming. An opportunity for joined-up good regulation would be lost.

Option 2 also canvasses the possibility of severing the responsibility for disclosing information from the Register and transferring that to the Health Department, with possible onward transmission to an external agency. A special HFEA unit that handles enquiries and requests for information from donor parents, donors or donor conceived individuals. As the number of adult (post 1991) donor conceived individuals grows, the volume of enquiries and requests is very likely to increase.

Whilst our objection to the transfer of HFEA functions and indeed to their splitting up remains, the balance of advantage here could be altered by another factor not canvassed or even mentioned in the consultation paper. That relates to the voluntary register of pre-1991 donors, recipients and donor conceived individuals, currently run by UK Donor Link. There has always been a strong case that these two registers should be brought together and the disclosure of information from both should be handled by a specially trained team with expertise in counselling, intermediation and family welfare.

Since the fate of the UK Donor Link voluntary register is under separate consideration it is difficult to comment further.

Conclusion

Our concern is that any fragmenting of the services will be detrimental to the quality of service: if the Register is separated, all the other services will lose the contact with the end-users and any new evidence that becomes apparent, if the Ethics section is separated (or ditched altogether, as some have suggested) the lessons being learned in one section will take longer to percolate to the other branches, to the detriment of consistency and effective regulation; if the research and the treatment regulating functions are separated, it more is likely to lead to inconsistency and incoherence.

While we have from time to time had cause to criticise the HFEA, we believe that the interests of donor conception families would be best served by retaining its functions in one place, under a specialist board. The consultation paper makes no proposals as to how the balance of lay, ethical and clinical input and expertise to be found on the HFEA board would be replicated in a CQC context.

Responses to questions

1. *Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.*

No. We believe that it will be highly detrimental to donor conceived people, to donor conception patients and to donor conception families to lose the specialist expertise of an authority that is familiar with the issues surrounding this subject.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

If the HFEA is retained there will be no impact at local level.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No. This would be detrimental to the coherence of the HFEA's focus on the ethical issues relating to the use in both treatment and research of embryos.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Not applicable since we believe that the HFEA should be retained.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

We believe that the HFEA should be retained with its existing functions. There is no reason to believe that the HFEA is not already efficient. It has already made substantial savings in its budget.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

Not necessarily. This should not be the sole purpose of the exercise. Since the vast majority of treatments are paid for directly by patients, the impact on the NHS of the HFEA is minimal.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

The impact assessment fails to assess the impact of the removal of senior managers on the quality of service, and naively assumes there would be no detrimental impact. There has been no assessment of the impact on bodies such as ourselves, should the HFEA's functions be split or transferred to the CQC. If either of these happened we would have to spend time engaging with a new set of organisations, helping them to understand the needs of our community. The time and energy would represent a cost to a small charity such as ourselves.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

We will engage with such bodies as are entrusted with the functions with which we are concerned when decisions have been made.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

The consultation starts from a premise – that current functions are mis-allocated and that savings can be made without detriment to service to users – for which no evidence is produced.

11. Can you provide examples of costs and benefits of these proposals?

As mentioned above, there would potentially be transitional costs for all those external organisations engaging with new and unfamiliar bodies. There are no benefits.

12. Do you have any comments on the consultation Equality Analysis?

No.

Response 45 : Royal College of Obstetricians & Gynaecologists

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

The Royal College of Obstetricians and Gynaecologists has considerable anxieties about this proposal. The HFEA and HTA represent two very specialist areas. It would be essential that the CQC has the necessary expertise to address the roles of these two regulatory bodies and if expertise has to be acquired then there may be little cost saving. It is likely that many of those individuals with expertise if they moved to another organisation would in fact be "the same people behind the same desk but with a different badge".

There is no doubt that a common understanding of the bigger picture is an enormous attribute particularly in informing the wider picture about research needs and thereby ensuring confidence both with the public and with the clinical areas concerned. These comments said, there are clearly areas of duplication in regulation and it is this "back office activity" where savings might be made.

The HFEA and HTA have extensive experience and expertise. There is an important need to get any aspect of regulation right and any changes from current practice would need to be clarity as to where the new benefits are. At the moment the document is insufficiently detailed to provide obvious evidence of benefit.

IVF has changed dramatically since the inception of the HFEA and its preceding bodies, and changes in its regulation that would bring it into line with inspection of other complex medical interventions are appropriate and timely. IVF should be perceived as a 'routine' medical intervention and regulated in that light, with some specific requirements specified by legislation. While the HFE Act has been a model internationally, other countries have not adopted similar regulatory models. We recognise that the HFEA has generally functioned well, although there has been a tendency for 'regulatory creep' which reflects its joint role as both policy-generator and regulator. The CQC is charged with regulating all comparable procedures and would therefore on the face of it appear to be an appropriate replacement, although there are many issues including regarding the need to extend its remit to the devolved nations.

We have very significant reservations relating to the ability and cost-effectiveness of the CQC to take on most of the activities of the HFEA (and the HTA). We do not have confidence that abolition of the HFEA would result in significant savings, although recent work by the BFS has shown how expensive and burdensome is data collection to meet current HFEA requirements, and that its value is increasingly undermined by changes in consent procedures.

The functioning of the CQC is very different from that of the HFEA and the HTA. Consisting of only 5 persons on their board, it would require separate boards to cope with the running of the reproductive and tissue regulatory functions – i.e. continuing the regulators under their respective Acts. Although success might be claimed that two ALBs had been removed, in fact their functions would continue, and the total reduction, with the establishment of a new one (the HRA) would mean all this disruption and reorganization for a reduction of one ALB. Of

most concern is the track record of the CQC to date. It has had a number of high profile failures and is inexperienced in almost all the areas covered by the HFEA.

It is essential that specialist regulators work in a collaborative manner together and thereby gain benefit from efficiency. This ideal should be encouraged. The concerns would be that any streamlining of regulation if undertaken should be achieved with the minimisation of disruption. It must be emphasised that the specialist expertise and experience within whichever regulatory body involved is retained.

We feel that the current situations in regard to the HFEA of having a single non-governmental body act as both regulator and policy-generator is a concern. This is not always bad: the robust and effective approach by the HFEA to driving down multiple pregnancies is a very positive example of how this can be done. However the RCOG supports the principle that these functions should be separate.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

It is appreciated that there is a need to make efficiency savings and therefore inevitable that there will be benefits and disadvantages whichever option is chosen. Issues may be different for England and Wales and for the devolved areas, e.g. Scotland. Both locally and wider it is very important that there is no damage to professional and public confidence, requiring robust establishment and communication of proposed changes ahead of implementation.

There is a huge amount of work needed to dissect in detail how a new regulator would pick up most functions of the HFEA while others are moved to other bodies, and revised in the process.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

We feel it is very clear that this function should be transferred. We do not think the HFEA has a good track record in this regard, other than protecting against the anti-embryo research and use sector. The UK has a robust research ethics framework which does not need duplication by the HFEA. There is already a mechanism by which research ethics committees can call on specialist advice if they feel they do not have it within the committee, and there are also 'grades' of ethics committee with responsibility for different levels of investigative risk. It would also be possible and probably appropriate for ethics committees to liaise with any future regulator to issue research licences behind the scenes.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

There are specific issues relating to donor-conceived children which require careful consideration. The RCOG is part of a BFS-led stakeholder group which is working on alternatives to the current situation, which include discussion of whether information handling and access might be better located with adoption/social services and the RCOG welcomes wider discussion of whether these very sensitive issues are best handled by the regulator. This group is also considering how data might better be collected; while it is possible that some aspects of data management might be best moved, it is clear that a regulator needs access to accurate and relevant data on activity and outcomes.

<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>This may be possible, with root and branch review of the key functions of the HFEA. This would require a change of culture at the HFEA, but we do not deny that there is some attraction in retaining the HFEA 'brand', which historically has enjoyed a generally positive reputation.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify</p>
<p>Quite possibly, given concerns about the ability of the CQC to pick up the various responsibilities involved, while at the same time reforming itself sufficiently to engender public and professional confidence in its activities. Clarification here would be required from HFEA regarding costs.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>We consider transfer of research approval to be essential regardless of other outcomes. We are aware that the BFS is considering how other key legislation-based activities of the HFEA, specifically data collection and activities in relation to donor conceived children, could be better delivered and we welcome wider discussion of these issues.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?</p>
<p>Until work is done to explore where HTA and HFEA could make cost savings it is difficult to give a view as to possible best option.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>We have mentioned above specific areas of work being undertaken by the BFS/stakeholder group which are examples of the complex issues that will need consideration. These will need to be worked through jointly with relevant professional bodies and patient representative organisations. In view of the serious concerns we have regarding ability of the CQC as currently established to deal with these novel responsibilities, we strongly urge DH to consider the issues in depth before any decision to abolish the HFEA and HTA is made.</p> <p>In the context of consent this is a specialist issue but certainly consideration about consent and use of tissue samples in future research is a point for future exploration and streamlining.</p> <p>It is appreciated that there is a need to make efficiency savings and inevitably benefits and disadvantages whichever option chosen. However any streamlining of regulation needs to minimise disruption and is absolutely essential that the very specialised experience and expertise which the HFEA and HTA are retained.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>

There is one area of research oversight which involves use of embryos that has been lacking distinctly from HFEA function; the regulation of implementation of new treatment modalities. In common with innovation in surgery, seldom has there been any kind of requirement for trial status before use in practice. Many reproductive treatments offered to patients, including genetic tests of embryo competence, have not been rigorously tested before implementation, nor monitored for efficacy *post hoc*. Bearing in mind the huge profits that can be made by purporting to show advantage in a new culture system, new device, or novel manipulation, desperate patients are often offered new and more expensive modifications with little credible data; assisted zona hatching, and preimplantation genetic testing for women of advancing age are examples. If the HFEA research functions do move to the HRA then it should be encouraged to improve this area in the interests of patient (and embryo) safety.

11. Can you provide examples of costs and benefits of these proposals?

This is not possible with current information

12. Do you have any comments on the consultation Equality Analysis?

No

Response 46 – Natural History Museum

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Transferring the HTA functions to the CQC is not the best option in our view for a variety of reasons. The most important of these is that the HTA was set up as part of the Human Tissue Act. This act was drafted to address serious concerns about the collection, retention and use of human tissue. Abolishing the HTA will remove the high profile necessary to retain public confidence that events such as the Alder Hey & Bristol Children's Hospital scandal cannot happen again. The arguments used to justify abolition, would down-grade the inspections made under the Human Tissue Act. These inspections would become just another part of hospital inspections. This latter is important, as although c. 60% of licensed premises are NHS facilities the remaining 40% are not. Accordingly, this would mean that, nearly half the current institutions needing a licence would be inspected under a regime not designed for their type of institution and (likely) by staff who have little understanding of the work these institutions do. Having been the subject of a recent HTA itself, the NHM can confirm their standard is exacting, objective, and thorough. Going through such a detailed inspection does concentrate the mind on how important this area is and what a special responsibility those institutions that hold human remains have. If this inspection was to become just another part of an inspection that focuses on other issues there is a danger that it will become little more than a 'box ticking' exercise.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The impact of such a change would for us as not only a national museum, but also a major research institution, be far reaching. Should a CQC be empowered to undertake our inspections we would be inspected under a regime designed for medical facilities not tailored to the specific needs of the sectors in which our work falls. This view is underscored (for us) by the reference to patient impact in the question.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Splitting functions which currently appear to work well doesn't make good sense although it is hard to comment specifically as the NHM is not involved in any HFEA activities at present.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Dividing the functions — even as apparently simply as between research and all other activities — in any respect between different licensing and inspecting bodies would, in our opinion, paradoxically increase potential inspections under the relevant acts for non-medical institutions.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

This option is the best of the three being offered, it preserves the role of an independent licensing and inspecting body. It also makes it very clear that these are the relevant bodies to consult about licensable activities. The savings proposed by the abolition of these bodies are relatively small and should be possible for each body to make in the same time period.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

The retention of the HTA could be cost neutral given that savings when changes are proposed and those actually realised are often different. The functions that the HTA carries out will still need to be undertaken as stipulated in the Human Tissue Act. Therefore large numbers of people currently employed by the HTA will need to be transferred to whatever new authority takes on these roles.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The NHM does not believe there will be any advantages gained by transferring any of the current functions elsewhere.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

You mention the reduction in senior management that could be made by the abolition of the HTA would be a loss of expertise and direction for the staff left to undertake this work. Further efficiency savings are also suggested. One way in which to retain the HTA would be to use common central functions such as HR, finance and IT across all the bodies discussed in the consultation. This would reduce senior management and also staff duplication without the need to lose technical expertise.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

We have nothing further to add.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

The focus of the consultation is health-service facing which is understandable. However, the Human Tissue Act regulates much more than this and it seems that the other areas are not a major focus of the consultation. They should be.

11. Can you provide examples of costs and benefits of these proposals?

In several of its recent reports (e.g., report on the reorganisation of arms length bodies) The National Audit Office has shown that savings due to reorganization of the sort proposed here are often not as great as expected due to issues such as costs involved in existing commitments such as building leases which may extend past the abolition of the body, the risk that debtors may not pay what is due, and that assets may not achieve a full value on disposal.

12. Do you have any comments on the consultation Equality Analysis?

This appears to have been addressed adequately.

Response 47 - Sheffield Teaching Hospitals NHS Trust - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	Yes. There is significant overlap between the inspections of all three bodies that could be simplified if they merged. The CQC has significant power which is not replicated by bodies such as the HFEA. With regard to research, the establishment of the HRA is long overdue and if it takes over responsibility for embryo research it will significantly streamline the process. The current HFEA process is perceived to be inhibitory to enabling research. A single approvals process through the current IRAS system will significantly improve matters.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	In terms of reducing regulatory overlap the proposals should deliver a cost saving, but it is difficult to quantify until after the event.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	The impact to research is greater in terms of potentially enabling research that may have a net contribution of GB PLC in the longer term. It is an aim of the coalition government to cut red tape and this seems to be the right thing to do.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	We feel the HFEA register should be given to the Social Care and Information Service and held along side other NHS databases. There is always debate about the confidentiality requirements of the HFE Act but with appropriate governance this need not be a problem. There are equally sensitive databases in existence. There have been some concerns about openness, accountability and quality of decision-making in HFEA policy development. There is greater satisfaction when policies are developed by the department of health and the professional bodies.
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	There is concern that this would not be possible in the long term unless there is political pressure for change.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

As above.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Yes, see answer to question 4. Their policy functions should be conducted by professional bodies/department of health and the HFEA data should be managed by the NHS Back Office along with everything else. The HFEA would still need access to the data to be able to discharge their regulatory functions, but the process of collection, storage, validation and retention should be managed by data experts elsewhere.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

No, more detail would be needed in the consultation document for robust feedback to be given.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

There are serious concerns about the role that a regulator should play in the provision of information exchange between sperm, egg and embryo donors and any donor-conceived adults. The way in which the HFEA are planning to discharge this function is worrying. This should be handed over to the post-Adoption services to deal with, there are more synergies here.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

No further comments

11. Can you provide examples of costs and benefits of these proposals?

There is insufficient detail in this document to comment

12. Do you have any comments on the consultation Equality Analysis?

None

Response 48 – Royal College of Surgeons

Submission from the Royal College of Surgeons

The Royal College welcomes the opportunity to submit evidence to this consultation by the Department of Health. The College is a professional body with a remit covering England, Wales and Northern Ireland. We hold licences from the Human Tissue Authority for anatomy and public display.

The College believes that option 3 - where the HFEA and the HTA retain their existing functions while delivering efficiencies - is the best option for the sector. It is our view that the regulation of human tissue is complex and would not fit well in the general regulatory structure of Care Quality Commission. Below are our responses to the consultation questions.

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

The College is concerned that the regulation of human tissue is complicated, and requires specialist expertise and appropriate regulation which is sufficiently different from the general regulation of health and social care currently undertaken by the CQC. There is insufficient information in the current proposals for us to see a beneficial effect of the proposals on the provisions of the HTA functions on a practical level. With the improved efficiency we have seen from the HTA in recent years, and further efficiencies possible with option 3, we see no persuasive reason to support the taking of this risk.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

As an organisation regulated by the HTA for both public display and anatomical examination we rely on the expert knowledge built up in the HTA. We are not currently subject to regulation by the CQC for either function so there would be no savings in duplication of regulation.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No comment.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

The College is of the opinion that the safe and ethical use of human tissue is the key priority of the HTA and that this will be best ensured if regulatory functions remain in a single organisation. If the HTA's functions were separated it is likely to result in a more complex and costly regulation without any significant benefit to the public. For this reason the College does not support this separation.

5. Do you believe the HFEA and HTA should retain existing functions but deliver

further efficiencies? Please explain why you think this.

Yes. To retain the HTA and make further efficiencies in our opinion is the best option for the regulated sectors and the public as a whole. It is the College's view that to continue the effective regulation of human tissue and organs by the HTA will protect public confidence and ensure safe and ethical use of human tissue is maintained.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

No comment.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No comment.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

With the emphasis on making efficiencies it is the College's belief that, while there may be some limited overlap in the remit of these organisations, the current HTA is an effective regulator and moving its responsibilities and abolishing it would be counterproductive.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

No comment.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

No comment.

11. Can you provide examples of costs and benefits of these proposals?

No comment.

12. Do you have any comments on the consultation Equality Analysis?

No comment.

Response 49 – The Royal College of Pathologists

1. The Royal College of Pathologists (RCPATH) is making this submission as part of the Department of Health's (DH) "Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority" which it was pledged would be undertaken in the document "Liberating the NHS: Report of the arms-length bodies review" published in July 2010.

2. This response provides information on the views of the RCPATH on the options proposed in the consultation document. The HTA regulates premises and activities in the following sectors in which the RCPATH has an interest

- a. Post Mortem
- b. Research
- c. Human Application
- d. Anatomical examination (linked to medical education)

3. The Royal College of Pathologists (RCPATH) is an educational and standards setting body which oversees clinical standards for the conduct of post mortem examinations. It promotes the use of human tissues in research, in teaching and training. Clinical practitioners who are Fellows of this College are involved in some activities related to the transplantation of human tissues which is presently regulated by HTA. RCPATH is committed to principles of working that ensure human tissue are stored and used ethically and with proper consent, and that the bodies of the deceased are treated with respect and dignity. RCPATH welcomes the Government's commitment to maintaining standards as noted in the Ministerial Foreword to the consultation.

4. The response does not comment in detail on proposals for the Human Fertilisation and Embryology Authority (HFEA).

5. The RCPATH notes that HTA's regulatory approach is underpinned by staff with significant expertise in highly specialised areas of working including in laboratories and mortuaries. This expertise is not duplicated elsewhere with other regulators. Transfer of regulatory function would imply transfer of this specialist staff with no perceived economies and significant risks associated with any transitional arrangements. The risk of a loss of expertise is highlighted in the consultation document and RCPATH believes this would be a significant risk.

6. The consultation document gives three options on the future of the HTA's functions. These are:

Option 1

Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the Health Research Authority (HRA); and abolish the HFEA and HTA. Page 1 of 3

Option 2

Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.

Option 3

HFEA and HTA retain their functions but deliver further efficiencies.

7. The RCPATH believes that of the options presented in the consultation, option 3 runs the least risks in ensuring the continued oversight of the uses of human tissues and oversight of post mortem examinations. RCPATH believes that there are larger risks were options 1 and 2 to be implemented.

8. As a general comment, and in line with a strategic desire to reduce the overall burden of regulation, RCPATH would seek to minimise duplication of inspection in relation to HTA, CPA /UKAS and MHRA as part of any review. An important component of review should also be to ensure that the inspection program is proportionate to the clinical or regulatory risk. RCPATH is of the opinion that at present, aspects of inspection are not proportionate. Organisations should be in a position to judge resource levels according to a more balanced view of risk; particularly in a resource scarce environment.

9. The consultation document notes that CQC is an England-only regulator and it is understood that the HTA has responsibilities across the UK including Scotland. It is not specified how this would be delivered after the transition of functions to other bodies.

10. Tissue for human application

HTA regulates and inspects laboratory facilities used to process tissues for human application. RCPATH interest in this area is mainly linked to bone marrow transplantation but increasingly will cover emerging stem-cell therapies. This is a highly specialised technical field. If the HTA was moved into CQC one could only imagine the need to transfer all functions and expertise into a directorate within CQC to preserve established expertise. This would lead to minimal efficiency gains with a significant risk that the direction and initiatives already established would become lost or diluted. The Act as it stands undermines the current appropriate ministerial interest in the generation of national wealth from biomedical intelligence and giving this responsibility to CQC would carry significant risks that developments in this area would not be translated to wider benefits.

11. Post Mortem Activity

RCPATH is the professional regulatory body that sets standards for clinical activities related to post mortem examinations in the UK. It has developed good working relationships with the HTA in its oversight of the PM sector, as part of a HTA working group on the post mortem. In this capacity a new national group has been established including representation from the Coroner's Society and Forensic Regulator. Developing such trusted relationships has taken time and there is a risk they would be lost in any transfer. HTA has acted as an effective organisation that has driven up standards in the sector by working in partnership with stakeholders and providers, often acting in an advisory capacity for ad hoc issues outside of any scheduled inspections. The HTA has been responsive in reviewing its systems of regulation and making these more proportionate. RCPATH has confidence in the HTA as an effective regulator in the sector.

If this function was moved to CQC there are no economies of operation predicted in terms of burden of inspection and regulation. A risk is seen in that some of the

present expertise established in HTA may become diluted if pulled into CQC. The philosophy of regulation for CQC is probably not aligned to this sector and this activity does not map on to anything presently within CQC oversight. The Health and Social Care Act 2012 requires the CQC to take-on additional responsibilities and these, combined with the possible transfer of HTA functions, will add significant risk to an organisation in a period of change. It will be important that any successor body is credible and has the confidence of the public and those it regulates. The HTA has been an effective regulator. The standards for post mortem facilities have improved nationally. There would be a risk if this momentum and direction was lost by moving activity to a larger regulator in which the identity of regulation might be dispersed. Transfer in of additional responsibilities given the fact that CQC has sustained damage to its reputation, culminating in the Public Accounts Committee Report of March 2012, carries risks.

12. Research

HTA regulates the storage of human material stored for research, both derived from the living or the dead with some exceptions as specified in legislation. While the RCPATH has voiced its continued concern about the burden of regulation in relation to use of tissues from the living, this is a concern related to the primary legislation, not the method of regulation by HTA itself. Transfer of these functions to HRA would lead to some organisations needing to be regulated by both CQC (to look after PM activity) as well as HRA (to look after research activity) so increasing the burden of regulation at an organisational level. HTA dovetails well into present application procedures for conduct of research as well as for biobank activity. Unless the primary legislation is changed (and our understanding is that this is not planned), it is debatable how much efficiency would be achieved in moving regulation of research use of human tissues to the HRA. If the subset of human tissue research oversight covered by HTA was covered by HRA it would imply a single point of regulation for all aspects of research to assure compliance with the primary legislation. In this respect the impact on individual research groups, as opposed to organisations, would probably be beneficial and is something that RCPATH feels would have a positive impact on research and would support. The relatively small proportion of research conducted on human material derived from post mortem examinations would presumably require oversight from both HTA and HRA were all research oversight to be transferred to HTA.

Although there is presently little detail concerning its operation, the HRA is designed to work closely with other bodies, including the MHRA and NIHR, to allow a unified approval process for research and develop standards for compliance and inspection within a national system of research governance. There is no reason to suggest that HTA would not work efficiently with HRA as a separate body in meeting these aims were its functions related to research to be retained.

The RCPATH will continue to press for review of primary legislation in this area, commending arrangements presently in place in Scotland.

13. Anatomy

The HTA presently oversee the important educational role of regulating anatomy. This is an activity almost exclusively located in Universities which have nothing to do with CQC. There is a risk that expertise in this area as presently developed in HTA would be diluted in CQC and a risk to compromise of oversight in any transition

Response 50 - Mid Yorkshire Hospitals (Dewsbury & District Hospital)

This is a response on behalf of Mid Yorkshire NHS Trust Hospitals and the conclusions to the questions below are as a result of agreement with clinical and managerial teams within the pathology and fertility services within the trust. Responses to questions within the consultation document are as follows:

Consultation Question 1:

The organisation neither agrees nor disagrees with this question. We believe transferring the powers to the CQC or otherwise would not adversely affect the functionality of our services

Consultation Question 2

We believe this change of functions would have no impact on the services currently regulated both in relation to pathology services and the infertility satellite unit at Mid Yorkshire NHS Trust

Consultation Question 3

This has no impact for Mid Yorkshire NHS Trust

Consultation Question 4

No we do not believe it would be beneficial to include other bodies in this process. We are satisfied with the proposals.

Consultation Question 5

We believe whichever statutory organisation remains to monitor these services should be required to deliver efficiencies in line with other NHS organisations

Consultation Question 6

No we do not believe retaining HFEA and HTA could deliver savings

Consultation Question 7

No we do not believe there are any functions of the HTA or HFEA that should be transferred elsewhere; we are currently satisfied with their service

Consultation Question 8/9/10/11/12

No further comments

This now concludes the response from Mid Yorkshire NHS Trust Hospitals.

Response 51 - King's College London - Individual

CONSULTATION QUESTIONS

Please note that the answers below relate to my views on the future of the HFEA

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No

I do not believe that the functions of the HFEA, as envisioned initially when proposed by the Warnock Committee, and later in legislation in the 1990 Act, can be served within these two organisations. Moreover, I see nothing to be gained, financially or in efficiency, by abolishing the HFEA and transferring its functions elsewhere; the organisation is funded by patients themselves, as required by legislation, and therefore the entire premise of its abolition in order to “save taxpayers’ money” is a nonsense.

However, the CQC could and possibly should take over the functions that the HFEA seems to have taken upon itself, over and above those enshrined in legislation; namely the inspection of clinical service provision, leaving the HFEA to do what it was originally established to do, ie to inspect centres for their compliance with regard to licensed activities

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

No – I defy anyone to do so. However, I cannot see how it can confer any advantage either in terms of efficiency or expenditure.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No.

As I understand it, primary legislation means that the HFEA must be the body that issues Research Licenses for research using human embryos, so how can this role be transferred to the HRA.

However, that this role should remain with the HFEA does not mean that the HFEA would not benefit from further scrutiny of its fulfilment of this function.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No. I can think of none that would sit better elsewhere.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes. The HFEA could be honed down, and divested of all tasks it has taken on that are over and above its original remit. These are considerable. The incorporation of additional functions by the HFEA, beyond those originally set

out in legislation, have contributed to the hostility with which the HFEA is frequently viewed by members of the professions with whom it interacts directly. (see later)

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

I cannot understand why the HFEA and its functions/roles has been included in any discussion about possible savings to the public purse, when it is not only paid for by fees levied to the patients who undergo licensed treatment, but has accrued at least £3,000,000 from these fees over the duration of its existence. Thus, this question is irrelevant and inexplicable.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

None of the HFEAs functions need be transferred elsewhere, provided they are scaled back to those only functions for which it was originally established; these would be and should be specific and unique to the HFEA.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

No

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

Of the options suggested in the consultation, I select Option 3, with the caveat that whilst remaining in place, there should be a rigorous review of the HFEA, with a view to restricting its roles strictly to those laid out in primary legislation.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

I cannot understand why the HFEA has been included in this consultation process at all. The process is aimed at saving money, through reducing quangoes.

11. Can you provide examples of costs and benefits of these proposals?

Not in precise terms, but the costs incurred by an authority that was honed down to restrict its functions from those carried out today, many of which are well beyond its remit, to those for which it was specifically established, will inevitably save money. Those savings would not, however, benefit the taxpayer or Government, since the funds for the HFEA are raised through fees charged to patients undertaking licensed treatments.

12. Do you have any comments on the consultation Equality Analysis?

No

Response 52 – Confederation of Cancer Biobanks

This response is submitted on behalf of the Confederation of Cancer Biobanks, which operates under the auspices of the National Cancer Research Institute. Our comments relate to the position of the Human Tissue Authority, in relation to which our interest lies particularly with its research-related functions; we do not hold any specific opinions with regard to reorganisation of functions of the Human Fertilisation and Embryology Authority.

Authors: The CCB Executive Group

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

We do not favour this option because we believe the culture and organisational focus of the CQC are fundamentally misaligned with those of the HTA. We agree that both have functions of accreditation via inspection and licensing to ensure compliance with predetermined standards on behalf of patients and the wider public. However, many premises licensed by the HTA for research storage of human tissues are not directly involved in healthcare delivery (e.g., universities and independent research institutions) and this is true also for premises licensed by the HTA for anatomical examination or public display. Of the HTA's scheduled purposes, only storage of tissue for human application and procedures undertaken in relation to post-mortem examination lie specifically and consistently within the remit of healthcare and related organisations.

The HTA exists because of several clinical scandals that arose from mismatched public expectations and medical behaviour arising in relation to post mortem retention of tissues. The legislative basis of the Human Tissue Act (2004) and its application in a risk-proportionate manner by the HTA have restored public confidence to a high degree. The HTA also commands generally high regard among medical and research professionals so that compliance with regulation is high. We consider it a risk for compliance that the proportionate approach of the HTA will be subsumed into a single CQC-dominated process that may lead to unduly burdensome regulation of the relatively low-risk human tissue research sector. The opposite risk also exists that, within the wide remit of the CQC, attention to the detail of areas regulated currently by the HTA will be lost. Nor can it be entirely overlooked that the CQC currently does not command full public confidence following recent instances of poor performance. Anticipated reorganisation of senior management of the CQC is welcome on the one hand but, on the other, will lead to a period of further uncertainty until a track record of good practice has been demonstrated.

Our greatest concern, which applies in relation to all three of the proposed options, is loss of the expertise that has been developed within the HTA over the past 7-8 years, which underpins current public and professional confidence in the governance of human tissue storage and use for scheduled purposes under the Human Tissue Act.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The potential adverse effects, on the UK's ability to contribute to (and generate income from) vital medical research, of a further failure of public confidence in regulation of human tissue storage and use is unquantifiable. The visibility and unambiguous purpose of the HTA since its inception have been invaluable in ensuring such confidence.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

We think it would be detrimental to divide the functions of the HTA, even though activities such as the use of human tissue for public display take place predominantly within social and cultural contexts. The requirement to ensure implementation of appropriate consent and safety procedures in relation to human tissue storage and use is a unifying, fundamental principle of the HTA.

Consent requirements and research-related activities of the HTA appear on some levels to be well aligned with the remit of the HRA. However, the scope of the HRA, beyond taking on the functions of NRES, is not yet fully clear; it would not currently have the infrastructure or expertise to support the inspection processes of the HTA.

Whichever option is selected for the future of the HTA, there is a clear need for more collaboration between regulatory bodies with regard to accreditation procedures.

Identification and elimination of duplication in regard to inspection requirements will deliver efficiencies across the spectrum of regulators, regardless of whether they stand alone or are split and re-shuffled. More importantly, reducing the burden of multiple inspections will ease substantially the bureaucratic demands placed on regulated institutions.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Overall, this would be our preferred option for the HTA, with the caveat that it must not become so small as a result of the drive for further efficiency that it loses critical mass to perform its functions effectively and visibly. There is an assumption in both of the alternative options that substantial cost savings can be made by reducing duplication in administrative costs between HTA, HRA and CQC. However, such savings would at least partly be offset by necessary extra costs associated with duplicating aspects of the HTA's expertise if its functions are split between organisations. We also believe that the HTA's specific and visible existence as the body responsible for delivering the legislative intent of the Human Tissue Act (2004) is important as a focus for professional and public approaches to refine the Act over time.

There is always potential for increased efficiency in any reorganisation or merger, and the HTA's own proposals for the future demonstrate its intention to achieve such. The cost benefits from any of the options have probably been over-estimated, since existing staff at all levels in these organisations are unlikely to be significantly under-employed in their current roles, and the transitional costs of redundancy payments etc. appear remarkably conservative.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public explain how and quantify.

See Section 5 above.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any think should be transferred elsewhere and, if so, which and why?

See Section 4 above

8. Do you have any comments on our assessment of the efficiencies associated with the different paragraphs 154-158 and in the accompanying consultation Impact Assessment?

See Section 5 above

9. This consultation focuses specifically on where functions might sit and implementation will be at the regulators. However, if you have any views as to how functions might be undertaken in future concern that we could share with the bodies undertaking these functions as they plan for the future know.

10. Do you have any other comments on the consultation proposals that you would like to share with

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Response 53 – Multiple Births Foundation

The Multiple Births Foundation's Response to the Department of Health Consultation on Proposals to Transfer Functions from the Human Fertilisation and Embryology Authority and Human Tissue Authority

Introduction

The Multiple Births Foundation (MBF) is a charity concerned with raising awareness of the medical and psychosocial consequences of multiple births and supporting and educating professionals concerned with their care about how to meet the special needs of multiple birth families. It is well recognised that multiple pregnancy after IVF presents the greatest single risk for the mother and babies. The MBF has supported and promoted the need to reduce multiple births arising from fertility treatments and aim for singleton births because of these risks since it was founded in 1988. This response to the consultation refers to the Human Fertilisation and Embryology Authority (HFEA) only. Thank you for the opportunity to comment on these proposals.

1, Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

The MBF has considered all the points and options raised on the consultation document very carefully and has reached the conclusion that a specialist regulator is required for this complex field. We would like the HFEA to retain its functions and therefore support option 3 as set out in this consultation.

We do not believe that there would be any practical benefits from transferring the functions of the HFEA to other bodies and we are not persuaded that there would be any financial savings which was the primary motive for making these proposals.

The HFEA has developed expertise in policy development and regulation which has given patients, professionals, the public and others concerned the confidence to allow treatments and research to progress in this field which is ethically challenging clinically, scientifically and socially while maintaining reassuring safeguards.

We would be particularly concerned about the functions of the HFEA being transferred to the Care Quality Commission (CQC) which has already had a significant expansion of its remit and appears to be struggling to manage current demands. The National Audit Office and Public Accounts Committee have also warned about serious risks.

2.Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The immediate impact would be the loss of an experienced, nationally and internationally recognised organisation which gives confidence in the

regulation of the sector to patients, providers and the public. Most importantly it is a specific source of highly specialised detailed information for patients, gamete donors and recipients, professionals, commissioners of services researchers and others. An example is the information about reasons for the policy which requires clinics to reduce the multiple birth rates from IVF which are explained in detail and support the clinics with the implementation of the policy.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

The MBF would be concerned about transferring HFEA research functions as embryo research is so closely integrated with the regulation processes. For example consent, transfer from the clinical to research area and monitoring of the use of the embryos in research would present greater administrative burdens, potentially greater costs and more risks for complex inter organisational systems to fail. We believe that there could be great benefit from streamlining the application process and for the HFEA and HRA to work collaboratively and understand that the HFEA is already considering how this could be achieved ready for when the HRA is fully established.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

The MBF view is that the functions should remain with the HFEA.

We are particularly concerned about the proposals regarding the HFEA register and data collection. The CQC does not have experience of collecting data as required by the HFE Act. Even though the Health and Social Care Information Centre (HSCIC) has experience of data collection on this scale it does not have the necessary expertise for the complex regulatory requirements of the Act. Its present remit is not UK wide so this would require significant changes. A greater administrative burden and costs would be imposed on the necessary collaboration between organisations.

The information on embryo transfer and multiple pregnancies is an example of where detailed data collection is vital to monitor practice in clinics and outcome of the pregnancies. The HFEA has recently introduced a system to alert the inspection team and centres to rises in multiple pregnancy rates which can only be operated with close coordination within the HFEA. With multiple births imposing not only the greatest risk for mothers and babies but also higher costs for neonatal services and long term health and social care due to the higher incidence of disability to would be a greatly detrimental if the close monitoring and implementation of the multiple births minimisation policy was severely jeopardised.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

The MBF believes the HFEA should retain existing functions. We are aware that the HFEA has already made considerable efforts and delivered efficiency savings

6.Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

The MBF believes that collaboration between the HFEA and other organisations could streamline some functions such as the inspection where there is overlap with the CQC. The HFEA is addressing this currently and working on joint protocols with the CQC and HTA.

7.Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

We do not think that any of the functions of the HFEA should be transferred.

8.Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

The MBF is concerned that the costs of transferring functions to other organisations may be underestimated because there is no detail about how this would work in practice. We believe that the anticipated actual saving of £3.8 million over 10 years is extremely low and cannot justify the risks of moving the functions.

9.This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

No comment

10.Do you have any other comments on the consultation proposals that you would like to share with us?

No

11.Can you provide examples of costs and benefits of these proposals?

N/A

12.Do you have any comments on the consultation Equality Analysis?

No

Response 54 - Individual

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No.

I favour option 3, that the HFEA and HTA should retain existing functions whilst delivering cost savings. See my answer to question 5 below.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The only advantage is a reduction in the duplication of inspection of services. There are numerous disadvantages – see question 5 – for service providers there are benefits in dealing with a specialist regulator, and for patients the HFEA in particular is well-recognised as a standard-setting body and seen as impartial. This is particularly important in IVF – a field of medicine in which most service providers are in the commercial sector and there is a risk of vulnerable and desperate patients being exploited. The HFEA provides excellent patient information.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No

This is a possible solution, but I favour retaining the functions of the HFEA which has established a sound position in gaining the trust of the public whilst handling difficult ethical issues of research on human embryos.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes.

The CQC is struggling with its current workload, it has been subject to recent criticism, and its Chief Executive has resigned: I am doubtful that the CQC could cope with the additional work of the HFEA and HTA to a satisfactory standard.

The specialist areas covered by the HFEA and HTA will require the CQC to employ additional specialist staff or create a specialist advisory board; I cannot see that this offers an advantage over the existing structures.

The amount of money saved by abolition of the HFEA and HTA is too small to

justify the proposal.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Yes.

Undoubtedly the inspection process could be simplified and the bureaucracy of the HFEA could be less cumbersome. IVF treatment is now “mainstream”, and the majority of clinics run to high standards, but specialist regulation is essential for donor gametes, surrogacy, pre-implantation diagnosis etc.

Data collection needs to be reviewed and there are potential savings. I cannot stress too strongly the importance of maintaining the HFEA data base, both for donor gamete/embryo children who may wish to seek their genetic identity, and as a unique resource for future research on long-term safety of reproductive technology.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

See question 3 above.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

See my comment on the HFEA database in (6) above.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

I think the consultation is asking the wrong question....moving the functions of the HTA and HFEA to another body does not offer improved functioning nor significant cost saving. I think you should be asking us to review the HTA and HFEA in order to to update and streamline their functions and processes for our current needs.

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Response 55 - Cym Taf Health

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	<i>Transfer of the functions is less relevant than ensuring that the functionality is retained. There are specialist skills within the HFEA and HTA which should be preserved. Many of the administrative elements will not be specific and could be covered off by the CQC (but see Q2)</i>
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	<i>The CQC does not have jurisdiction in Wales so this would have to be dealt with appropriately. The Welsh Assembly Government in my view should be instrumental in the decision making particularly because Health policy is an entirely devolved matter.</i>
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	<i>There are advantages to bringing all research matters under one organisation in particular ensuring a consistent approach to research regulation.</i>
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	<i>There are no obvious candidates.</i>
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	<i>This may well be preferable given the expertise already embedded in these organisations. Although the HTA got off to a difficult start, the disruption associated with changing the organisational structure could be considerable and may compromise their functionality as regulators. Further efficiencies may be possible through shared administration. There have been questions recently about the effectiveness of the CQC as a regulator (in relation to care homes for instance) which should not be ignored.</i>
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	<i>Shared administration, avoidance of duplication may yield savings but these are difficult to quantify without financial data.</i>
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	<i>There are no obvious candidates.</i>
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	<i>No</i>
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?
11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?
<i>No</i>

Response 56 - British Medical Association

The BMA is an independent trade union and voluntary professional association which represents doctors from all branches of medicine across the UK. It has a total membership of over 150,000.

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No, we do not agree that the HFEA and HTA should be abolished and their functions transferred to the Care Quality Commission (CQC). We can see no advantages to this option and considerable disadvantages. The BMA believes that both the HFEA and the HTA should be retained with some improvements and efficiencies to the way in which they carry out their functions.

Many of those within the regulated sectors believed that abolishing the specialist regulators and transferring the regulatory function to the CQC would result in reduced fees. Paragraph 128 of the impact assessment makes clear, however, not only that there may be no reduction in fees but that there is also a possibility of increased fees if the transfer goes ahead. This has removed one of the few arguments in favour of this option.

The BMA's reasons for wishing to retain the HFEA and the HTA are set out in response to question 5. It is important to be clear, however, that part of our reason for rejecting this proposal is our serious, and increasing, concern about the ability of the Care Quality Commission to carry out its functions effectively and efficiently and to invoke public confidence. We also note that from 2013 the CQC will become responsible for inspecting GP premises and that it is already behind plan on the inspection of healthcare premises beyond NHS trusts for 2012/13. To add to those pressures further by transferring these complex and specialised areas of practice would be very risky. It is important to bear in mind the potentially very serious adverse consequences of any failure in the regulation of these areas. If errors are made in fertility treatment, for example, with the wrong embryos transferred or the wrong sperm used, the impact on patients and children born following fertility treatment is very severe.

Both the Public Accounts Committee and the National Audit Office, following detailed investigations, warned of the serious risks of transferring these functions to the CQC. The significant risk to the effectiveness and standing of the regulatory framework and to the credibility of the Government should anything go wrong, make it, in our view, foolhardy to ignore the warnings given and press ahead with this proposal. A desire to reduce the number of arms length bodies is not, of itself, a good enough reason to implement these changes.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The BMA has serious concerns about the impact of abolishing the HFEA and HTA and transferring their functions to the CQC. Both the HFEA and the HTA regulate sensitive areas of practice where public confidence in regulation, and the regulator, is important. The publicity given to the recent failings of the CQC in other areas of its work would inevitably impact on public confidence about its ability to properly and effectively regulate these areas. It is therefore unlikely that public confidence would be maintained if these functions are transferred to the CQC.

In relation to the HFEA, an obvious and immediate impact will be the loss of the HFEA's 'brand' which is recognised and respected both nationally and internationally. Patients, prospective patients, donors and donor conceived individuals know where to go for impartial

advice and information. The HFEA has also built up public confidence in the regulation of this area of practice over the last 20 years which has enabled the UK to proceed with new areas of research – such as embryonic stem cell research and the use of human admixed embryos – which has proved far more difficult to undertake in other countries. Over this time the HFEA has also accumulated significant knowledge and wisdom in relation to the very sensitive ethical areas it regulates and the loss of this expertise would have very significant and wide-ranging implications, affecting not only service providers and patients but also public confidence in this area of practice.

It is difficult to comment on the impact of this change for the regulated sector because so little information is provided about how it will be implemented. Loss of expertise is, however, a significant concern and one that would have a serious negative impact on these areas of practice. The extent of this loss will depend upon the model of transfer adopted. As no change to the regulation itself is proposed, the two most likely models for transferring the functions of these two authorities appear to be either the ‘the umbrella model’ or ‘the assimilation model’, both of which are problematic.

Under an umbrella model the functions of the HFEA and HTA would be moved into the CQC as ‘fertility’ and ‘tissue’ directorates. The wholesale transfer of functions and personnel (including the respective Boards) would ensure that expertise is not lost and that things will continue much as before. Such a move is, however, likely to be seen as ‘window dressing’ giving the impression that an ALB has been abolished when, in practice, it continues to exist as before, but under a different name. We can see no advantages to this and, as previously mentioned, transferring these functions to the CQC, could lead to a significant reduction in public confidence. This is the least damaging way of implementing the proposals but it seems unlikely to result in real savings or efficiencies.

Under an assimilation model the functions will be assimilated into the existing work of the CQC. The CQC remit would need to be expanded from England only to incorporate establishments in other parts of the UK and licensing and inspection would be placed with registration and inspection of other healthcare establishments. The CQC remit would also need to be expanded to develop codes of practice, provide information for patients and, in the case of fertility work, to develop policy on ethical issues and collect and analyse large amounts of data.

Under this model, the regulator would have no specialist expertise in the areas being regulated. This has been a matter of serious concern in the past. In 2010 there was a significant breakdown in relations between the HTA and the pathology sector and a lack of confidence in this aspect of the regulator’s work. We firmly believe that these problems can be attributed largely to the lack of specialist expertise within the HTA which led to decisions being made without an understanding of the way the sector worked. Fortunately these issues have now been resolved and the HTA, with specialist advice, has worked hard to address the problems that were identified. This is a clear example of the problems that can arise if the regulator does not understand fully the sector it is regulating and, in our view, this should serve as a warning for the future.

The CQC board (made up of five individuals) is very different from the HFEA and HTA and does not have expertise in any of the areas regulated. If this expertise is required, the CQC will need to set up one, or more, specialist committees to decide issues in this area. It will be difficult for the CQC Board to reject the advice of these committees because it lacks the specialist knowledge and expertise to do so, and so is likely to be seen as simply “rubber stamping” their decisions. The real power will therefore rest with these specialist committees whose members would not be bound by the usual standards of probity in public appointments and would not be accountable to Parliament. Such a model also increases, rather than decreases, bureaucracy because key decisions would need to be considered both by the specialist committee and the CQC Board. These are exactly the same problems the previous Government faced when trying to merge the HFEA and HTA in 2007 – a proposal that was widely opposed and finally rejected on the advice of the Parliamentary Pre-legislative Scrutiny Committee.

3. Do you agree that HFEA functions relating to research should be transferred to

the HRA? Please explain why you think this.

We believe the inspection and licensing of embryo research should remain with the HFEA but that there should be close liaison with the Health Research Authority, supported by a memorandum of understanding if appropriate. Some aspects of the Authority's work, such as peer review and co-ordinating ethical approval, could potentially be transferred to the HRA. The reasons for our view are set out below.

Inspection

- The requirement for premises to be inspected is unique to embryo research and, if this task is transferred to the new HRA it would be required to set up an inspection procedure similar to that already established at the HFEA.
- The HFEA's inspection process has a number of purposes such as to assess the extent to which centres comply with the Act, licence conditions, directions and the provisions of the Code of Practice, to provide an independent and professional perspective on the running of the centre and to provide centres with a positive learning experience. These functions can only be provided by an Authority and staff with expertise in the field.
- For those centres undertaking both research and clinical practice, inspections from two different bodies would be required, thus increasing the regulatory burden.

Licensing

- No other area of research, within the HRA's remit, requires the issuing of licences for each individual project. If this task is transferred to the HRA it would need to establish a licensing procedure similar to that already in existence at the HFEA.
- The Human Fertilisation and Embryology Act requires that licensing decisions are made by a licence committee, appeals against decisions are heard by a second licence committee and, ultimately, by an independent appeals panel; the HFEA has these mechanisms in place but the HRA does not and does not need them for any other area of its work.
- Embryo research is closely interrelated to the HFEA's other functions: most of the embryos will be donated from IVF clinics, much research takes place within the clinical setting and some research is directed towards improvements in clinical practice. Research projects also sometimes raise policy issues that need debate – such as when a licence application was received to undertake research using human admixed embryos.

This view that inspecting and licensing embryo research should not transfer to the HRA, is dependent upon the HFEA being retained. Because of the ethical sensitivities around embryo research and the need to maintain public confidence in this area we would have serious concerns about this work being transferred to the CQC. The HFEA has been successful in maintaining and promoting public confidence, including new areas such as the research use of stem cells and mitochondrial disease research. The CQC does not have the same level of public support and there is a legitimate question as to whether the CQC would be able to maintain public confidence in the regulation of this sensitive area of research. Hence if the HFEA were to be abolished, and its functions transferred to the CQC, there may be an argument for passing embryo research to the HRA as the body most likely to be able to retain public confidence.

In relation to the Health Research Authority's role more generally, the BMA is pleased that the Government has decided not to transfer licensing of the storage of tissue for research to the HRA. Most of the establishments that have a licence for storage also have a licence for other activities, such as post-mortem examination, use of tissue for human application or anatomical examination and that licence covers all related activities. An establishment's

licence to perform post-mortem examinations might, for example, also include the removal of tissue for a scheduled purpose and the storage of tissue for a scheduled purpose. If the research elements were transferred to the HRA, those establishments would be required to make two applications to different organisations, with two different licences and pay two fees; this would increase bureaucracy and the regulatory burden.

The BMA does not believe that establishments storing tissue from living individuals for their own research should continue to need a licence (see comments on question 7).

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

HFEA

As noted previously, we believe that the HFEA should retain all of its functions but that some improvements could and should take place (see comments on questions 6 and 10). We are not convinced that there are any viable alternative locations for these functions.

The BMA would have serious concerns about the policy functions of the HFEA transferring to the Department of Health. Although the consultation only refers to payment for gamete and embryo donations, the policy function is much broader than this and has, in the past, included issues such as the use of human admixed embryos and the use of preimplantation genetic diagnosis (PGD) for predisposition to cancers. It is essential that such decisions are made independent of Government and free from political interference. It is also difficult to see how the separation of policy from licensing would work in practice since many policy decisions are prompted by applications for licensing such as the so-called 'saviour sibling' cases. Under the Act the HFEA is required to be satisfied that the activity being licensed is 'necessary or desirable'. It is not clear how it could do this if it had not previously been involved in the policy decisions. In the past some of the HFEA's licensing decisions have been challenged through the courts by pressure groups, but if the licensing decision was based on a policy decision made by the DH, it is unclear who would face legal challenge.

There is no mention in the consultation of who will make decisions about approving individual conditions for preimplantation genetic diagnosis (PGD) or for approving individual requests for HLA testing. We assume the intention is to transfer this role to CQC but this does not sit well with the current structure and it is questionable whether the CQC will have the necessary knowledge and expertise to fulfil this function.

HTA

Although the HTA appears to regulate a diverse range of activities, most of them involve the removal or use of material from deceased patients. This links the activities and provides a clear rationale for keeping the functions together.

Regulation of living organ donation is the exception to this rule but the new system appears to be working well and we would be reluctant to disrupt an effective system. Given that deceased organ donation is now regulated by the HTA it is sensible to keep the two functions together. We therefore believe that the regulation of organ donation – both living and deceased – should remain with the HTA.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes, the BMA believes this is the only sensible option at the current time.

HFEA

The main reasons why the BMA believes the HFEA should be retained are set out below.

- We have been unable to identify any practical benefit in abolishing the HFEA and handing its functions to the CQC – the ‘advantages’ set out in the impact assessment, such as reduced administrative burden through closer liaison, joint inspections etc, can and should be achieved without abolishing the HFEA.
- The HFEA has accumulated significant knowledge and wisdom in relation to the ethically sensitive areas it regulates, loss of this expertise would be very damaging.
- We are very concerned about the loss of the ‘HFEA brand’ which is recognised nationally and internationally. We believe there is a serious risk of loss of public confidence in this sensitive area if the work is transferred to the CQC (see comments in question 1).
- Repeated reviews have found that the CQC is not carrying out its current duties effectively and, as noted above, it is shortly to acquire further responsibilities. Handing it significant new, complex and very sensitive, duties presents a serious risk to this work. It is not reasonable or responsible to take this risk, in the vague hope that things will improve sufficiently before 2015.
- We believe there is merit in retaining a single, specialist regulator for this area and have serious concerns about the lack of relevant expertise on the CQC Board and the likely impact of this, particularly on the regulated sector (see comments under question 2).
- The HFEA’s functions are very closely interrelated, eg data impact on policy and policy impacts on licensing of both treatment and research. (The policy decision about human admixed embryos, for example, was prompted by a research application.) In practical terms the only way in which these functions can be kept together, if the HFEA is abolished, is by using the ‘umbrella’ model described above. This is unlikely to be seen as ‘abolishing’ the HFEA but simply removing its name which, in itself, is likely to have a detrimental effect on public confidence.

HTA

When the BMA began considering the Government’s proposals in 2010 it was evident that there had been a serious problem with relations between the HTA and those within the pathology sector (see comments under question 2). The Government’s review gave us the opportunity to look again at the way these sectors were regulated and to consider whether there was a more efficient way of regulating them. At that time, the BMA was generally supportive of the Government’s original plan to split the functions of the HTA between different organisations, and abolish the HTA. Since then, however, the HTA has responded extremely well to the feedback we, and others, provided and has clearly taken steps to work with the sector to improve the way it regulates and to reduce overlap with other regulators. The regulated sectors are now beginning to see the impact of these improvements and are reasonably confident that the HTA will continue to look for further efficiencies. At the same time confidence in the CQC has declined and doubts about the wisdom of adding further to its remit have increased significantly. The BMA therefore believes that the HTA should be retained.

Past experience has led to greater emphasis being placed on the importance of the regulator having a good understanding, or having easy access to individuals who have a good understanding, of the way the sector works. Even if the CQC were to radically improve its performance, the problem of lack of expertise would remain a real issue. As mentioned above, we are very pessimistic about the possibility of the CQC being able to improve its performance, regain public trust and be ready to take on these new and complex areas by 2015. In our view, transfer to the CQC is not a realistic or sensible option, at least for the foreseeable future.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Yes. We understand that significant, and recurring, savings have already been made by both HFEA and HTA through sharing back-office functions, making efficiencies and reducing staff over the last two years. The HFEA has reported savings of 25% (from £8 million to £6 million) with a reduction in headcount of 20% over that period and the HTA has reported savings of 27% and a headcount reduction of 31%. Investigating further opportunities for sharing back-office functions and support staff could lead to additional savings.

We believe there are further savings and efficiencies that can be made, both for the HFEA/HTA and for the regulated sector. The clearest example is the work that is already ongoing to identify and, as far as possible, eradicate regulatory overlap and inconsistencies between the guidance from the various regulatory bodies and to streamline the inspection process. This might involve having joint inspections (as has already been started by the HTA) or for certain aspects of the inspection process to be delegated to another regulator (for example from CQC to HFEA), or joint working to ensure that if a laboratory has ISO or CPA accreditation, the HFEA or HTA can be satisfied that this aspect of the establishment's work is acceptable and does not require further inspection. Through closer working, clear memoranda of understanding and the sharing of information it should be possible to ensure that the same establishment is not inspected at different times, by different bodies, looking at the same things.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The BMA believes the requirement in the Human Tissue Act for establishments to be licensed to store tissue from living individuals for research (principally left over tissue samples, urine, faeces, cervical smears etc) should be removed. Given that there was no problem with tissue from living individuals before the 2004 Act was passed, it is difficult to understand the benefit that is derived from this to justify the considerable additional work and expense; it seems to be an unnecessary bureaucracy.

The original intention was that this should not apply to individual researchers but only to tissue banks but this has not proved to be the case. This has led to concern that the requirement to have a licence encourages people to destroy samples that could be useful for future research. Material stored for an individual research project that has ethics approval does not need a licence but once that research is finished, if it is retained for possible future research, a licence is required. We understand that many researchers simply destroy tissue rather than go to the trouble and expense of getting a licence and potentially important research material is lost.

There may be some benefit in the licensing of large tissue banks but the function should be modified, using the powers in the Public Bodies Act, to ensure that this requirement does not apply to the storage of tissue by individual researchers or establishments for their own research use.

Another sensible option might be to consider following the Scottish example regarding the regulation of public display. In Scotland, established museums are exempt from licensing and other exhibitions, or displays, require a licence from Scottish Ministers.

The preferred option for many of those working in the anatomy sector would be a move back to having an Inspector of Anatomy as still exists in Scotland. We recognise, however, that this would increase, rather than reduce, the number of organisations and is therefore unlikely to be accepted. Of the options offered – HTA or CQC – continued regulation by the HTA would be the best option.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

Although the ALB review and the impact assessment both focus on reducing costs as a motivator for change, the actual savings anticipated are very low (£3.8 million over ten years) compared with both the level of savings that have already been made by the HFEA and the HTA over the last two years (see above) and the extent of the likely disruption, and the risks, associated with the proposed changes.

As mentioned above, the proposal to reduce the administrative burden by improving and streamlining the regulatory processes of the different regulators can and should occur without the need to abolish the HFEA and HTA. Both bodies are currently moving towards joint inspections and far greater collaboration with other relevant bodies.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

We are aware that the HFEA is seeking advice from the Health and Social Care Information Centre about the information collected for the register and we believe that this is an area where improvements – and potentially savings - could be made.

We also believe the provision of information to donor conceived individuals could be improved and might benefit from more involvement of those with related expertise. This is a new task for the HFEA and we understand that no new money was provided for this activity. We believe that some of the savings made by the HFEA should be diverted to this activity in order to ensure that this important and very sensitive task is conducted in the best possible way. Shifting the function to the DH to contract out would, of course, also require additional funding.

We understand that those members of staff at the HFEA who handle such requests have received basic training in counselling skills and handling difficult conversations. Relevant checks are made and the donor conceived individuals are informed of the option of counselling (although there is currently no direct and dedicated support service that individuals can be directed to). Information about the donor – which could include identifiable information – is then sent to the applicant by mail.

We are concerned about the lack of ongoing support for those receiving this information and making the decision about whether to seek contact with the donor. This is of particular concern given recent research from New Zealand, presented by Ken Daniels at a recent PROGAR event, that 29% of the donors questioned were 'open to' establishing a 'parent-child' relationship with the donor offspring. (At the meeting the figure of 32% was quoted but further communication has established that the actual figure was 29%.) This research has yet to be published and so it is not possible to see the context within which these comments were made, but, nevertheless, this raises a number of issues that need to be explored. It also emphasises that great care is needed to ensure that those setting out on this journey have the necessary support. This is an area where experience from adoption could be very helpful. The HFEA might, for example, want to consider linking in with those working on adoption in local authorities. One option might be for the HFEA to train, and accredit, a small group of adoption staff in donor conception to provide a regional presence to allow for face-to-face contact and ongoing support as and when required. This would be a similar model to that used by the HTA for independent assessors for living donation.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Throughout this process the BMA has been arguing that the HFEA should be subject to an independent review. This should assess what the HFEA does and how it does it. It should identify areas where improvements or changes can and should be implemented and should look to where efficiencies and savings could be made. There is a natural tendency for organisations that have been around for a long time to take on new tasks, without dropping or modifying others, what is sometimes referred to as 'regulation creep'. There is a legitimate question, for example, about whether standard IVF treatment, without the use of donated gametes, could be subjected to lighter touch regulation with greater focus on a much smaller number of 'high-risk' activities.

Although we have proposed this in relation to the HFEA it raises a more fundamental question that needs to be addressed – in relation to both the HFEA and the HTA – which is what do we, as a society, want from our regulators? Is it simply to ensure an Act, or regulations, is upheld and that practice is generally safe? Or do we expect something broader and more comprehensive, such as detailed information for patients, consultation and advice service for licensed establishments, public consultation on policy issues, expert advice to the Government etc? The HFEA, for example, currently responds each year to around 1,500 enquiries from licensed clinics (on non data-related questions such as the law, code of practice etc), 2,500 enquires from patients and the public and around 100 Parliamentary Questions. In 2011/12, the HTA responded to more than 2,800 enquiries.

If the amount of guidance, thoroughness of inspections or level of scrutiny is reduced, the cost and regulatory burden will also be reduced, but there will be risks to all parties. We need to decide whether we want to have an all-embracing regulatory system which provides licensed establishments, patients and the Government with protection but comes at a cost (both financial and, for regulated establishments, time), or a much leaner and more remote organisation, acting as a safety net against the worst excesses, but not providing the same level of protection for patients, establishments, the public or Government. A question that is not raised in the consultation, but deserves consideration, is where on this spectrum the regulation of assisted reproduction and tissue should be (and the answer may be different for each case). There are undoubtedly savings that could be made, by reducing the range of activities undertaken by the HFEA and the HTA and the thoroughness of the regulation, but that would inevitably have consequences.

11. Can you provide examples of costs and benefits of these proposals?

No

12. Do you have any comments on the consultation Equality Analysis?

No

Response 57 - Human Tissues Group

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

This response deals only with the storage and use of human tissues in research. On this subject, we do not believe that the option of transferring all HTA functions as they relate to human tissue research to the CQC is the best option.

This is for the following reasons:

- 1) Human tissue use for research is relatively low risk. Combining the regulation of premises licensed to store human tissues in research in a body responsible not only for regulating post mortem facilities and human tissue for transplant facilities, but also a diverse range of other patient care facilities, from care homes to hospitals and (in the longer term) GP surgeries, risks either sidelining the regulation of human tissue for research or over-regulating this relatively low-risk sector.

Culturally, there is a significant gap between the regulation required for HTA-licensed facilities dealing only with research tissues and facilities that care directly for patients. Many HTA licences for research storage are held by universities or other institutions not directly involved in patient care and in separate premises.

- 2) The HTA was established to oversee implementation of legislation deemed essential in the wake of political and public concern following organ retention scandals which broke in 2001. Since then, public confidence in the governance of tissues retained from living and deceased individuals has grown; supporting this view of public confidence, research tissue banks find that the vast majority of patients asked to consent for surplus tissue to be used in research are happy to do so. The CQC, on the other hand, has suffered from negative publicity, particularly in connection with its regulation of care homes. We are concerned that this may have a negative impact on the current public view of regulation of human tissue for research, if the CQC were to become responsible for administering the licences for facilities storing human tissue for research. This could lead to a decrease in public willingness to donate tissue for research.

We prefer Option 2, specifically, the proposal outlined in paragraph 116, which states that responsibility for regulating premises licensed to store and conduct human tissue research could be transferred to the HRA.

This is for the following reasons:

- △ The functions of NRES have already been transferred to the HRA. NRES also has an important role in regulating human tissue research, and we consider that it makes sense to have both regulatory elements dealing with human tissue research in the same body.
- △ It is proposed that HFEA functions pertaining to research be transferred to the HRA. It makes sense to have these research-regulating functions co-located with the related HTA and NRES functions.
- △ Transferring the HTA functions relating to human tissue research would minimise the risk of fragmentation or loss of expertise in this area.

Valid concerns relating to this option are raised in paragraphs 117 and 118, which point out that many bodies requiring an HRA licence for human tissue storage for

research purposes would also require another licence for their other human tissue storage purposes. In order to prevent this from becoming unduly burdensome, close cooperation for dual-licensing arrangements would need to be ensured but this should be entirely feasible and there are no <i>a priori</i> reasons why it should be inefficient.
2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
N/A
4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
We do not believe that the HTA should retain its existing functions while being expected to deliver further efficiencies over those already achieved and planned. We are concerned that additional pressure on HTA to downsize its establishment will lead to the loss of valuable specialist expertise in the shape of staff responsible for overseeing human tissue storage for research. We wish to emphasise how vitally important licence-holders and potential licence-holders find the support and advice that the HTA is able to provide currently. Any reduction in the timeliness and genuine expertise offered will be severely adverse for confidence and regulation in this sector.
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
The impact assessment provided does not allow an informed, balanced comparison of Option 3 to be made with Options 1 and 2. There is no obvious reason why these regulatory bodies should not manage to make ongoing, reasonable, efficiency gains over time with consequent financial savings.
7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
No, were Option 3 to be pursued, the functions of these bodies should be retained intact to preserve the expertise that they have. It would be essential that they work closely with the HRA and, over the longer term, synergies may allow for redistribution of some functions with HRA.
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
See comment above. The direct financial costs arising from dis-establishment of the HTA and HFEA seem remarkably low, although expressed in the impact assessment as a likely over-estimate.
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?
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11. Can you provide examples of costs and benefits of these proposals?
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12. Do you have any comments on the consultation Equality Analysis?

Response 58 - Stratum (Strategic Tissue Repository Alliances Through Unified Methods)

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

This submission deals only with the use of human tissues in research. On this subject, we do not believe that the option of transferring all HTA functions as they relate to human tissue research to the CQC is the best option.

This is for the following reasons:

- 3) Human tissue use for research is relatively low risk. Combining the regulation of premises licensed to store and use human tissues in research in a body responsible not only for regulating post mortem facilities and human tissue for transplant facilities, but also a diverse range of other patient care facilities, from care homes to hospitals, risks either sidelining the regulation of human tissue for research facilities or over-regulating this relatively low-risk sector.

Culturally, there is a significant gap between the regulation required for HTA-licensed facilities dealing only with research tissues and facilities that care directly for patients.

- 4) The HTA was established in the wake of political and public concern in the wake of organ retention scandals which broke in 2001. Since then, public confidence in this sector may generally be expected to have grown, and tissue banks find that the majority of patients asked to consent for surplus tissue to be used in research are happy to do so. The CQC on the other hand has suffered from negative publicity, particularly in connection with the regulation of care homes. We are concerned that this may negatively impact the public view of the regulation of human tissue for research, if the CQC were to become responsible for administering the licenses for human tissue for research facilities. This could potentially lead to a decrease in human tissue for research donations.

We support Option 2, specifically, the proposal outlined in paragraph 116, which states that responsibility for regulating premises licensed to store and conduct human tissue research could be transferred to the HRA.

This is for the following reasons:

- △ The functions of NRES have already been transferred to the HRA. NRES also has an important role in regulating human tissue research, and so it makes sense to have both regulatory elements dealing with human tissue research in the same body.
- △ It is proposed that HFEA functions pertaining to research be transferred to the HRA. It makes sense to have these research-regulating functions together.
- △ Transferring the HTA functions relating to human tissue research would minimise the risk of fragmentation of expertise in this area.
- △ Alignment of the HTA functions relating to human tissue research and NRES within the same organisation would bring clarity to a complex area.

Valid concerns relating to this option are raised in paragraphs 117 and 118, which point out that many bodies that would require an HRA license for human tissue for

research purposes would also require another license for their other human tissue storage purposes. In order to prevent this from becoming unduly burdensome, close cooperation for dual-licensing arrangements would need to be ensured.
2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
N/A
4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
We do not believe that the HTA should retain its existing functions whilst being expected to deliver further efficiencies over those already achieved. We are concerned that this could lead to the loss of valuable and specialist expertise in the shape of staff responsible for overseeing human tissue for research facilities.
6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
10. Do you have any other comments on the consultation proposals that you would like to share with us?
11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?

Response 59 – British Heart Foundation

1. The British Heart Foundation (BHF) is the nation's heart charity. From new discoveries about how the heart develops in the womb, to developing the treatments that could mend broken hearts in the future, we are the single biggest independent funder of cardiovascular research in the UK – funding around £100 million each year.

2. Our research portfolio extends from fundamental laboratory-based molecular, biological and genetic studies to large scale clinical trials of novel and existing preventive and therapeutic interventions.

3. We welcome the opportunity to respond to this consultation on the future of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). Both organisations carry out important roles in licencing and overseeing key types of research funded by the BHF, and it is important that the roles currently carried out by both are effectively preserved in any organisational changes.

4. In 2010, we responded to the review of regulation and governance conducted by the Academy of Medical Sciences. Within this, we highlighted that improvements to the regulation and governance of medical research should ensure rigorous scrutiny to ensure patient safety, while also following principles of rationality and proportionality. It is with these same principles in mind that we respond to this consultation. We also add our support to the responses from the Academy of Medical Sciences and the Wellcome Trust.

Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA?

5. We expect that the Health Research Authority (HRA) will, as it develops, play a key role in streamlining regulation and governance for medical research. However, we do not agree that splitting the functions of the HFEA and HTA between the HRA and the Care Quality Commission (CQC) provides the best option for researchers.

6. Our concerns centre on the potential:

- increase in the administrative burden on researchers
- loss of current expertise, and
- reduction in public confidence.

7. Under the Department's preferred solution (Option 1), the HFEA's functions would be split between two very different organisations. The HFEA carries out important clinical and research roles – with its role in embryonic research being of particular interest to the BHF. Some benefits around streamlining of research could be realised by moving the research functions to the HRA. However, separating oversight between the HRA and CQC could duplicate administrative costs and processes and, ultimately, result in complicating the regulatory landscape for those involved in research using embryonic stem cells.

8. In our response to the Academy review, we stressed that it was essential that any creation of a single research regulator comprising bodies such as the HFEA and HTA should not result in a dilution of expertise from these bodies. We do not believe there

is anything to indicate that the efficiency savings envisaged by the Department in abolishing both the HFEA and HTA will maintain existing expertise. We are very concerned by the suggestion that the HTA's functions be added to the CQC, given that the Commission has indicated in oral evidence to the Health Committee that it does not have the expertise to take on these functions.¹ In March 2012, the Public Accounts Committee also recommended that the CQC not take on these functions at this time.²

9. Both the HFEA and HTA perform valuable stakeholder engagement roles around developing issues in research, which has helped to maintain public confidence in the research carried out in the UK. This is important to help the UK maintain its strong reputation for research. We have seen nothing that gives us assurances that these roles would be continued to the same standard within Option 1.

10. We believe that the research community will be best served by retaining both organisations and agree we agree with the Academy of Medical Sciences that an enhanced Option 3 presents a preferable solution.

Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies?

11. For the reasons highlighted above, we believe that in order to maintain the expertise provided by both organisations and retain public confidence, both the HFEA and HTA should for be retained in the immediate term. The Department should conduct exploratory work alongside the HFEA, HTA and HRA to examine whether further streamlining and reducing duplication in administration could be achieved. .

12. In the future, as the HRA becomes more established, it may be appropriate to consider transferring functions of both the HFEA and HTA. At present, we do not believe the interest of researchers and the public is served by abolishing both organisations – both should continue to make progress in improving the regulation of research as separate entities.

¹ House of Commons Oral Evidence taken before the Health Committee. *Annual accountability hearing with the Care Quality Commission*; 2012. Available at:

<http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm>

² House of Commons Public Accounts Select Committee. *The Care Quality Commission:*

Regulating the quality and safety of health and adult social care; 2012. Available at:

<http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpublicacc/1779/177902.htm>

Response 60 - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	<i>I emphatically do not agree with the option to transfer these functions, and would oppose that decision. I am concerned that the quality and concentration of service will decline, and this will have a major impact on my family's wellbeing.</i>
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	<i>The fragmentation would result in a loss of essential communication between relevant departments and a loss of focus on the goals and aims of the HFEA functions. My son was conceived using an anonymous donor, and I worry that information and assistance that would have been available to us will now be lost in a bureaucratic quagmire, and nobody there will give a damn about his welfare, needs and state of mind. From what I can tell, use of donor sperm and eggs is increasing and it would be wrong to debilitate the essential resources that accompany this service.</i>
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	<i>No. I believe that the service would be stronger if all elements work together under the same umbrella. Dilution would lead to lack of communication and a loss of quality and care.</i>
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	<i>No. I believe that all of the functions should remain as they are. If changes need to be made, they can be dealt with in a different manner without dissolving the HFEA and HTA.</i>
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	<i>I believe that organisations should continually self-monitor in order to adapt and improve, depending on the environment. I realise that change is necessary in order to remain valid and efficient, but do not believe that this has to mean the dissolving of an organisation, particularly if that would lead to a loss of care and service as I believe it would.</i>
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	<i>I am not in the position to say what savings might be delivered by retaining functions with the HFEA and HTA, but trust in the ingenuity and creativity of those who work there to find a way to make the necessary changes. I would wish for savings to be made without losing the organisations and diluting/losing the services they offer.</i>
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	<i>No, I am not in a position to comment on that.</i>
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

No, I do not have any comments on that.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

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10. Do you have any other comments on the consultation proposals that you would like to share with us?

No.

11. Can you provide examples of costs and benefits of these proposals?

No.

12. Do you have any comments on the consultation Equality Analysis?

No.

Response 61 - NHS BLOOD & TRANSPLANT

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

NHSBT makes no specific comment on the most appropriate regulatory body for the transfer of any HFEA functions: this response relates solely to the functions provided by the HTA.

NHSBT supports the principle of achieving efficiency savings across the regulatory bodies and recognises that there are a number of ways in which these savings could be achieved. However it is noted that the forecast savings predicted within the Impact Assessment for Option 1 appear relatively low.

While NHSBT recognises that the transfer of HTA functions to the CQC may reduce the cost of regulatory inspection for transplant centres in England as transplantation activities could fall within the remit of a wider hospital inspection, we have a number of concerns about this proposal. The concerns which would need to be addressed with regards to the transfer of HTA functions to the CQC are as follows:

- 1.1 The primary focus of the regulatory activities to support compliance with the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 is to ensure the quality and safety of the tissues, cells or organs. Whilst the focus of the CQC is to monitor compliance with essential standards of safety and quality, this is from the perspective of the patient journey. It is difficult for NHSBT to understand how the same approach would be appropriate in respect of deceased organ and tissue donation.
- 1.2 The nature and geographical diversity of the NHSBT operational functions would make “CQC inspections on an unannounced basis” challenging. NHSBT would have concerns that the value of the inspection for both NHSBT and CQC would be compromised.
- 1.3 The CQC is a large organisation with a diverse scope of regulatory responsibility. NHSBT is concerned that the necessary focus and expertise for tissues, cells and organs would be diluted or lost were it to be subsumed into the CQC. This is at odds with the high public profile for this area of clinical practice and with an ongoing need to drive up public perception and confidence, particularly in organ donation and transplantation. The HTA has developed significant levels of expertise in both organ and tissue donation with a growing understanding of the clinical, legal and ethical issues surrounding this complex area of clinical practice. NHSBT would want to be assured that any changes would maintain and support further development of this expertise.
- 1.4 NHSBT would also seek assurance that appropriate mitigations would be put in place to avoid any transfer of function from the HTA adversely impacting on the operational activities for tissues, organs and cells.
- 1.5 Whilst NHSBT would not expect all the detail to be included within the

<p>consultation papers, NHSBT does seek assurance that the necessary and timely reporting mechanisms for the management of Serious Adverse Events and Serious Adverse Reactions (SAEARs) incidents would be a mandatory component for any transfer of HTA function.</p>
<p>2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?</p>
<p>For NHSBT, option 1 would reduce the number of regulators as NHSBT is currently regulated by CQC, HTA and MHRA. This would be reduced to CQC and MHRA. Whilst supporting the principles of the consultation, NHSBT would state that we are less concerned with the number of regulatory bodies than we are with ensuring that appropriate regulatory approaches and expertise within the regulatory bodies are retained and developed.</p>
<p>3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.</p>
<p>NHSBT has no comment with regards to the transfer of the research functions within the HFEA to the HRA.</p>
<p>4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?</p>
<p>NHSBT considers the proposals in option 2 to be largely undesirable for the following reasons:</p> <ul style="list-style-type: none"> • it would introduce regulatory fragmentation for tissues, cells and living donation. • the potential (real or perceived) conflict of interest with NHSBT's core functions relating to living donation. • for tissues and cells, option 2 would result in regulatory functions transferring from one to potentially three regulatory bodies, namely the CQC, MHRA and HRA. <p>The proposal to transfer of the Assessment of Living Donation Applications to NHSBT has the benefit of transferring the regulatory function to an organisation with an expert understanding of the clinical issues, although NHSBT has no track record as a regulator.</p> <p>In the specific proposal for the transfer of the Assessment of Living Donation Applications to NHSBT, NHSBT recognises that this is potentially advantageous as it would help to ensure the retention of existing skills and knowledge. However this advantage needs to be balanced against the perception of a potential conflict of interest with NHSBT's core functions relating to living donation.</p> <p>For tissues and cells, the proposal within option 2 would result in regulatory functions transferring from one to potentially three regulatory bodies, namely the CQC, MHRA and HRA. This approach would not be supported by NHSBT and it is difficult to see how this transfer of functions would demonstrate the necessary assurance for healthcare providers and the general public of the quality and safety of tissues and cells. If the HTA functions relating to tissues and cells have to transfer to another regulatory body, then it would be NHSBT's preference for all tissues and cells functions, including those relating to research, to transfer to the MHRA.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but</p>

<p>deliver further efficiencies? Please explain why you think this.</p>
<p>NHSBT strongly supports the option for the HTA to retain their existing functions whilst delivering further efficiencies.</p> <p>Since its inception in 2005, the HTA have developed a significant knowledge base which, in conjunction with the development of excellent working relationships with the clinical community, has contributed greatly to the advances made within tissues, cells and living donation.</p> <p>The HTA has a regulatory focus for tissues, cells and organs which in the context of healthcare regulation is small. This focus of attention lends itself to a collaborative and consultative style with the regulated stakeholders to ensure that appropriate risk based frameworks for regulation to drive up quality and safety standards are delivered.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify</p>
<p>NHSBT does believe that the retention of the HTA could deliver savings to the public purse. Whilst it cannot be quantified at this stage, one option to be developed further would be the introduction of a self assessment regulatory framework based on a risk:benefit assessment which could significantly reduce the number of inspections needing to be resourced and supported by the HTA.</p> <p>It is noted however that the current legislation for tissues and cells could not support a self assessment framework as it mandates a regime of inspection.</p> <p>Further consideration could also be given to further merging of back office functions within the HTA with another body.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>We think it is unlikely that some of the HTA's functions could be transferred without incurring additional costs.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?</p>
<p>NHSBT is concerned that the areas identified for achieving the anticipated efficiency savings within the HTA are across the Senior Management and Board levels and that this is where the current expertise and responsibility for the approval of living donation applications sits.</p> <p>NHSBT would be very concerned that this expertise would be lost in order to achieve the efficiency savings proposed and that this loss would directly and significantly impact on living donation activity in the UK.</p> <p>In addition, since its inception in 2005, the knowledge and expertise of the HTA has grown in line with the increased numbers and complexities of National Living Donation Schemes. The loss of such expertise would have a significant detrimental effect on living donation and transplantation activity for the UK and potentially on the emerging likelihood of increased sharing of organs from living donors across EU Member States.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>NHSBT would like to highlight the following issues, all of which are relevant to a</p>

thriving transplant programme in the future, regardless of which organisation is the regulator.

- The assessment of all living donation applications includes a detailed mandatory requirement for independent assessment. The Independent Assessors are employed outwith the HTA organisation (normally within a Hospital Trust/Board) and undertake this pivotal role for the HTA on a voluntary and unfunded basis. This poses a significant vulnerability for Living Donation activity in the UK as it relies on goodwill of both the individual and/or their employer. NHSBT would recommend commitment and development for this necessary Independent Assessor role through the introduction of appropriate funding mechanisms.
- Furthermore the HTA provide initial training and ongoing performance and quantitative assessment for the Independent Assessor role to ensure that appropriate accreditation levels are maintained and that the integrity of the process is assured. NHSBT would seek assurance that the role of the Independent Assessor and the role of the HTA in ensuring IA standards are maintained should the HTA function be transferred.
- The options for the regulatory body for research in Tissues, Cells and Organs are discussed within the Consultation paper. NHSBT wishes to highlight that the current legislative framework for the licensing of the removal of material from deceased organ donors for the primary purpose of research is unfit for purpose and hinders necessary research initiatives.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

No

11. Can you provide examples of costs and benefits of these proposals?

NHSBT have nothing further to contribute with regards to the costs and benefits.

12. Do you have any comments on the consultation Equality Analysis?

No

Response 62 – Health Ethics and Law, University of Southampton

Health Ethics and Law University of Southampton is an interdisciplinary network of scholars working at or connected with the University. We have met to discuss the consultation document and we provide our comments below on the consultation questions on which we have formed views.

Question 1.

In broad terms, we support the proposed Option 1. We are aware of criticisms that the HFEA is perceived to be unwieldy, expensive and slow. These concerns arise from the continued use of a framework that was developed to provide public reassurance about the responsible use of reproductive technologies that were untried and controversial. However, the contemporary context is one in which the technologies are well established and have broad public support, even to the extent that limitation of their availability on the NHS in some parts of the country is regarded as scandalous. In this context, there is no longer any need for a special regulatory regime. In the longer term this implies reform of the substantive law to subsume licensing of assisted conception into a single system of health provider licences and the inspectorate functions of the Care Quality Commission. In the short term, functions from the different legislative regimes can be brought together provided that the CQC has the capacity to take them on, develops expertise in the current legislation (which would be available by transfer of relevant staff from the HFEA), and could give sufficient priority to the tasks given its other challenges (particularly following the report of the Francis Inquiry expected in January 2013).

We are concerned, however, that there is insufficient clarity on the Government's proposals for facilitating public debate on emerging policy questions, which has been one important role of the HFEA in the past. Currently, such questions include the acceptability and level of payments for donors and issues emerging from new technologies to address diseases caused by defective mitochondrial DNA. We do not believe that these problems need a special regulator, or that reproductive technologies and the use of human tissue raise more (or less) problematic issues than other areas of bioethics. However, we do need to have mechanisms to address them carefully and this needs to be explained more clearly. The solution may be consultations managed by the Department of Health, with Ministerial or Parliamentary discussion and decision where appropriate. A number of bodies exist in the UK that work on such issues, including the Department of Health's internal committee on emerging science and bioethics and the Nuffield Council on Bioethics (an NGO). There is no need to establish new bodies, but it would be helpful for the Government to explain how it expects policy on ethical issues to be developed.

Question 3

We believe that it is important to distinguish research project approvals, which could be done by the HRA, from the wider requirements of the licensing regime under the HFE Act 1990 such as site visits. This is a different function from those that HRA currently undertakes and is not consistent with the approach to research governance in other areas of health research. We believe that it is sensible for project approvals to be brought within the National Research Ethics Service, possibly through designating one of the Research Ethics Committees as dealing with embryo

research. However, the HRA is not resourced to inspect premises and we doubt it would be sensible ask it to extend its role in this way. The division of responsibilities in respect of research on human tissue, whereby the Human Tissue Authority is the competent authority under the Cells and Tissue Directive but project approvals are undertaken by Research Ethics Committees could usefully be extended to the embryo research context.

Questions 4 & 7

We would propose that consideration be given to the transfer of responsibilities in respect of registers and information for donor conceived individuals. This seems to us closely analogous to providing information to people who have been adopted, for example the adoption contact register. These could usefully be brought together through the Registrar General.

Questions 5 & 6

It makes sense to have a single competent authority for the directive, to provide assurance on quality and safety in the handling of such material. This could become the CQC, but there may also be case for bringing this together in the short term in either the HTA or the HFEA through the delegation of functions, or indeed transfer of functions under the Public Bodies Act. At present, it seems that the HTA is more cost effective in this function, although the HFEA has recently addressed its own efficiency and made considerable progress in this area.

http://www.southampton.ac.uk/law/research/centres/health_ethics_and_law_network.page

Response 63 – All Party Parliamentary Group on Stem Cell Transplantation



APPG on Stem Cell Transplantation

A response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

The APPG has consulted its stakeholders to ascertain views on the proposed changes to the Human Tissue Authority (HTA) and Human Fertilisation & Embryology Authority (HFEA). Our primary concern is in line with the Government's primary objective – to ensure safe and ethical research and treatment using human tissue and cells. However, we believe the Government's preferred option of the three outlined in the consultation, will not meet this objective.

The regulation of tissues and cells is a complex and specialised field and regulation must be exemplary to ensure patient safety. The HTA is a leader in the sector and sets the benchmark for standards and excellence. The customers of the organisations regulated by the HTA are assured that practices are of the highest quality. In order to regulate effectively, a certain amount of knowledge and training is required, particularly at senior and board level.

We are concerned that the expertise that has been developed within the HTA over a number of years will be lost in the proposed transfer to the Care Quality Commission (CQC). The CQC is a large regulator and has a wide set of responsibilities over activities across the healthcare sector. With such a wide remit, we remain unconvinced that the CQC will be able to appoint enough time and resource to the complexities of tissue and cells regulation. There is a concern that the specialised knowledge needed at senior level to scrutinise and evaluate performance will not survive the proposed transfer, which would have a detrimental effect on patient safety, with no one to take accountability.

Furthermore the CQC is currently going through a stage of transition as it audits its procedures and processes to ensure that best practice is maintained. We have recently witnessed some high profile cases of failure at the hands of healthcare providers, with regulator oversight a contributing factor. In light of such incidents, we are apprehensive about the proposal to assign additional responsibilities to the CQC, as their focus will (and should) remain on improving the standards of those providers they currently regulate.

The Department of Health has stated that the abolition of the HTA will save £3.7m over 10 years. We note that this does not take into consideration the costs associated with abolition, transferring new skills and knowledge to the CQC, and streamlining working practices in the devolved nations. Furthermore any proposed savings should be balanced with the potential risks to quality of regulation.

The HTA is a small regulator and it is committed to delivering a programme of efficiencies that will significantly reduce its budget. It has already reported efficiency savings of 27% in the last two years and 34% since the review of arm's length bodies was announced. We believe that the savings anticipated by transfer are negligible, particularly against the costs of failing to meet the Government's primary objective of the review. We support the proposal that the HTA continue to make efficiency savings in operating costs, where appropriate and achievable.

The APPG agrees with the Government's preference to retain the HTA's functions with one body, rather than separate them. This fragmentation would result in additional regulation for many of the organisations currently regulated by the HTA. This would achieve little more than create additional burdens for regulated bodies, while also deepening the loss of expertise. This would therefore denigrate from the review's aim to ensure safe and ethical treatment and research with human tissue and cells, by demanding more of the organisation's time for regulatory requirements.

With these issues in mind, and in consultation with its stakeholders, the APPG on Stem Cell Transplantation agrees that patient safety and public confidence can only be maintained by retaining the HTA in its current arrangement, as a separate regulator. It is for this reason, we favour Option 3.

Chair: Mark Tami MP

Vice-Chair: David Burrowes MP

Response 64 – Professional Guidelines and Practices (Anatomy) Committee

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No.

Operational parameters that have been set since the establishment of the HTA have been beneficial to the Anatomy Sector, encouraging consistency and clarity in the way that licensed Institutions conduct processes such as Donor bequest programmes, anatomical examinations and storage of specimens. At an Institutional level the fact that each licence has a 'Designated Individual'(DI) with responsibility for 'policing' that licence and the introduction of 'Persons Designate' (staff with daily responsibilities for the preparation, storage and disposal of parts) have both been welcomed by the Sector, which in turn has led to an increase in public confidence in it. If the Regulatory functions of the HTA are to be transferred, we would suggest that the staff working currently for the HTA be transferred to the CQC *en bloc* to maintain continuity and expertise in the regulation of our sector.

The three professional societies that represent the vast majority of the staff working in the Anatomy sector, the Anatomical Society (AS), Institute of Anatomical Sciences (IAS), and British Association of Clinical Anatomists (BACA), came together in 2008 to sign a Memorandum of Understanding to work together to drive forward 'best practice' throughout the Sector. The Professional Guidelines and Practices (Anatomy) Committee (PGaPAC) has been established to do just this and is made up of three representatives from each society (the current Presidents of AS and BACA and the Chairman from IAS and two other representatives from each society). PGaPAC has met with the Head of Regulation at the HTA and his/her team regularly to discuss issues that required clarification and to offer ideas for comment as to how to improve best practice. An example of this is that the PGaPAC is looking to establish a network of experienced Designated Individuals and Persons Designate to act as 'consultants' during Internal audits of licensed premises.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

We consider that transfer of HTA function to the CQC and subsequent abolition of the HTA will considerably jeopardise the Expertise that has been established by the HTA since inception with regard to advice and guidance available to our Sector and rigor during inspection and audit. Anatomy is a small Sector and has stable and embedded working practices based on 170 years of regulation and we feel transferring Regulatory function to a much larger organisation who has a distinctly different 'style' of regulation to the HTA would be detrimental. The whole body

donation schemes that operate in Anatomy Departments rely on the good will of Donors and the confidence they have in the Regulators of the schemes. The HTA has developed a 'trusted' and reliable name, something we feel is lacking from the CQC at present. Furthermore, there is no 'care' element to the practice of Anatomical Examination and therefore, the Sector does not fit within the remit of the CQC.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

HFEA is outside of our area of direct expertise, but we can see some benefit of separating the research functions of the HFEA from the 'treatment' functions.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

We have argued in the past and continue to believe that for the Anatomy Sector, a return to a separate Inspector of Anatomy (as pertains in Scotland and Ireland) would be more efficient, cheaper and provide a better service than at present. The costs associated with the last Inspector of Anatomy must be a matter of record and can be compared with the costs of regulation under the HTA.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

See response 4. If the HTA is to retain its existing functions, it should deliver further efficiencies. Anatomy is a very low risk sector with a history of regulation under Inspectors of Anatomy and HTA. Through the PGaPAC, we have worked closely with the HTA in trying to drive down the cost to Anatomy departments. The HTA have responded by reducing the cost to stakeholders for full and satellite licences. We see no reason why this should not continue and further efficiencies be identified and implemented. We feel that any transfer of function to CQC at this time would be a 'risk' and would not guarantee cost efficiencies whilst maintaining the standards that have been set by the HTA.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

See responses to 4 and 5. While delivering savings to the public purse is important we consider that the effectiveness of the organisations regulatory activities is also important. Public, Clinical and Professional trust and confidence are developed by how effectively a body operates and not by cost to the public purse alone.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

See response to 3. If the HTA is to be retained as an independent regulator, we

consider that the devolvement of Anatomical Examination from its remit and the reintroduction of an Inspector of Anatomy as is the case in Scotland and Ireland would be beneficial to the Anatomy Sector. The fact that the HTA also regulates the Pathology Sector has caused confusion between the two Sectors in the minds of the public and has damaged the reputation of the Anatomy Sector.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

See comment 6. Following the Alder Hay and Bristol incidents, Public Trust in hospitals and Medical Schools was at very low ebb. Public, Professional and Clinical Confidence in the regulatory framework are vital to our Sector. The HTA has responded to this over the past 6 years building confidence in the 'damaged' Sectors We would be very concerned if cost is a bigger driver for change than public confidence and trust in a Regulatory body.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

See Response 1. If the Regulatory functions of the HTA are to be transferred as a whole, we would suggest that the staff currently working for the HTA be transferred to *en bloc* to maintain continuity and expertise in the regulation of our sector. A major concern is that if the functions of the HTA get transferred, the knowledge, expertise in guidance and regulation of our Sector may be damaged or lost. For example, the CQC has no experience in Anatomy and indeed their Regulatory 'style' is different from that of the HTA. And this could impact negatively on the Anatomy Sector.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

11. Can you provide examples of costs and benefits of these proposals?

See previous comment on the benefits offered by the re-introduction of an Inspector of Anatomy or secondarily retaining the HTA as is, compared to the CQC taking over the role of Regulator of the Anatomy Sector

12. Do you have any comments on the consultation Equality Analysis?

Response 65 - Cardiff University - Governance & Compliance Division

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	<p>No. It is difficult to see how the CQC (an organisation that only speaks for England) will regulate licences held in Wales and Northern Ireland. It is possible that if the functions were transferred to the CQC it could eventually be devolved to the equivalent in Wales and Northern Ireland, resulting in three regulators for the same activities relating to the same Act.</p> <p>Furthermore, the CQC does not currently have expertise in the areas regulated by the HTA. It has taken years for the HTA to acquire the expertise to run efficiently and to advise in the current regulatory framework. How long would it take the CQC to gain equivalent skills and at what cost to the regulated establishments?</p>
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	<p>There is a risk that end users would bear the real cost of a new organisation having to develop the expertise now developed by the HTA.</p> <p>Devolved regulation could result in differences in regulation and different standards, which could make transferring tissue between UK countries difficult.</p>
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	<p>The HRA should be responsible for regulating all research functions, including those of the HTA, or none at all. It makes little sense to transfer some research functions to the HRA and transfer the remaining research functions to the CQC; this would result in continued differences in regulation within the research sector and confusion for researchers and their establishments.</p> <p>If functions were transferred from the HTA, the HRA would be better placed to regulate the research sector than the CQC for a number of reasons.</p> <p>Through NRES, the HRA is responsible for the majority of exemptions to the research licence. Given this existing link it would be sensible if the organisation responsible for the research licence exemptions also regulated this sector to ensure that exempt projects complied with the Act. Furthermore, there are already several areas where the HRA and the HTA have worked together, eg in establishing the ethical/licensing position statement for Research Tissue Banks, thus demonstrating an existing knowledge-base at the HRA. The HRA also has access to many specialist advisors both inside the organisation and external, who could be called upon to assist with human tissue regulation.</p>
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	<p>Although there are a number of organisations that would be much better suited to regulate specific areas, by splitting the functions it would make it very difficult for establishments that have multiple activities under one licence or multiple licences within one establishment. However there would be clear benefits to sectors if they</p>

<p>were regulated in their entirety by specific organisations that understood, and had previous experience working within, that sector, eg all research going to HRA.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>The preferred option for Cardiff University as a whole would be for the HTA to retain all existing functions and to liaise more effectively with the HRA (see questions 3 and 9). Cardiff University has three types of HTA Licence and multiple activities are carried out under two of these. If these functions were regulated by different organisations it could become difficult to manage overlap between licensable activities. Therefore we would prefer the functions to remain together. The HTA has taken years to become an efficient regulator and to build up its knowledge-base; it should be allowed to continue regulating the area it knows so well.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>It is difficult to see how the HTA could deliver further savings to the public purse. However the £3.8m that would be saved in total over the next 10 years by abolishing the HTA and HFEA does not seem a significant amount and it would cost the establishments they regulate more in terms of time and money to compensate for/adapt to the changes. This would be particularly frustrating if the organisation taking over the functions knew less about each sector than the current regulators. Ultimately, the HTA governs a range of activities that are essential for public safety in a politically sensitive area. In light of the international reputation of the UK for high standards of regulation, reducing the effectiveness of this organisation should not be risked simply to reduce the cost to the public purse.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>No</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>See comments above in Question 6.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>There needs to be more communication between the HRA and the organisation responsible for the research functions. Even though the HRA/NRES endorses holding tissue according the HTA Codes of Practice this is not stipulated in the NRES SOP or made a condition of approval; projects with NRES approval that are exempt from the HTA Licence are not monitored by an external organisation to ensure compliance with the Human Tissue Act. It is currently down to the host establishment to ensure projects with NRES approval comply with these standards. This can cause confusion and frustration amongst individuals involved in activities that do and do not come under the HTA Licence and establishments hosting those activities.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>
<p>No</p>

11.	Can you provide examples of costs and benefits of these proposals?
	n/a
12.	Do you have any comments on the consultation Equality Analysis?
	No

Response 66 – Cancer Research UK

Cancer Research UK¹ is leading the world in finding new ways to prevent, diagnose and treat cancer. We are the largest independent funder dedicated to cancer research in the world. Over half of all cancer research in the UK is carried out by our doctors and scientists. Cancer Research UK's work is entirely funded by the public. We spend 80p in every pound we receive on our life saving work. In 2010/11 we spent £332 million on research, supporting the work of more than 4,000 scientists, doctors and nurses.

Cancer Research UK funds research into all aspects of cancer from exploratory biology to clinical trials of novel and existing drugs as well as epidemiological studies and prevention research. We welcome the opportunity to respond to this consultation.

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Cancer Research UK welcomes the Government's commitment to produce a streamlined system of regulation and governance. We have fed into several consultations and responses on this issue including the Government's Arms Length Body review and the Academy of Medical Science's report *A new pathway for the regulation and governance of health research*. Throughout these processes we have not identified any particular issues with where the functions of the HTA and HFEA sit.

Cancer Research UK currently has no studies within its portfolio that involve the use of human embryos, and as such we do not have extensive experience of interacting with the HFEA. Cancer Research UK does not directly fund tissue banks but is associated with the functions of several banks through our Experimental Cancer Network Centres (ECMC) which are jointly funded by the NIHR. Many of Cancer Research UK's funded projects rely on the use of tissue. This research often takes place in universities and other institutions that hold tissue licences. We are therefore keen to see a supportive environment for tissue research which enables our researchers to access and use tissue samples without excessive regulatory burdens.

We would want to see the expert regulatory knowledge retained by the HTA to ensure that proportionate regulation continues to operate. Similarly, quick timelines and clear and consistent advice, proportionate inspection, no increase to cost for the researcher/research funder would all need to be retained wherever the HTA's functions are located in the future.

We would like to highlight that there have been concerns expressed about the CQC's ability to handle complex regulation in what have previously been controversial areas. The House of Commons Public Accounts Committee stated that the CQC currently has a compliance rate of

less than 20% which would be unacceptable in terms of human tissue and embryo regulation. Compliance to both HTA and HFEA are cornerstones to public confidence in research. Therefore, we would want further reassurance that the CQC was in a position of taking on these functions if this option was to be pursued.

The swift formation of the HRA has demonstrated the Government's commitment to streamlining the regulatory processes for clinical research in the UK. While we agree that moving functions into the HRA could be effective we do not see it as the only mechanism for creating a streamlined environment.

We support the formation of the Health Research Authority and have confidence in its approach and the proposals that it has laid out to date. We believe that whichever model is followed to locate the functions of the HTA and HFEA, the HRA should take an overarching role with regards to the research functions. The HRA has the means to act as a single point of entry and contact when gaining approvals to conduct research, this model could function for researchers seeking to gain approvals from the HTA and HFEA. For example, the HRA should still be able to act of the first port of call for information regarding HTA and HFEA licences and for advice about undertaking regulatory approvals. The HRA is also best placed to lead on public engagement on research issues and for reassuring public confidence.

Cancer Research UK is open to supporting an option that maintains existing compliance and expertise in human tissue and embryology legislation. Whichever option the Government chooses to pursue, its functions must continue to be performed to a standard that will support researchers in gaining approvals and also public confidence in the handling of human tissue and embryos. Should the existing functions of the HTA/HFEA be moved into other bodies there should be comprehensive scrutiny of the bodies' ability and willingness to take on these potentially controversial topic areas. Cancer Research UK believes that any changes should not affect researchers or research funders' experience of the regulatory system and that wherever possible they should seek streamline and improve it.

Response 67 - Centre for comparative and Clinical Anatomy, University of Bristol – Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	<p>No.</p> <p>Operational parameters that have been set since the establishment of the HTA have been beneficial to Anatomy, encouraging consistency and clarity around the way that licensed premises conduct processes such as Donor bequest programmes, anatomical examinations, and storage of specimens. At Institutional level the fact that each licence has a 'Designated Individual'(DI) with responsibility for 'policing' that licence and the introduction of 'Persons Designate' (staff with daily responsibilities around the preparation, storage and disposal of parts) have both been welcomed by the sector, which in turn has led to an increase in public confidence in Medical schools. If the Regulatory functions of the HTA are to be transferred, we would suggest that the staff working currently for the HTA be transferred to the CQC en bloc to maintain continuity and expertise in the regulation of our sector.</p>
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	<p>I feel that transfer of HTA function to the CQC and subsequent abolition of the HTA will considerably jeopardise the expertise that has been established by the HTA since inception with regard to advice and guidance available to our sector and rigor during inspection and audit. Anatomy is a small sector and has stable and embedded working practices based on 170 years of regulation and we feel transferring Regulatory function to a much larger organisation who has a distinctly differing 'style' of regulation to the HTA would be detrimental. The whole body donation schemes that operate in Anatomy Departments rely on the good will of Donors and the confidence they have in the Regulators of the schemes. The HTA has developed a 'trusted' and reliable name, something we feel is lacking from the CQC at present.</p>
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	<p>No comment as HFEA is outside of my area of expertise</p>
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No, the HTA have delivered a very satisfactory service to our sector.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes I do, See response 1. We are a very low risk sector with a history of regulation under the Inspector of Anatomy and HTA. Through the Professional societies that represent the sector, we have worked closely with the HTA in trying to drive down the cost to Anatomy departments. The HTA have responded and have a proven track record of reducing the cost to stakeholders of full and satellite licenses. Having been personally involved as Chairman of both the Institute of Anatomical Sciences and the Professional Guidelines and Practices(Anatomy) Committee see no reason why this should not continue and further efficiencies be identified and implemented. I feel that any transfer of function to CQC at this time would be a 'risk' and would not guarantee cost efficiencies whilst maintaining the high standards that have been set by the HTA.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Yes I do(see previous comment). While delivering savings to the public purse is important I feel that by far the most important consideration is the effectiveness of the organisations regulatory activities. Public, Clinical and Professional trust and confidence are developed by how effectively a body operates and not by cost to the public purse.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

With regard to the HTA, No. I have no comment regarding the HFEA.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

See comment 6. Following the Alder Hay and Bristol incidents Public Trust in hospitals and Medical Schools was at very low ebb. Public, Professional and Clinical Confidence in the regulatory framework are vital to the Anatomy sector. The HTA has responded to this over the past 6 years building a strong platform from where we can deliver our Body Donor schemes. The phrase 'Donating your body to Medical Science' is widely used and the public need to feel assured that the confidence they have in the organisation that regulates the Donor programmes is well founded. I would be very concerned that cost was a bigger driver for change than public confidence and trust in a Regulatory body.

9. This consultation focuses specifically on where functions might sit and

implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

See Response 1

If the Regulatory functions of the HTA are to be transferred, I would suggest that the staff working currently for the HTA be transferred to the CQC *en bloc* to maintain continuity and expertise in the regulation of our sector. A major concern of mine is that if the functions of the HTA get transferred to the CQC, the knowledge, expertise in guidance and regulation of our sector will be diluted by the sheer size of the organisation. The CQC has no experience in Anatomy and indeed their Regulatory 'style' is different from that of the HTA or their predecessor(HM Inspector of Anatomy)

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Since the inception of the HTA, Anatomy departments have been working much more closely in delivering Post Graduate Surgical Training using donated cadavers. Giving the opportunity to Surgeons to further advance their skills and to practice innovative approaches to operative technique. Also it has allowed for Anatomical research to be carried out under license. These changes have been hugely welcomed from our Clinical colleagues. Option 3 in the consultation document will allow for these benefits to continue under a tried and trusted regulator.

11. Can you provide examples of costs and benefits of these proposals?

See previous comment on the benefits offered by retaining the HTA as is, and earlier comments re cost savings already made by the HTA.

12. Do you have any comments on the consultation Equality Analysis?

Response 68 - Society and College of Radiographers

The Society and College of Radiographers is grateful for the opportunity to respond to this consultation. We would like to respond in particular to question 5

Background information

The Society and College of Radiographers is the professional body and trade union for all members of the diagnostic imaging and radiotherapy workforces in the UK. Membership of the organisation includes radiographers and sonographers as well as members of a number of other professions associated with the provision of diagnostic clinical imaging and radiation therapy/oncology services. The Society and College of Radiographers is the only body representing the whole of the radiographic and imaging workforce.

The Society and College of Radiographers exists to promote the science and practice of radiography and ultrasound in the interests of furtherance of the profession and in the public interest, to support and promote education and research in imaging and to represent the interests of members of the radiographic and ultrasound community.

You may publish this response on your website or in another format if you wish.

Response

1) Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

We **do not** agree with this option. Our rationale is set out in response to question 5 below.

5) Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this?

We would **support** this. Both the HFEA and HTA have specialist and expert knowledge in their respective fields which also includes the ethical considerations of various complex procedures. Both bodies have established a very high reputation for ethical and academic rigour. This extends internationally and crucially commands public confidence throughout the UK.

This option will ensure that the considerable expertise built up in the existing bodies is not lost; it is also the option most likely to retain the confidence of the public.

This has been tested once again recently with the retention of human tissue following autopsy of military personnel killed in the line of duty.

We believe this option also addresses the UK wide issue; the CQC acts in England only with regards to its current remit.

The CQC has very wide regulatory oversight across health and social care in England already and we question its ability to take on further areas of work, particularly where these are highly specialised and carrying so much public and

scientific profile. We are not confident that the CQC has the resources necessary to even fulfil its current role without further adding to its burden.

Response 69 - Bereavement Services Association

Bereavement Services Association (BSA) is a network organisation of people involved in providing care to bereaved people. The majority of members are employed in the NHS but there are also members employed by charities and commercial organisations. Members work in various bereavement support functions including provision of information and advice, administration of peri-death procedures including transplantation and donation of tissue and Some are involved in direct care of the body in mortuaries and others in facilitation the issue of medical certificates and correct referral to the coroner. The great majority have direct and frequent contact with bereaved people as well as a wide range of other professionals within the sector. Facilitation of consent for post-mortem examination, early resolution of potential complaints and psychological support of bereaved people are also services provided by members and the arranging of public health funerals.

As our experience is primarily of the HTA our response is confined to the future of that organisation.

Many BSA members were involved in providing bereavement care during the late 1990's and early 2000's so have very clear recollection of the varying standards of practice and absence of regulation prior to the creation of the Retained Organs Commission and later the Human Tissue Authority. There is a deep understanding among our members of the need for clear, rigorous and transparent regulation of this sector by an organisation that engages openly and with respect for all the various stakeholders. The HTA is an organisation which has gained the respect of the professionals it regulates which is not easy to achieve. It has made occasional mistakes but has rapidly learned from them and taken corrective action. It operates by dialogue with key parties and uses as light a touch as possible consistent with robust regulation.

A key aspect of the HTA is the partnership between committed members of staff and the highly engaged critical friends who make up the Board. We are very concerned at any possibility of dilution of the expertise and rapport that the HTA has established with this sector which would be damaging to all. Trust is very difficult to win and easy to lose. While the CQC can learn much from the HTA we do not believe it should be at the expense of the independence of the HTA.

We are also aware of increasing cooperation between the HFEA and the HTA.

Close attention is paid to the needs of the public and one can rely on the HTA for timely and considered responses to current issues and appropriate communication to the media when required.

As far as financial issues are concerned, we believe an organisation that has been able to reduce its fees for licensing because of its careful stewardship of limited resources should be used as an exemplar of what can be achieved. The current option 3 which allows for continued independence if further efficiencies are made does not demonstrate this and is to be regretted.

We support Option 3 for the continued independence of the HTA because of its proven excellence, without there being threats of budget cuts as it is clear that the existing organisation has a culture of seeking every opportunity for further efficiencies. We do not support the other options.

Bereavement Services Association

Response 70 - NHS National Services Scotland

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No.

NHS National Services Scotland's Division, the Scottish National Blood Transfusion Service (SNBTS) is the preferred provider of bones, tissues and other cell therapies in Scotland. We have been at the forefront of clinical tissue/cell banking activity for a number of years and have been involved in the evolution of the regulation of tissue banking activities from the start. Initially we were part of the voluntary accreditation scheme (inspected by MHRA), followed by inspections by HTA and HFEA and more recently again by MHRA as regulation evolved and our range of activities increased. We are also aware that HTA is the newly appointed competent authority in the UK for organ donation purposes. This is relevant since a significant proportion of tissues are derived from organ donors as well.

The inspections from HTA and HFEA (the subjects of this consultation) have been handled well, they are proportionate and risk based and we have built a good degree of mutual trust and respect. This has, in no small way helped to build and maintain professional and in particular, public confidence in clinical tissue and cell banking and transplantation.

We are aware that the role of HTA in Scotland is limited to the licensing of clinical tissue establishments to ensure compliance with the EUTCD (2004/23/EC) and to a few other UK retained functions (particularly in relation to live organ donation) and our response needs to be seen with that in mind. There are a number of concerns from a Scottish perspective:

- A. The CQC has no locus in Scotland and it is our understanding that primary legislation would be required for this to change.
- B. The inspection processes are geared towards the safety and quality of the products we release for therapeutic use (human application) and to ensure that all consent processes are ethical. Although we have no experience of CQC, it seems to us that their processes are mostly geared towards standards of patient care-not product related /regulatory issues. These are specific and require an in depth knowledge of regulation concerning complex manufacturing processes.
- C. The HFEA and HTA have, over the past years, in their roles of competent authorities built significant expertise and knowledge of regulations and therefore our preferred choice would be to maximise the synergies between the 2 organisations to meet the necessary financial savings rather than replace them with an inexperienced organisation.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Different EU and national directives in relation to tissue and cell banking have been transposed into UK law in a way that some tissue establishments including ours, are inspected by three different regulatory authorities - HTA for tissues and some cells, HFEA for gametes and MHRA for Advanced therapeutic medicinal products

(ATMPs). Whilst this ensures high levels of safety and quality of all products, it does mean separate inspections from each regulator (in our case three on a biannual basis) resulting in different requirements (some important, some less so) and different processes (e.g. SOPs/validations) for each group of products as each set of inspectors interpret the rules slightly differently. This causes inspection saturation, some confusion (all products should be of a similar quality and safety standards) and a significant degree of duplication of effort.

We feel that synergies amongst the three regulators should be fully explored and exploited. It is somewhat strange that the possible extended role of MHRA has not been explored further in this consultation exercise. MHRA has extensive experience in regulating and licensing blood and it was the first competent authority to inspect tissue establishments (under the voluntary accreditation scheme).

Currently the three regulators have already started to cooperate (either by having joint inspections or by accepting the findings of another regulator during a previous inspection). Such synergies should be fully and further explored to streamline inspection processes significantly and to produce the required financial savings both within the regulators themselves and within regulated organisations.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No comment.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Possibly. As discussed in our response to Q2 the synergies of the regulatory functions of HTA and HFEA should be fully exploited as well as looking at possible synergies between them and those of MHRA.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

This would be a viable option. As already stated, streamlining of inspection processes would be very beneficial to all parties. Financial savings can also be made through either joint inspections or mutual recognition of inspections of common areas of interest. Clearly further savings can be made if management of either organisation is more integrated with each other.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Yes.

Both by reducing the regulatory burden and by management streamlining. See response to Q5.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Possibly. In Scotland the HTA functions are limited to licensing of tissue and cell establishments, so difficult to comment. As a principle however, it is important that expertise, wherever possible should reside in one body. This ensures a critical mass

of knowledge in specialised (e.g. regulatory) matters.
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>We are not in a position to comment. Further synergies with e.g. MHRA may produce further financial benefits</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>It is our view that the regulatory functions should be streamlined, either by integrating regulatory management or streamlining the inspection processes in ways described above. It is important that the regulation of clinical tissue/cell banking remains integrated from the consent stage to retrieval, processing storage and release.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>
<p>Our National Services Division (NSD) which commissions national specialist services on behalf of NHSScotland has a direct interest in this proposal because its Pre implantation Genetic Diagnosis and transplantation services rely on HFEA and HTA; specifically, NSD relies on HFEA to accredit centres for pre-implantation genetic diagnosis services.</p> <p>We have consulted clinicians who provide the services in Scotland and they are now reassured that their early concerns when the announcement was originally made have been addressed satisfactorily in the consultation document.</p> <p>However the aspects of genetics covered by HFEA are not issues devolved to the Scottish Parliament and it is essential that the difficult decisions taken by the bodies that will now replace HFEA continue to be undertaken on a UK basis. The consultation document confirms that this will be the case but refers to NHS Healthcare Improvement Scotland as the Scottish equivalent of the Care Quality Commission. However, NHS Healthcare Improvement Scotland does not have a role in licensing genetic centres for molecular or cytogenetic procedures involved in Pre-implantation genetic diagnosis, or in the other specific areas covered by HFEA.</p>
<p>11. Can you provide examples of costs and benefits of these proposals?</p>
<p>Not applicable</p>
<p>12. Do you have any comments on the consultation Equality Analysis?</p>
<p>No</p>

Response 71 – University of Bristol – Human Tissue Working Group

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No, I do not agree with the transfer of HTA functions to the CQC and HRA. I cannot comment on the HFEA, but I would imagine similar concerns existing among their stakeholders. The HTA functions must not be transferred to the CQC, which is far too large, diverse and remote to instil in the public and other stakeholders the same levels of confidence and trust enjoyed by the HTA. As a former President of the British Association for Tissue Banking who was deeply involved in the development of regulation of tissue banking from the DH Code of Practice for Tissue Banks through to the development and implementation of the EU Tissues and Cells Directive, I firmly believe that the HTA has performed exceptionally well. Being a small, efficient and effective organization has helped stakeholders enormously in the implementation of this important and complex set of regulations, spanning the Human Tissue Act 2004, the Human Tissue (Scottish) Act 2006 and (at least for human application) the Human Tissue (Quality and Safety for Human Application) Regulations 2007. It has been straightforward to contact the appropriate HTA personnel who provide expert advice and assistance. The HTA has worked hard and successfully to build excellent working relations with all the sectors covered by the HT Acts and the Quality & Safety Regulations. The result is that the sector is regulated in an atmosphere of trust, which was so important and so difficult to build following the Bristol and Alder Hey incidents. Public trust is also essential for those of us working with human tissue. The public must be able to feel confident that there is an independent and effective system of regulation. I only need to contrast the rather differing views expressed in the press, regardless of their veracity, concerning the CQC and the HTA – public trust in regulators is key. By transferring the HTA's responsibilities, I would fear that HTA's specific expertise would be diluted to the detriment of all those who are currently regulated by the HTA. Speaking also as Chair of the University of Bristol Human Tissue Working Group, which was established to oversee and co-ordinate the several HTA licences held by the University, I would be greatly concerned that instead of there being a single regulator for all aspects of our licences covering the research, anatomy and human application sectors, the regulatory functions would be split between different regulators. This opens the significant potential for confusion, errors and unintended consequences, especially where a licence currently covers activity across multiple sectors (e.g., human application, research, surgical training). In summary, the maintenance of public and professional confidence is essential to the highly sensitive area of the ethical and safe use of human tissue from living and deceased donors. I understand that the HTA would need to further improve efficiencies beyond the significant efficiency gains it has already achieved. However, I have seen absolutely no specific and robust evidence that the CQC could take over the functions of the HTA and achieve the same excellent levels of efficient and cost effective regulation while maintaining the same high degrees of public and professional trust and confidence that have been achieved by the HTA.

2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	The possibility of having to deal with more than one regulatory authority will substantially increase the administrative and bureaucratic burden on organizations currently regulated under the Human Tissue Act 2004.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	No comment as HFEA is outside my area of expertise and experience.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	No, at least for the HTA I can see absolutely no reason to distribute its functions to other regulatory bodies.
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	I understand from the public meetings held by the HTA and from its reports that it has already delivered significant efficiency savings. This is clear from the noteworthy falls in licence fees across all sectors. The HTA has also engaged stakeholders in the development of the licence fee structure. This gave licensed organizations an opportunity to express their views and opinions as well as an opportunity for the HTA to explain, and be questioned about, how the money generated through the licence fees was being spent.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify
	While delivering savings to the public purse is important, by far the more important consideration is the effectiveness of these organizations' regulatory activities. Public and professional trust and confidence come not so much from how cheaply regulators operate but by how effectively they operate.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	No
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?
	No
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
	I firmly believe that the HTA performs effectively and that there is therefore no need to transfer its functions to other regulators.
10.	Do you have any other comments on the consultation proposals that you would like to share with us?
	No
11.	Can you provide examples of costs and benefits of these proposals?
	No comment
12.	Do you have any comments on the consultation Equality Analysis?

No

Response 72 - Bereavement Advice Centre

Dear Colleague

I am the Head of Bereavement Advice Centre, a national helpline and website service providing information, advice and signposting to people on a wide range of practical concerns affecting people after a death. This includes issues relating to post mortems and donation of tissues and also whole body donation.

Individually I am a member of the steering committee of the Bereavement Services Association.

I am therefore aware of the response to the consultation that has recently been sent to you by that organisation. I would like to state that Bereavement Advice Centre supports the response made by Bereavement Services Association which states our position on the future of the Human Tissue Authority also.

Response 73 - Mission and Public Affairs Council of the Church of England

The Mission & Public Affairs Council of the Church of England is the body responsible for overseeing research and comment on social and political issues on behalf of the Church. The Council comprises a representative group of bishops, clergy and lay people with interest and expertise in the relevant areas, and reports to the General Synod through the Archbishops' Council.

The Mission and public Affairs Council presents a Christian ethos, drawing on the witness of the Christian Scriptures and reflecting on Christian tradition and contemporary thought. Belief in God as Creator and Redeemer, in human beings' intrinsic value as creatures made in the Image of God and in the imperatives of love and justice, underpins the Council's approach. The Council believes that the ethical and social principles that are developed from this foundation may be embraced by people of other faiths or of none.

Background

1.1 The Government has affirmed its commitment to reforming Arms-length Bodies by stating, '*Services must be delivered in the most efficient way possible. By making sure that the right functions are being carried out at the appropriate level, we will free up savings to support front-line NHS services.*' In this context, the Department of Health has identified three main options for the future of both the HFEA and the HTA

'All functions should transfer to the CQC except the HFEA functions relating to research that would pass to the Health Research Authority; and the HFEA and HTA be abolished;

All functions should transfer, as set out above, but a limited number of functions would transfer to organisations other than the CQC;

The HFEA and HTA should retain their functions but deliver further savings.'

Comment

2.1 While streamlining of Arms-length Bodies is, in general to be welcomed, where it can be shown that it will result in greater financial, administrative or practical efficiency, this is subject to the key proviso that it will not diminish corporate expertise, patient safety or public confidence. It is necessary, therefore to demonstrate not only that greater efficiency will result from transferring the duties and responsibilities of the HFEA and the HTA to the Care Quality Commission or other bodies, but that the Care Quality Commission and other bodies would be able to conduct the business of the HFEA and the HTA to comparable standards.

2.2 A parliamentary review of the Human Fertilisation and Embryology Act (1990), conducted between 2004 and 2008, considered a proposal to replace the HFEA and the HTA with the Regulatory Authority for Tissue and Embryos (RATE). After considering the views of major stakeholders, however, the Joint Committee on the Human Tissue and Embryos (Draft) Bill, recommended abandoning the proposal because it found that it would lead to a significant loss of expertise. **There has been no significant change in the roles of either the HFEA or the HTA since then to suggest that a different conclusion would now be reached.**

2.3 There is no suggestion that any of the current functions of the HFEA or the HTA ought to cease. These functions require both considerable executive expertise and detailed non-executive scrutiny, the continuance of which would have to be ensured if they were transferred to other bodies. In particular, because of the specialist and, at times, controversial nature of the work they undertake, it is essential that expert scrutiny continues.

2.4 This is currently ensured by both authorities having strong non-executive teams, representing individuals with expert knowledge relevant to their particular authority. Both authorities meet six or more times each year in public, enabling the work of both the HFEA and the HTA to be conducted in a detailed, transparent and accountable manner. It is doubtful that this would continue to the same degree if the functions of the HFEA and the HTA were to be scrutinised either by a Board dealing with a large number of other issues or by a sub-committees of such a Board.

2.5 Since 2010, the HFEA has made 25% efficiency savings and the HTA 27% savings. Both authorities believe that there is limited scope for them to make further efficiency savings, but it seems sensible to explore this avenue before resorting to wholesale change with its accompanying greater degree of risk

2.6 The government's analysis suggests that up to £500,000 per year would be saved by incorporating the HFEA and the HTA into the CQC, presumably through greater sharing of support services and spreading of fixed costs. Although that is only the equivalent of running the NHS for three minutes, it is a significant amount and such a saving, if delivered, would be worthwhile provided it was not secured at the expense of placing at risk the current effective delivery of the crucial services undertaken by the HFEA and the HTA. The question then is whether savings of this order could really be delivered if the work were absorbed into CQC.

2.7 We remain very doubtful indeed. First, there are operational risks involved in transferring the functions of the HFEA and the HTA to other bodies. The HFEA, for example, maintains a detailed data base enabling coordinated tracing (and, where appropriate, care) of donors, patients, embryos and children born following assisted reproductive techniques. We see some risk that this service would be compromised by being absorbed into the workings of a much larger organisation

2.8 Secondly, big organisational transfers rarely go smoothly; in this case there is much at stake if errors were to occur. Similarly, while it might be argued that the research functions of the HFEA could be absorbed by the Human Research Agency, public education and public confidence are more likely to be better served by a small agency dedicated specifically to the particularly sensitive issues surrounding human

fertilisation and embryology. The current HFEA public education and consultation process on mitochondrial replacement is a good example of this.

2.9 Thirdly and most fundamentally, there are grave concerns with regard to the ability of the Care Quality Commission, with its very wide range of functions, to absorb the complexity and volume of the work conducted by the HFEA and the HTA. The CQC has encountered significant problems since its formation in 2009 when it assumed the roles of three earlier commissions: the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. It has recently been criticised by the Commons Health Committee, the Public Accounts Committee and the National Audit Office for a number of significant failings. It is also in the process of undergoing senior leadership change.

2.10 There is little doubt that even if other factors did not militate against disbanding the HFEA and the HTA, the CQC is not currently equipped to take on their functions and this is not likely to change for some time to come.

2.11 While a simple accounting approach can always be taken in creating ever larger leviathans there are some activities of a specialised and sensitive kind that are best delivered by focused, niche organisations with a good track record and reputation. In our view getting rid of the HFEA and HTA would be a misguided and false saving.

Conclusion

3.1 For the reasons outlined above we recommend the third option identified in the government consultation document: *'The HFEA and HTA should retain their functions but deliver further savings'*

Response 74 – South Eastern Health and Social Care Trust

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	<i>No. I have been very happy with the HTA as a body work efficiently and robustly, with a clear and defined role. I would be concerned that some of this efficiency could be lost if they were merged into a larger organisation.</i>
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	<i>This may make it more difficult to receive timely and appropriate advice from the HTA. In other clinical settings, my experience has been that creating larger bodies from smaller, self-contained bodies dilutes the ability for the body to retain its expertise as staff are rotated through different departments.</i>
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	<i>Yes. To date, I think the HTA have a clear track record of delivering efficiencies, with large reductions in licence fees for licenced bodies.</i>
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify
	<i>See above.</i>
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
	<i>I have been very happy with how the HTA has functioned as a regulator since it was formed.</i>
10.	Do you have any other comments on the consultation proposals that you would like to share with us?

11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?

Response 75 – Genetic Alliance UK



Genetic Alliance UK
Supporting. Campaigning. Uniting.

Introduction

1. Genetic Alliance UK is the national charity of over 150 patient organisations supporting all those affected by genetic conditions. We welcome the opportunity to respond to this consultation.

2. The majority of our member organisations represent patients and families affected by genetic conditions for which there is neither a cure nor a treatment. Patients and families in this situation look to medical research as the only potential source of solutions to their unmet medical needs. They therefore believe that our research community should be able to explore all reasonable avenues that may lead to a cure or a treatment for genetic conditions. The Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) are regulators that play an important role in ensuring that these avenues remain open. They play an important role in maintaining public confidence that access to and the treatment of ethically sensitive research material is controlled properly and effectively.

3. Whilst there are few cures or treatments for the majority of genetic conditions, those interventions that do exist are powerful and valued by our patient community. Two of the most valuable of these, which both cut across disease groups and potentially provide a significant benefit to large proportions of genetic conditions, are haematopoietic stem cell transplantation (HSCT) and preimplantation genetic diagnosis (PGD). These are regulated by the HTA and HFEA respectively. Again, both organisations play an important role in maintaining public confidence that the delivery of these ethically sensitive treatments is controlled properly and effectively.

4. We believe it is essential for the continuation of research towards cures and treatments for genetic conditions and for the continued public confidence in those treatments that do exist that the regulation and oversight currently provided by the HFEA and HTA continues to be delivered at least to the standard that it has been provided since the foundation of each authority.

Preimplantation genetic diagnosis

5. PGD is a treatment which allows couples at risk of having a child affected by a genetic condition to use assisted reproductive technology and embryo screening to ensure their child is unaffected. For couples for whom prenatal testing and possible termination of pregnancy is not an option, it is the only way they can be sure of having an unaffected

child to whom they are both genetically related. For many genetic conditions this treatment is the only means by which families can have any control over the impact a genetic condition has on their family.

6. Opponents to the use of PGD cite the “unnatural”, “slippery-slope”, or “playing god” arguments to assert that it is wrong to allow families to use the intervention.

7. PGD is regulated on a condition by condition basis. In addition to the necessity that the embryologist and the centre performing the procedure both have licenses from the HFEA, the HFEA Licence Committee must have granted a condition specific licence to allow embryos to be screened for the condition. One of the key criteria that must be satisfied for this licence to be awarded is that the HFEA Licence Committee considers there to be:

“a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.”
Human Fertilisation and Embryology Act 1990 (as amended)

8. There are more than 200 conditions that have been granted this licence to date. The rate of applications is increasing, in part due to advances in our understanding of the human genome, and in part due to increases in public awareness of the treatment. The complexity of licence applications is also increasing. The majority of the most straight-forward candidate conditions have now been considered by the HFEA Licence Committee, and the majority of new applications fall into one of two groups: very rare conditions for which there is scarce information and expertise; and conditions for which an assessment of their seriousness is more difficult to provide.

9. The conditions which have been licensed so far illustrate the enormous range of factors that the HFEA Licence Committee must be able to consider before making its judgement. These include: age of onset of the condition; variability of the impact of the condition; the penetrance (likeliness of causing the condition) of the gene concerned; aspects such as inherited predisposition to disease; inheritance patterns; and the myriad ways in which a condition can affect a patient and their family in their medical, social, educational, vocational, and recreational life.

10. Though we may not agree with every decision the HFEA Licence Committee has made to date, we strongly support the rigorous approach the committee takes to make these decisions and the opportunity for the public and patients to contribute to the decision making process by submitting evidence to the committee.

11. The HFEA Licence Committee is required to make an ethical decision regarding treatment when licensing PGD. Genetic Alliance UK believes that the ability of the HFEA to augment and support the decisions of the HFEA Licence Committee is vastly improved by its experience in its role as a regulator in the area of research, and by the Authority’s sub-committees the Ethics and Law Advisory Committee and the Scientific and Clinical Advances Advisory Committee.

12. The complexity of decision making required of the HFEA Licence Committee is in our view likely to increase, as advances in our understanding of the human genome increase and as public understanding and acceptance of PGD increases. We do not believe that regulation of PGD will become easier as the technology “matures”, at least not in the medium term future. We believe that the next few years of regulating PGD will bring with it ethical questions that will continue to require the expertise and experience of the HFEA Licence Committee, supported by the HFEA and its instruments.

13. We therefore believe there is significant value in maintaining the whole of the HFEA as a single body with responsibilities across research and care delivery.

Public confidence in regulators

14. The HTA and the HFEA both regulate in ethically sensitive and contentious areas. Consent for storage of tissue, regulation of donation of gametes and live donation of organs, research involving embryos, saviour siblings, and preimplantation genetic diagnosis all fall under their remits and have been the subject of either scandals or significant debate.

15. The risks attached to the results of poor regulation, control, or monitoring of any of these activities are great, and have the potential to damage the future of these activities and to any activities that may be associated with them. The ability of our regulatory system to produce a responsible agency, with a descriptive name, and an informed chief executive and/or chair, to speak authoritatively regarding the activities they govern is priceless in terms of continuing public confidence and in the ability to manage crises.

16. Genetic Alliance UK does not believe the Care Quality Commission (CQC) can be this authoritative body and continue to perform its current responsibilities. In a cost cutting environment, we do not believe the CQC will be given adequate resources to do so, and nor that the CQC will be able to ring-fence sufficient funds within its organisation to carry out the duties of both the HTA and the HFEA to current standards.

17. We therefore believe there is significant value in maintaining both the HFEA and the HTA as individual organisations with the reputation and expertise to maintain public confidence in the areas which they regulate.

Cost cutting

18. While we recognise the need to cut the financial cost of regulation, we believe this potential saving should be balanced against the risks associated with any reduction in the quality of regulation that the HFEA and HTA can provide after implementing cost reduction.

19. We understand that both the HTA and the HFEA have made significant efficiency savings since the announcement of the Review of Arm's Length Bodies more than two years ago. We therefore believe any measure of cost reduction should take the end of the financial year 2009-10 as the baseline for cost reduction.

Policy development

20. The consultation document does not focus on the unique position that both the HTA and HFEA fill in developing policy in each of their areas of remit.

21. The HTA has utilised its annual review event to put contentious issues within its remit of regulation under the spotlight. The last three events have covered cord blood donation, organ donation, and tissue for research from post mortem examinations. We believe it is important that these issues are discussed in open forum, and that it is valuable that we have a regulator capable of hosting, mediating and reacting to these discussions.

22. Recent events demonstrate the capability of the HTA to react to policy developments. In advance of the publication of a new framework for the assessment of altruistic donations, the HTA's reaction to a social network site which matches donors was measured and proportionate. This is an illustration of how expert regulators such as the HTA and

HFEA can manage the risk of potentially damaging events with a quick and considered response.

23. The HFEA made the change from case-by-case licensing of late onset conditions to condition-by-condition licensing after a consultation process run in early 2010. This was a discussion of an aspect of the regulation of the delivery of a controversial treatment. The treatment itself had been previously discussed in Parliament. The discussion therefore required careful steering to avoid reopening previously held debates on the ethics of the broader issue of the treatment itself.

24. Though we disagreed with part of the outcome of the review, we applaud the methodology of the consultation process itself, and strongly believe that discussions of policy in these ethically sensitive areas are best hosted by expert bodies such as the HFEA.

25. Indeed, as this consultation ends, the HFEA has been asked by the Secretary of State for Health and the Secretary of State for Business, Innovation and Skills to seek public views on emerging techniques designed to prevent mitochondrial disease. Genetic Alliance UK welcomes the choice of the HFEA as leader of this consultation.

26. Genetic Alliance UK cannot see this excellence in policy development continuing if the HTA and the HFEA are abolished.

Consultation questions

Question 1: Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

27. We believe the HFEA and HTA should retain existing functions.

28. We do not believe the CQC has the expertise to carry out the functions of the HFEA and HTA.

29. We do not believe it would be desirable to lose the HFEA and the HTA as individual regulators with defined remits, as explained in paragraphs 14-17, or as policy developers in their fields, as explained in paragraphs 20-26.

30. We do not believe that it would be desirable to separate any function of the HFEA from the whole, as explained in paragraphs 5-13.

Question 2: Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

31. We believe there is potential for a drop in public confidence in the regulation of the areas currently regulated by the HFEA and the HTA, as explained in paragraphs 14-17 and paragraphs 20-26.

Question 3: Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

32. We believe the ability of the HFEA to carry out its functions as a regulator of PGD is augmented by its function as a research regulator and its sub-committees that inform both process, as explained in paragraphs 5-13.

Question 4: Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

33. We believe the HFEA and HTA should retain existing functions.

Question 5: Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

34. We believe the HFEA and HTA should retain existing functions. Both organisations should be properly resourced to continue regulating their respective areas effectively. Account should be taken of efficiency savings already made since the announcement of the Arm's Length Bodies Review. (Please see paragraphs 18-19)

Question 6: Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

35. We do not take a view on this question.

Question 7: Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

36. We believe the HFEA and HTA should retain existing functions.

Question 8: Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

37. We do not take a view on this question.

Question 9: This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

38. We do not take a view on this question.

Question 10: Do you have any further comments on the consultation options that you would like to share with us?

39. We do not take a view on this question.

Question 11: Can you provide examples of costs and benefits of these proposals?

40. We do not take a view on this question.

Question 12: Do you have any comments on the consultation Equality Analysis?

41. We do not take a view on this question.

Alastair Kent OBE
Director

Response 76 – Wellcome Trust Sanger Institute

27th September 2012

ALB Transition Team
Department of Health
Room 218, Richmond House
79 Whitehall
London SW1A 2NS

Your ref: HFEA and HTA Transfer of Functions Consultation

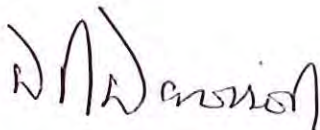
Our Ref/Re: WTSI Response to HTA Transfer of Functions Consultation

Dear ALB Transition Team

Please find attached the response from the Wellcome Trust Sanger Institute to the 'Consultation on Proposals to Transfer Functions from the HFEA and HTA'.

The response was drafted by the Regulatory Adviser in consultation with several Faculty members from the Human Genetics and Cancer Genetics Programmes at the Institute.

Yours sincerely



Mr. David Davison

Director of Corporate Services
01223 834244
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Encl: 1

Consultation on Proposals to Transfer Functions from the Human Fertilisation & Embryology Authority and the Human Tissue Authority

Response from the Wellcome Trust Sanger Institute

Note: This response is focused on those aspects of the consultation that refer to the HTA only.

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

No. In the Executive Summary relating to this consultation, the important role that the HTA has played in ensuring research is appropriately regulated, and in giving both the public and professionals confidence in regulatory areas that are complex, has been acknowledged. This is fully justified and researchers at the Sanger Institute have indicated their satisfaction with the way that the HTA has played its role as regulator.

We agree that dispersing the HTA's functions among a number of different bodies runs the risk of confusion and inconsistencies in professional practice, and our researchers believe that confidence in UK regulation would be reduced by the removal of the HTA - an important and high profile regulatory authority. Confidence takes time to accrue and the transfer of the functions of the HTA to the CQC would require the confidence building process to start again.

The HTA has increased public confidence in the use of donated samples for research; this confidence must continue if research is to progress as it cannot do so with a paucity of samples to study. Researchers at the Sanger Institute agree that the HTA is functioning well, and some had no knowledge of the CQC, thus showing a lower profile for the CQC in the research community than other regulators. Researchers at the Institute were concerned that a larger organisation may lose focus and that their interests may become a low priority, in particular, the CQC's primary responsibility is to hospital patients and people in care, and not in enabling or regulating research.

We would be alarmed if any loss of expertise occurred during the transfer of the functions of the HTA. Currently, the HTA offer excellent, consistent and rapid advice to researchers and administrators, and any loss in the speed or ability to reply to queries posed by researchers could lead to frustration and confusion amongst staff within research institutions.

The HTA should be commended for their willingness to work with other regulators and advisors, as shown by the initiation of Memoranda of Understanding with these other bodies. Training courses attended by the Sanger Institute's Regulatory Adviser concerning the use of human samples in research have been led by HTA, NRES and NIGB staff, and this has

engendered confidence in the messages given at these training courses and illustrated how well the HTA works and cooperates with other regulators. Researchers at the Sanger Institute hope that all these organisations will continue to work closely together, regardless of whether or not the HTA functions are transferred to the CQC.

Researchers at the Sanger Institute questioned the need to abolish the HTA and regarded this as a political exercise, indeed, there has been no account that has stated that the HTA is not fit-for-purpose so the reason for its demise may be viewed as a political 'russian doll', where one authority is placed within another to give the appearance of a reduction in number and to claim financial savings have been made. Our researchers were able to name other arms-length bodies more suited to be abolished and who did not serve such an important purpose as the HTA.

In March 2012, the cross-party Commons Public Accounts Committee branded the CQC's performance as a failure, and the findings raised questions about the organisation's governance, leadership and culture. Incorporating the functions of the HTA into the CQC could blight the excellent reputation the HTA has built up.

One researcher at the Sanger Institute expressed concern that there was a potential for conflicts of interest should the functions of the HTA move to the CQC, which has responsibility for checking that hospitals, care homes and care services meet government standards. This researcher felt that the use of samples in research should be regulated by a body which was independent from one which had oversight of the establishments into which researchers would need to gain access in order to procure samples - conflicts could arise if one authority had responsibility for both the donors of samples and the researchers using them. This conflict may be exacerbated in decisions where diagnostic samples could potentially be used in research.

Researchers do not believe that the autonomy of the HTA functions within the CQC has been clarified – will the CQC have oversight of the HTA functions or lead on and administrate these functions?

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

We can predict that transferring the functions of the HTA to the CQC, with a concomitant loss of expertise, would delay research studies (especially translation projects) and reduce the competitiveness of British biotechnology. As well as the likely 'day-to-day' delays in obtaining information from a larger organisation, there will need to be a 'tools down' period during the transfer of functions which would lead to substantial delays in research projects.

Researchers were concerned that they would lose the good working relationships and contacts that they had made with staff within the HTA, and this would lead to delays in obtaining information as time would need to be spent finding new contacts and building confidence in new staff. Researchers

were also concerned about possible increases in bureaucracy which would accompany the transition to a larger organisation.

Public confidence in the regulation of research using human materials has grown with the establishment of the HTA. Confidence would need to be rebuilt should the HTA be abolished, and it is in doubt that public confidence in the CQC is at a satisfactory level since the BBC filmed abuse taking place in Winterbourne View Care Home, Bristol, last year.

Researchers require a certain amount of time to understand a regulatory system. The HT Act and the associated system of regulation are understood, and researchers are reluctant to learn a new process which could lead to misunderstanding and delays in research programmes and thus affect UK competitiveness. It is imperative that the transfer of functions, if they are to occur, proceed as rapidly as possible in order to reduce any impact on research through licensing delays or a reduction in response times to queries.

Researchers at the Sanger Institute were not familiar with the work of the CQC and some were not aware of the existence of this regulator or what the role of the Commission was. This led to understandable uncertainty regarding the ability of the CQC to engage with researchers and form a sustainable relationship with them. There was confusion about why the research functions of the regulators were being moved into an organisation primarily responsible for patient care.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

We would not want to see any changes which may prevent the HFEA and HTA working closely together, especially in light of the significant increase in stem cell research which is predicted to occur in the future.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

We would prefer the HTA to remain as an autonomous regulatory body, but suggest that if transfer of functions has to occur, consideration should be given to embedding the HTA into the CQC but retaining it as an entity.

The predicted increase in stem cell research will require both the HTA and HFEA to work closely together to effectively regulate studies in this growing area of research. Work of this nature is predicted to rise dramatically over the next few years and regulators should be prepared to deal with the increasing number of studies using stem cell technology. The future escalation of work of this type should be considered now and changes to authorities must react to predictions of where biomedical research may be headed in the future. There was concern that researchers would need to send duplicate applications to regulators for studies using stem cell technology, as it was likely that such

<p>studies could involve the use of tissue samples, DNA and human embryonic stem cells.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>Yes. Sanger Institute researchers agreed that this was their preferred option for the HTA. Expertise within the HTA would be maintained and this was important in order to offer researchers the support they needed. Further explanation as to why this option is preferred has been given above.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>Although Sanger Institute researchers would prefer the HTA to retain its existing functions, if this option was considered impossible, we suggest that consideration should be given to embedding the HTA into the CQC but retaining it as an entity, similar to how NRES has retained its autonomy within the HRA. Under this proposal, the HTA retains its expertise and functions, but savings are made due to overhead costs being shared within the CQC. This option would be less disruptive to researchers seeking licences and information as current links and expert personnel would be maintained.</p> <p>Moving HTA functions wholesale to the CQC could lead to a loss of expertise and, therefore, an inevitable increase in recruitment costs.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>No comment.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>Consideration of costs to researchers has not been included.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>We would like the predicted, rapid increase in stem cell research to be considered with a particular focus on how regulators will work efficiently together and interpret the regulations pertaining to this area of research.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>

No.

11. Can you provide examples of costs and benefits of these proposals?

The cost to competitiveness of delaying projects during transfer of HTA functions has not been included.

12. Do you have any comments on the consultation Equality Analysis?

No.

Response 77 – Anthony Nolan

Anthony Nolan is currently regulated by the Human Tissue Authority (HTA) for its role as a register of volunteer blood stem cell donors, as well as the Care Quality Commission (CQC) for purposes of screening donor samples. Anthony Nolan supports on-going regulation to maintain the high standards and public confidence gained from the outset of the Human Tissue Act.

Of the options presented by the government in its review of the arm's length bodies that regulate our work, Anthony Nolan favours option 3, in which the HTA retains its current structure and role, while delivering further efficiencies.

In terms of financial efficiency, the HTA states that it is already delivering efficiencies which could be at risk if the organisation merged with such a large partner as CQC. HTA has already delivered its "low hanging fruit" in this regard and is able to concentrate on more complicated efficiencies. CQC is at an earlier stage of this process and HTA's gains so far would be lost.

In its statement on the arm's length body review, the HTA commits to realistic efficiency savings, beyond those already implemented over the last two years. We believe these further efficiencies could be delivered in partnership with CQC without the need for, and risks associated with a merger. For example, we believe there should be a joint inspection regime between the two organisations where relevant.

The government cites concern with this option, warning that the delivery of efficiencies may be overlooked in favour of service delivery. While regulation should remain the paramount concern for any existing regulator, Anthony Nolan has experienced proactive coalition working from the HTA with the CQC, aimed at reducing overlaps and regulation burden. We are satisfied that this demonstrates the requisite culture to negate the government's concerns.

Anthony Nolan also believes that the financial gains to be made through implementing options 1 and 2 are negligible in terms of the savings the government is seeking to make through this review. Moreover, option 3 is the only option from which Anthony Nolan is satisfied that current high levels of patient safety and public confidence will remain, as it is the only option which retains the HTA's senior level expertise.

More broadly, Anthony Nolan supports keeping the functions of the HTA together (as outlined in options 1 and 3). We believe this is imperative to maintain the high standards of patient safety in tissue storage and application. A separation of such functions (as proposed in option 2) would require that Anthony Nolan take on further regulatory requirements overseen by the MHRA, at additional cost to the organisation.

Furthermore, we agree with the Department of Health's own assertion that the storage of human tissue and cells for human application does not 'sit well with the CQC.' We are not satisfied that due diligence can be given to regulating the use of human tissue and cells by extending the already broad remit of the CQC. In its short tenure, the competence of the CQC has been tested and questioned. Anthony Nolan believes the

CQC's remit should not be extended (as proposed in option 1) until it demonstrates strong management of its current role and can win the government's own support to regulate bone marrow donation.

We are concerned that HTA will be overwhelmed by CQC. The knowledge required at a senior level is very different from that at CQC and we are not clear that the CQC board, however it is made up, will ever prioritise learning about the law and practice around the use of tissues and cells when it has such large volumes of work in other fields. Similarly, if tissues and cells become a "niche" area of work for CQC, it is hard to envisage it ever becoming a priority for time spent at a senior level and at board meetings, except reactively in the light of adverse events.

It is Anthony Nolan's view that high standards of public confidence and patient safety can only be maintained through implementing option 3 – to retain the HTA as a separate organisation, but which delivers further efficiencies. Due to this, substantial concerns regarding the capability of the CQC to take on further regulatory responsibilities (proposed in options 1 and 2) and to reticence to take on additional regulatory requirement (option 2), Anthony Nolan supports option 3.

Answers to consultation questions

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Anthony Nolan does not agree with Option 1. The Department of Health has outlined its aims as a result of reviewing Arm's Length Bodies – most pertinently, to maintain patient safety and public confidence, retain high ethical standards, while delivering savings in the government's administrative costs. Option 1 appears incongruous with all of those aims.

Despite a transition period of three years, Anthony Nolan has strong doubts that the CQC would be prepared to take on responsibility for the HTA's current function during that time. The CQC already has a large remit in regulating healthcare providers. In its three year tenure, the CQC has suffered some high profile failures in carrying out its task. In the interest of maintaining public confidence, Anthony Nolan recommends that the CQC improve regulation under its current responsibilities before a broader remit be considered.

The potential for a major oversight is further compounded by a loss of expertise, together with the reduction in focus. An organisation as large as the CQC would not be able to provide the same level of scrutiny to the use of human tissue and cells as it currently enjoys under the HTA. Furthermore, the CQC is unlikely to allocate one of their seven board positions to provide expertise on what will be such a small area of work. Sector knowledge and scientific knowledge will be lost. But the most important facet here is that accountability will be lost.

Anthony Nolan also casts doubt over the scale of savings that can be made by abolishing the HTA. The consultation document outlines savings of approximately

£3.7m to be made over ten years as a result of abolishing the HTA, against a cost to the government of £800,000 in 2010/11. In balancing the savings to be made with the potential risks to the quality of ethical standards, the savings appear negligible.

In addition, the consultation document has not outlined the short term costs in executing a transition stage, for consideration in this context, nor the costs to the CQC in acquiring the new skills, knowledge and extension of focus that the consultation document outlines as necessary. Nor are the long term costs outlined of coalition working with the devolved nations and the HRA, which the Department acknowledges as necessary under this option. Without these figures, Anthony Nolan believes that this option has not been subject to adequate scrutiny.

For the above reasons, the Department of Health itself concedes in the consultation document that the regulation of bone marrow and peripheral stem cell donation does not sit well with the CQC. Anthony Nolan agrees with this assertion and disagrees with the government's recommendation that option 1 be implemented.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

No comment.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No comment.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

The consultation document suggests the licensing of human tissue and cells for research purposes as one such function, which is the only suggested separation affecting Anthony Nolan's work.

We do not agree that this activity would sit better with another organisation (MHRA being the organisation stipulated) other than the CQC, in the event of a transfer from the HTA.

Anthony Nolan is currently regulated by the CQC for some of its functions; by transferring this function to the MHRA, it would require that the organisation seek additional licensing. As one of the primary objectives of this exercise is to reduce government spending, Anthony Nolan objects to the notion that this merely be passed on to the regulated organisations.

More generally, Anthony Nolan does not agree with the proposal that the HTA's functions be separated. This measure is costly, fails to retain the HTA's expertise, which in turn puts in jeopardy the safety and ethicality of treatment with, and research into, tissue and cells.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Option 3 is Anthony Nolan's preferred option. In terms of meeting the government's primary objective to ensure the safety and ethicality in treatment and research, this option is the best way to meet said goal. The HTA has a strong track record of upholding the ethical safeguards enshrined in legislation.

Furthermore, in terms of meeting the objective to make financial savings, the HTA has reported 27% efficiencies made in the last two years and 34% since the ALB review was announced.

The Department of Health cites concerns that, by continuing with the proposed structure of regulation, the existing bodies would become engrossed in executing their roles, without considering how to reduce overlaps between them, or deliver further efficiencies.

Anthony Nolan's experience of HTA as one of its regulators negates this view. After enquiring as to areas of overlap between the CQC and the HTA with particular reference to our work, the HTA provided us with a full break down of responsibilities and overlaps of the two regulators. The HTA also offered to consult with the CQC, demonstrating a willing for coalition working, without any duty to do so. Anthony Nolan has confidence that the HTA would continue with this approach to its clients and fellow regulators, should option three be implemented.

Furthermore in their statement on this consultation, the HTA commits to delivering further efficiencies, assuming they are of a realistic level and achievable level. The HTA have requested feedback from Anthony Nolan on their methods, with a view to modifying them to make additional savings. This demonstrates a commitment to the efficiencies required by implementing option 3, but without safety and ethics being compromised.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Anthony Nolan agrees that the HTA could deliver further savings. According to their statement, the HTA has identified small areas of their work where efficiencies could be made. These would be in addition to the 34% savings since the ALB review was announced.

Those areas include streamlining regulations, which would have the additional benefit of passing savings on to those they regulate, together with reviewing their structure.

The HTA has asked for Anthony Nolan's feedback in how they could provide greater value for money, as opposed to simply reducing cost.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Anthony Nolan is currently the subject of several inspections by accreditation bodies, to meet standards and gain the relevant industry accreditation. We suggest that the HTA consider accepting these accreditations as a means by which to gauge whether regulations have been met, contravening the need for additional regulation. Specifically, this could eliminate the need for the HTA to regulate testing facilities.

Some organisations have cited concerns with the notion of substituting regulation for accreditation. However the HTA has previous experience of mapping standards alongside accreditors, ensuring a high level of rigour in the accreditation process. Anthony Nolan is satisfied that this presents a viable option of a function which could be transferred.

Anthony Nolan suggests that the JACIE method of accreditation is one such body which could take on one of the HTA's functions; JACIE promote high quality patient care and laboratory performance in haematopoietic stem cell collection.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

Anthony Nolan believes that the £3.8m saving, to be made over ten years, is negligible in terms of the savings the government hopes to achieve by reviewing arm's length bodies, particularly in terms of the risks presented by transferring functions to the CQC.

Additionally, Anthony Nolan believes that the Impact Assessment for Policy Option 3 should include details of the efficiency savings already made by the HTA and HFEA in recent years. This, together with a schedule of savings the HTA and HFEA would be expected to meet if Policy Option 3 were to be pursued, would give the regulators and their regulated bodies greater insight into the viability of Option 3, improving the evaluation exercise.

No comments for the remaining questions.

Response 78 – Royal College of Physicians

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 26,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The RCP is grateful for the opportunity to respond to the above consultation on the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). We will predominantly address the implications of the proposals for health research. The UK is a world leader in this area and must ensure that it retains this position. We welcome the formation of the Health Research Authority, which will help to deliver this aim and we support the government's ambition to simplify the regulatory landscape, including by reducing the number of arm's-length bodies where necessary. Health research is a core function of the NHS and underpins improvements in the prevention, diagnosis and treatment of diseases, as well as acting as a key driver of economic growth. Research must be subject to proportionate regulation, which appropriately balances risks with the capacity to progress our understanding and practice, and ultimately improve patient care and standards – an ambition which is also at the heart of the RCP's mission.

The RCP's views are most closely aligned to the proposals outlined in option 3 of the consultation in which the *'HFEA and HTA retain their functions but deliver further efficiencies.'* We would stress that this should not simply involve continuing with the current system, but must instead be underpinned by further efforts to streamline research regulation and governance, combined with closer collaboration between the HFEA and HTA, as well as with other relevant bodies, including the Care Quality Commission (CQC), Health Research Authority (HRA) and Medicines and Healthcare Regulatory Agency (MHRA). We understand that many of the views of the medical research community are also most similar to option 3. We would highlight, in particular, the series of measures set out by the Academy of Medical Sciences, which would deliver greater streamlining and improved regulation without formally disbanding the HFEA or HTA and therefore losing the valuable roles delivered by these organisations.

The strengths of these organisations

There is great value in retaining organisations that are subject to clear professional and public confidence. The HFEA and HTA differ in their regulatory approaches, but the research community is generally very positive about the functioning of both organisations:

- They are widely recognised to be effective regulators that have developed strong expertise and significant experience.
- The advisory role associated with the inspections carried out by both these bodies is valued by the research community.
- Researchers value the support systems that have been established by the HTA and the risk-proportionate approach it takes to its work, according to the terms of the Human Tissue Act (2004).
- The HFEA is recognised internationally for its operation in, and regulation of, an often sensitive and complex area. In particular, the HFEA:
 - has achieved important continuity between clinical practice and research.

- not only facilitates research, but also helps to deliver efficient translation of research into clinical practice.
- has established strong communication channels with patients, the public and the media on sensitive issues such as fertility treatment and research.
- is a valued source of evidence-based advice and policy on such issues.
- applies its expertise to respond swiftly to the evolving environment.

The proposals

Transferring the regulatory functions of the HFEA and HTA to the CQC would see the CQC take on new areas of regulation, for which it would need to acquire new skills and expertise. The nature of the HFEA's work, in particular, is scientifically and ethically complex. However, there are strong messages that the CQC is not currently in a position to take on the functions of either body. Such concerns emerged from the National Audit Office in December 2011¹⁶ and have since been echoed by the House of Commons Committee of Public Accounts (March 2012).¹⁷ Moreover, the CQC itself has stated that it does not wish to take on these functions and that it is working with the HFEA and HTA to achieve greater efficiency, for example through shared back office functions.¹⁸

The operation of the CQC also differs from that of the HFEA and the HTA. Acquiring the skills and expertise to take on the new functions would likely entail making significant internal changes within the CQC, such as creating new sub-committees or working groups. This could have significant cost implications, which are not analysed in the consultation; equally, the cost of the disruption to services during the transition is also not assessed. Such changes may in turn impact on the CQC's ability to work as an efficient and effective regulator and to improve its performance. As highlighted above, the CQC has been subject to significant criticism and it should be given the opportunity to respond to these particular criticisms before being asked to significantly expand its remit. These issues are compounded by the challenges presented by the differing geographical remits of the HFEA, HTA, CQC and HRA due to the devolution of powers.

We are aware that specific issues have been raised in relation to the regulatory processes overseen by the HFEA and HTA. Where particular problems have been identified, they should be addressed directly. We do not see that significant structural changes would target these issues and could, in fact, distract from efforts to deliver solutions or could even increase costs.

Regarding the HFEA in particular, we believe that the benefits of keeping its functions together outweigh the risks of separating them between the CGC and HRA. The continuity between clinical practice and research is a helpful aspect of the HFEA's work and has been an important factor in the HFEA's success in facilitating the efficient translation of research into clinical practice. If these functions of the HFEA are separated, it could be detrimental to future translation efforts. In addition, this continuity underpins the HFEA's system of gaining consent for the use of embryos in research. Because it regulates both research and treatment, the HFEA is better able to ensure that individuals receive appropriate information from competent persons, which facilitates their making an informed decision about whether they will donate their embryos for this purpose. There is a risk that the ethical and legal framework

¹⁶ National Audit Office. *The Care Quality Commission: Regulating the quality and safety of health and adult social care*. London: TSO, 2011.

¹⁷ House of Commons Committee of Public Accounts. *The Care Quality Commission: Regulating the quality and safety of health and adult social care*. London: TSO, 2012.

¹⁸ House of Commons Health Select Committee annual accountability hearing with the Care Quality Commission, Tuesday 11 September 2012. *Uncorrected transcript of oral evidence, HC 592-i. Questions 129-135*. www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm

that the HFEA has established for this process could be weakened if these functions are separated. This continuity also underpins the HFEA's role as a single and trusted source of information and advice to patients and professionals, as well as its position as a source of evidence-based and expert policy advice.

Creating the HRA is an important step towards achieving more streamlined regulation and governance of health research and it is currently establishing good relationships with key organisations. However, this organisation is still less than a year old and, although we welcome the commitment to establish it as a non-departmental public body, it is yet to be established in primary legislation. It is still in the process of building capacity to take on and develop its various functions around ethical approvals and confidential patient information. We are therefore concerned that the HRA does not currently have the expertise to assess research applications. In addition, we are not convinced that should it be asked to take on this role, it would receive sufficient resources to do so to a similar standard as currently achieved by the HFEA.

Nonetheless, should the government decide to disband the HFEA and HTA, we would support the research functions of the HFEA being transferred to the HRA, rather than the CQC. Expertise in research is of paramount importance here and the HRA would need to receive sufficient resources to acquire adequate skills and experience to successfully take on these functions.

Moving forward

The RCP supports the government's efforts to make cost-savings, but would stress that potential savings must be balanced with the value that both the HFEA and HTA deliver, which could be lost if they are disbanded. It should also not be forgotten that health research can deliver cost savings in the long term. Therefore ensuring that the UK has an environment conducive to research, through streamlined regulation and governance with efficient approvals, will deliver not only patient benefits, but economic benefits as well.

There are examples of duplication and the need for streamlining within the system, which should be resolved to reduce the burden on establishments including research institutions and to help deliver efficiency savings. We commend the HFEA and HTA's efforts to achieve cost-savings and would stress that wherever the functions of these organisations sit, adequate resources must be provided for these functions to be delivered to a high standard that maintains public confidence. We welcome the moves by the HTA and HRA to streamline research approvals and this should be supplemented by greater cooperation between the HFEA and HRA. We also welcome the work of the HTA and MHRA to streamline inspections to reduce the burden on those establishments being inspected and to deliver cost savings. Further savings could be seen through moves to streamline inspections among other organisations, including the HFEA.

We would stress that our position is based on current circumstances. While the changes outlined in the proposals would not come into effect until 2015, we are not convinced that this provides sufficient time for the CQC, in particular, to develop adequate capacity to take on these additional functions and, further, that its efforts to manage the transition and subsequently undertake those functions could distract it from its core functions and from its efforts to make operational improvements elsewhere. We welcome, however, the Cabinet Office's ongoing review of the status of arm's length bodies and support the regular review of the functions and arrangements around the HFEA and HTA.

We are aware that some concerns exist around the Human Tissue Act (2004) and support calls for an independent review of this legislation to explore whether the burden of regulation on research could be further reduced.

Yours faithfully

A handwritten signature in black ink, appearing to be 'A. C. C. C.', written in a cursive style.

Registrar

Response 79 – Individual

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Response on HFEA only:

No. CQC is too large an organisation to retain the dedicated focus and expertise that the HFEA has on human gamete. Very simply the issues that are so important to fertility patients, donors and the child conceived through ART will be lost in the CQC.

The CQC does not currently have a good reputation and would not inspire the confidence of a potentially vulnerable group of people who are dependant upon the HFEA for effective regulation.

The CQC also does not have a UK wide remit and as a Scottish citizen I would not want an English body to regulate this sensitive area. The consultation is lacking in the implications for the devolved administrations and does not appear to have considered how this will be implemented and the associated costs of doing this.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

HFEA –

The proposal to abolish the HFEA does not appear to have the interests of patients and the donor conceived at its heart. This is a potentially vulnerable group of people that society (and Parliament) have decided should have additional support. The proposals in options one and two do not provide the confidence that the needs of those using or being created by ART will be met.

For donor conceived children there needs to be confidence that their information on the register will be securely held until they need it – potentially tens of years into the future. At the point of requesting this information there needs to be expert advice to support them. This will not happen within a large organisation such as the CQC. The HFEA prioritises the needs of the donor conceived and has a body of knowledge and experience within its staff and Members that enables it to make sensitive decisions about supporting them.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

No. There is benefit from retaining the functions together so that the expertise is retained in one organisation and the knowledge gained from embryo research and licencing is utilised by the organisation making policy and licencing decisions.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and

what do you see as the advantages of the alternative organisation?

HFEA:

No. There is benefit from retaining the expertise in one organisation. This is a specialist organisation that is more than the sum of its parts. Expertise in licensing influences policy making and regulation. If the parts were split up there would be a loss of the joined up policy making that exists and enabled the donation review to be undertaken last year that took into account the needs of donors, patients and the donor conceived but also was responsible for the implementation of the policies so worked with clinics to understand their needs as well.

Transferring policy making to Department of Health (DH) would probably costs more, not be undertaken with the rigour that it is currently or would not happen because it was of lower importance (particularly in times of other challenges in health).

It would not have the independence that reviews undertaken by an arms length body provides so would be subject to greater ministerial interference and would therefore not have the confidence of key stakeholders. From the perspective of Ministers, there may be difficult or controversial decisions that they would not want to make that are more politically acceptable to be made by another organisation.

As a parent of donor conceived children I do not want the Registry with their details to be held by DH. I do not have confidence in their ability to secure this information and hold it in trust until my children are ready to access it. At this point I want someone who is trained and experienced at dealing with these requests – and understands the profound importance and implications of this information to them - to respond to them. I do not have the confidence in DH – or another large, generalist organisation – to provide this level of support.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

HFEA –

Yes. The HFEA is a specialist organisation that places the protection of the embryo, patients, donors and the donor conceived at the core of what it does. It has the expert knowledge gained through the sum of its parts (licensing, information provision, policy making and maintaining the register) to support those that it regulates and supports.

It is not perfect and there is the potential to make changes and possibly savings but there is no need to dismantle this specialist organisation.

The savings to be made from structural changes to the HFEA are infinitesimally small in the scale of DH budgets and are not worth the potential harm to vulnerable members of society that successive governments have committed to support. The breach of this trust is not to be taken lightly.

Given the experience of other structural changes the transition costs appear to have been substantially under-estimated and could possibly make this a very expensive

<p>exercise that would end up costing more than it would save.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.</p>
<p>HFEA –</p> <p>The DH grant to the HFEA is very small as the HFEA is predominantly funded through treatment fees. Removing the functions of the HFEA and placing them with another organisation (that will have to meet all of the same statutory functions) will not save significant amounts of money.</p> <p>It is not worth the risk and the potential cost of something going wrong. The Assisted Reproductive Technology sector is one that the public has great interest in and would be very quick to criticise the government if there were interests and problems resulting from the CQC's lack of expertise or ability to handle incidents in centres or loss of patient information. The political cost of this is much greater than the potential savings from merging a small ALB.</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>HFEA</p> <p>No. Retain the functions as they are so that the cumulative effects of knowledge and experience of licensing, policy making, information provision and managing the register are retained. It is greater than the sum of its parts.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?</p>
<p>The transition costs appear to be very low and understate the real costs involved in an organisational restructuring such as this.</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>No. Implement option three.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us?</p>
<p>I'm surprised that the Scottish Government has not explicitly provided input and comment on the implications for Scottish centres.</p>
<p>11. Can you provide examples of costs and benefits of these proposals?</p>

The costs or timescales involved in importing an English regulator into the devolved administrations has not been taken into account.

The political costs and consequences of doing this if there is a significant incident in a Scottish centre (that the CQC manages badly) in the run up to the independence referendum in Scotland could be extremely high.

12. Do you have any comments on the consultation Equality Analysis?

No.

Response 80 – Right to Life

The following is the submission of Right To Life (RTL) to the Department of Health's Consultation on proposals to change responsibility for regulating fertility treatment and human tissue.

1) Areas of Concurrence with Reform Intentions

1.1 RTL concurs with the intentions and aims of the proposed reforms under question:

a) Simplification of Regulatory Bodies and Bureaucracy:

Since over time there has been an increase in the number of quasi-autonomous bodies, and an rise in the complexity of their workings, it is opportune now to improve the efficiency and render more simple these institutions and heir functions. The nascence of the Care Quality Commission (CQC) and Health Research Authority (HRA) is thus to be welcomed in this light.

b) Improved Efficacy of Regulation in the Areas Overseen by Current Bodies:

The development of new and advanced reproductive technologies and procedures prompts the necessity to guarantee properly efficacious legal protections to the safety of individuals and society.

c) Perspicuity with regards to Current Rules affecting Service Providers:

A consolidation of the functions of current regulatory bodies in fewer organisational structures allows for such institutions to give a clearer idea of their purpose and activities with service providers, and may allow for appropriate reduction in unnecessary rules or oversight.

2) Democratic Executive Action

2.1 Given the profound ethical concerns raised by new and advancing assisted reproductive technologies, regulatory procedures concerning such developments must be assisted and informed by ethical debate and consideration that possesses both clarity in its operation and democratic accountability. This should also have a breadth of representation when it comes to bioethical thought. This competence, and the improvement thereof, is of primary and fundamental significance, which can be served well by the abolition of the HFEA.

2.2 In the report of the Parliamentary Joint Committee on the Human Tissue and Embryos (Draft) Bill, Sir Ian Kennedy is quoted as saying that "in all such amalgamations history tells us that very often you go back to ground zero"¹. Due to the HFEA's history of carrying out important decisions of a political and ethical character and relevance without the adequate ethical competence or democratically endowed mandate to do so, functional transferral and abolition *could* be a deeply positive occurrence *if it resolves these problems*.

2.3 The HFEA has failed to regulate new developments adequately, and possesses an apparent greater concern to enable scientific research, even in the absence of appropriately serious consideration of differing ethical concerns, philosophies, and submissions. The lack of any minority reports from the commission often reflects the unanimity of its decision-making, which shows a lack of internal debate.

2.4 The central purpose of the 1990 HFE Act was “the special status of the embryo means regulation of both research and treatment continues to be appropriate and desirable. In addition we recognise that regulation of IVF treatment provides assurance and protection to patients”². The primary *raison d’être* of the HFEA is the maintenance of respect and protection for the human beings *in embryo*.

2.5 Baroness Mary Warnock has subsequently expressed her regret over the use of the phrase “respect for the embryo” which she perceives as leading to certain absurdities³. In response, the House of Lords Committee stressed the respect with which embryos must be treated by ensuring that “research on embryos is carried out only if there is no alternative available and it is necessary or desirable to achieve one of the permitted purposes”; thus, on this basis the HFEA must decide whether embryo research is warranted. This admirable requirement is even more noteworthy when one considers that since 1999, when a central record of licence committee decisions has been maintained, the HFEA has refused only one application for a research licence. This refusal was then accepted upon appeal⁴. In defence of the HFEA, it has been argued that they have worked with applications to ensure that the necessary requirements were fulfilled. Consequently, submission of project applications which would not be considered suitable for licensing tends not to occur⁵. There are two perspectives from which one can view this assertion. On the one hand, one can see this as effective regulation in action helping to direct and control scientific advancement within a defined framework. Alternatively however, it can be considered to make a mockery of any form of regulatory control, given that it is in reality merely adapted to suit the needs of the science research community. Working with science is necessary and essential, but surely if regulation were effective, objective, and disinterested, there would be a fair share of applications being accepted *and* rejected?

3) HFEA Membership and Operational Consequences

3.1 The composition of the HFEA does not properly represent the wide spectrum of views within society. Eighteen members of the HFEA are selectively appointed to only represent certain views, and they have too much discretion to act, without consulting Parliament, in the important area of human reproductive technologies.

3.2 The Warnock Report commended that “if the public is to have confidence that this is an independent body, which is not to be unduly influenced by sectional interests, its membership must be wide-ranging”. The unfortunate

and unacceptable reality, is that the HFEA has excluded from its membership those who wish to protect the embryo.

3.3 The HFEA is an unelected body set up to implement the regulations of the 1990 HFE Act, and therefore fulfils an undemocratic mandate. This point was made all too clearly when the then Chair of the HFEA, Baroness Deach, suggested to the House of Commons Science & Technology Select Committee that the HFEA was making ethical decisions to save Parliament direct involvement. In reply, Bob Spink MP questioned the Baroness's reply, saying "How can it be democratic if you are preventing the democrats, the Members of Parliament who are elected to make difficult decisions on behalf of society as a whole, and protecting them from having to make such complex, fundamental decisions?".⁶

3.4 Both the Houses of Lords and Commons, as the lawful legislative and deliberative bodies of the United Kingdom, should be more involved in the decisions of the HFEA.

4) RTL Recommendations for Future Policy

4.1 RTL argues that the HFEA, or whatever future equivalent body is given its present functions, should include individuals who represent varying different bioethical viewpoints. Not only would this better reflect society, but it would enable genuine debate and more thus more properly rigorous regulative oversight, which is precisely the purpose of having such bodies, with such functions, in the first place. If this is not achieved, the impotent unanimity that has characterised the operations of the HFEA will only be perpetuated, and any new body will continue to fail to represent the diverse opinions within British society, even as it makes decisions on behalf of that society.

4.2 New solutions and alternatives to embryonic research should be actively and seriously considered both on ethical grounds, as well as efficiency. Given the relative costliness (and thus far unproven research value) of embryonic research, a proactive and critical approach would be appropriate to take up and adopt. Moreover, the HFEA or any alternative body should take it upon itself to help ensure that the general public are better informed about the issue with which it deals, and more engaged in the decision-making process relating to what should be considered ethically and practically acceptable. This should involve regular and thoroughgoing consultations.

4.3 RTL believes that licensing and inspection responsibilities should remain within the remit of the HFEA or any alternative future body. However, with regards to the regulation of any new biological or reproductive technologies and techniques, this should involve to a far greater extent the consultation of expert opinion, engagement with the general public, and the democratic representatives of Parliament. This would require a different way of working than that to which the HFEA has hitherto engaged.

4.4 The demise of the HFEA allows for the opportunity to create an alternative National Bioethics Committee, with the sort of inclusive membership mentioned above, and whose function would be to advise the democratically-

elected Government on the ethics of new developments, rather than create policy.

¹ House of Lords House of Commons Joint Committee on the Human Tissue and Embryos (Draft) Bill Session

2006–07. Human Tissue and Embryos (Draft) Bill Volume I: Report. p.27, para. 67.

<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169.pdf>

² House of Lords House of Commons Joint Committee on the Human Tissue and Embryos (Draft) Bill Session

2006–07. Human Tissue and Embryos (Draft) Bill Volume I: Report. p.34, para. 105.

<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169.pdf>

³ Stem Cell Research: Select Committee Report, HL Deb 05 December 2002 vol 641 cc1311-53, 1327

⁴ Hansard (2008), Reply to House of Commons Written Parliamentary Question tabled by Jim Dobbin MP and

answered by Minister of State for Public Health, 29th January 2008, (2007-08), col. 342

<<http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080129/text/80129w0037.htm#080130300005>

0> [accessed 14th September 2012]

⁵ Hansard (2008), Reply to House of Commons Written Parliamentary Question tabled by Jim Dobbin MP and

answered by Minister of State for Public Health, 29th January 2008, (2007-08), col. 342

<<http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080129/text/80129w0037.htm#080130300005>

0> [accessed 14th September 2012]

⁶ <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmsctech/791/2042402.htm>

Response 81 - GE Healthcare

Corporate response on behalf of GE Healthcare, compiled through discussion and consultation with the company's scientific, business and public policy experts that work in business areas whose activity is in part regulated by the HFEA and HTA.

About GE Healthcare

1. GE Healthcare welcomes the opportunity to contribute to this consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).

2. GE Healthcare provides transformational medical technologies and services to researchers, pharmaceutical companies, the life sciences industry and healthcare providers around the world. Our broad expertise in drug discovery, biopharmaceutical manufacturing, medical imaging and IT, medical diagnostics, patient monitoring systems, and performance improvement services help our customers to deliver better care to more people around the world at a lower cost. Headquartered in Chalfont St Giles, Buckinghamshire, GE Healthcare employs 46,000 people worldwide.

3. GE Healthcare's preference is for Option 3 with the HFEA and HTA retaining their functions and delivering further efficiencies. For reasons outlined below, we believe the risks inherently associated with the abolition of the HFEA and HTA in Options 1 and 2, considerably outweigh the proposed benefits.

Consultation Question 1: Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

4. In the current climate, the NHS has to deliver £20bn in efficiency savings by 2015 and we understand that Government must look at different ways to cost-effectively reduce the burden of unnecessary regulation. While GE Healthcare does not comment on the organisational design of bodies that regulate areas in which it operates, we do maintain that it is critical that regulation be robust, appropriate, transparent and efficient, and that its implementation and operation be informed and supported by the necessary specialised scientific knowledge and experience. During periods of organisational change or transition, it is critically important that this expertise does not get lost or diluted and that the credibility and competence of the regulator remain intact.

5. GE Healthcare is concerned that Government's preference for "Option 1" (HFEA and HTA be abolished with all functions transferred to CQC, except HFEA research-related functions, which would transfer to the HRA), will return relatively small financial savings at considerable risk. It could lead to a loss of expertise, efficiency and effectiveness and a less competent regulatory landscape for two areas so important to the success of the UK's health and bio-science industries.

6. The HFEA and HTA fulfil important roles in regulating the work in the field of embryo and tissue research. Over the last twenty years the UK has developed a world class regulatory system which has public and professional confidence. Transferring the functions of these organisations to the Care Quality Commission (CQC), the regulator for health and social care services and the Health Research Authority, a newly established organisation, could jeopardise this.

7. The technical and ethical challenges that the use of human embryos or tissues can raise are extremely complex and require specialised scientific knowledge and experience in fields at the cutting edge of science. Any regulator in this field needs the clinical, research and commercial communities whose work it regulates to be confident in its capabilities and expertise.

8. The risks we have identified include a possible impact on the regulating body or bodies' ability to safeguard patient safety, and effectively monitor that research is conducted with the highest ethical standards. Furthermore, disturbing the current effective regulatory environment could act against Government's commitment and support of the life sciences industry as outlined in its recently published strategy for life sciences.

9. We are concerned that the Care Quality Commission (CQC) as the regulator for all health and social care services will not have the necessary resources or expertise to carry out the additional duties if Options 1 or 2 are adopted. We are concerned that if the CQC adopts the regulatory functions of the HFEA and the HTA, the effect would be a dilution of the existing regulatory framework.

Consultation Question 5: Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

10. GE Healthcare's preference is for Option 3 where the HFEA and HTA retain their functions but deliver further efficiencies. As outlined above, the abolition of the HFEA and HTA could hinder progress and investment in research and development in life sciences in the UK and could adversely affect the country's reputation as global leader in the emerging bio-science and medical fields these bodies regulate.

11. In GE Healthcare's experience, as a major commercial organisation that operates in areas regulated by both the HTA and HFEA, we have found both these regulators to be efficient, knowledgeable, transparent, and above all extremely helpful to us in our maintaining compliant operations.

12. Any dilution of the already well-established and respected regulatory system could hinder the development of areas of research which rely on the use of human embryos and tissues. We urge Government to ensure that it considers this in conjunction with its approach to supporting the UK's life sciences industry.

Consultation Question 6: Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

13. The HFEA and HTA receive about 80-90% of their funding from licence fees and therefore receive little by comparison in funding from Government. We support the HFEA and the HTA in their cost reducing exercise and believe they should be encouraged in their effort to deliver savings to the public purse whilst ensuring they have the necessary resources to carry out their regulatory functions. We are assured that these organisations have already made significant cost savings and are continually looking at ways to reduce unnecessary regulatory burden and duplication. For instance the HFEA is now located in the CQC and shares back office functions as well as other resources with the HTA. Furthermore, the HFEA has consolidated its senior management team and proposed further efficiency savings.

14. If the functions of the HFEA and HTA were retained, other models of revenue generation could be explored to reduce the direct cost to the public purse. For example, a small portion of funds being channelled into relevant areas of research could be rerouted to provide

support for constructive regulation. As Government invests in new science and technology to ensure the UK's continued place at the forefront of global life sciences research, development and commercialisation, a commensurate focus on good regulation of emerging technologies and therapies is crucial to ensure the continued safety of patients and delicate reputation of these sometime controversial fields.

Consultation Question 7: Within the option of retaining functions with the HFEA and HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

15. The HFEA and HTA operate at the boundary between the latest cutting-edge research and the implications of those new discoveries for the clinic. In our view, the functions and responsibilities of both organisations are too complex, both scientifically and ethically, for them to be successfully replicated within another regulator such as the CQC. This is for a range of reasons including the level of scientific and ethical expertise in the organisations, the national and international respect these bodies command from the professions and patients but also the competitiveness of the UK in this field.

16. The HFEA and HTA have been responsible for creating a robust regulatory environment allowing for the safe and responsible development of fertility and human tissue-based research in the UK. As a result, the UK is acknowledged as a leader in this specialised area of Life Sciences. We would urge the Government not to do anything that may jeopardise that.

Consultation Question 8: Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

17. GE Healthcare is a global organisation with a reputation for effective change management. The projected £3.9million saving over a ten year period is marginal compared to the potential problems we foresee in abolishing the two highly effective organisations and transferring their functions to what could be a less competent authority. Furthermore, it does not take into account the costs of delivering the organisational changes required were HTA and HFEA functions to be transferred elsewhere.

18. We urge the Government to re-evaluate its preferred position.

Response 82 - Human Tissue Working Group, University of Bristol

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

We do not agree with the transfer of HTA functions to the CQC and HRA.

The HTA has achieved a high level of trust and confidence by the public and other stakeholders. The delivery of greater synergy and cost effectiveness through the transfer of HTA to CQC is questionable as the CQC is a large, diverse and remote regulator while the HTA has performed exceptionally well as one of the most recently established regulators.

On an ongoing basis the HTA has demonstrated efficiencies, savings and effectiveness through the organisation whilst supporting stakeholders in a positive culture of development and the sharing of best practice, while implementing a complex set of regulations, spanning the Human Tissue Act 2004, the Human Tissue (Scottish) Act 2006 (at least for human application) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

In our experience the HTA has fostered successfully working relationships with all the sectors covered by the HT Acts and the Quality & Safety Regulations. The result is that the sectors are regulated in an atmosphere of trust, which was so important and so difficult to build following the Bristol and Alder Hey incidents.

We recognise that NHS organisations have experience of working with the CQC, however this is not the case for Higher Educational Institutions (HEI). From a HEI perspective the fact that each licence has a 'Designated Individual' (DI) with responsibility for 'policing' that licence and the introduction of 'Persons Designate', staff with daily responsibilities around the preparation, storage and disposal of parts, has been welcomed by all stakeholders. Compliance with the HT Act is considered one function within the University regardless of the sector that is regulated.

We have concerns that the CQC does not currently have the expertise to take on all the functions of the HTA and would not be able to provide the support and guidance for licence holders to the standard that is currently delivered by the HTA. There is a real danger that HTA expertise would be diluted to the detriment of all those who are currently regulated by the HTA.

If the regulatory functions would be split between regulators there is concern that this would open up significant potential for confusion, unintentional errors and additional bureaucracy that would completely defeat the Government's aims to reduce administrative burden, especially where a licence currently covers activity across multiple sectors (e.g., human application, research, surgical training).

2. Can you quantify what impact this could have at a local level (either in

relation to service providers or patients or both)?

The possibility of having to deal with more than one regulatory authority will substantially increase the administrative and bureaucratic burden on organizations currently regulated under the Human Tissue Act 2004.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

We cannot comment specifically about the HFEA.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Not for HTA functions. We can see absolutely no reason to distribute its functions to other regulatory bodies.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Our preferred option is option 3, to retain the HTA as an independent regulator. In recent years the HTA have made tangible and transparent efficiencies that have been passed onto the Licence Holders. E.g. reduction in licence fees, rebates on previous fees paid in previous years, and a pilot of themed inspections. This is not something that has not been seen by other regulators

We believe that the way forward is to foster closer working relationships between the CQC, HRA, MHRA, HTA and HFEA. In this forum specific action plans for the delivery of further efficiencies can be tested and developed while aligning working practices.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

While delivering savings to the public purse is important, by far the more important consideration is the effectiveness of these organizations' regulatory activities. Public and professional trust and confidence come not so much from how cheaply regulators operate but by how effectively they operate.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Our preferred option is option 3, to retain the HTA as an independent regulator. Therefore in our view we would not want to see any functions transferred elsewhere.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying

consultation Impact Assessment?

While we acknowledge the potential savings as stated in these paragraphs we would be concerned about the additional cost that might be incurred by each sector arising from a split in the regulatory functions and more complex regulatory frameworks that would then govern the work with human tissue. In addition there is an as yet indefinable cost to regulatory effectiveness, public and sector confidence and workload to those already working well with existing well-functioning frameworks.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

We firmly believe that the HTA performs effectively and that there is therefore no need to transfer its functions to other regulators.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

The HTA has fostered a regulatory approach that has come away from silo thinking and enhanced collaborative working and sharing of best practice in the four standards of licensing across all sectors, while achieving regulatory compliance that has public confidence.

11. Can you provide examples of costs and benefits of these proposals?

See previous comment on the benefits offered by retaining the HTA as is, and earlier comments re cost savings already made by the HTA.

12. Do you have any comments on the consultation Equality Analysis?

No comment

Response 83 – The Academy of Medical Sciences

Summary

1. Health research underpins the prevention and treatment of ill health and brings benefits across the UK population. To ensure that maximum benefits are delivered it is essential that the regulation of health research should be proportionate to the risks and benefits to individuals and society. It is also vital that stakeholders have confidence in the regulator. The Academy's response focuses on the research functions of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA); however it also takes into account clinical practice where it has a close relationship with research.

2. There is a great deal of support among our community for the HFEA and the HTA; both are perceived as having developed the experience to respond in a balanced, practical way to the changing landscape that reflects the evolving risks and benefits of research. The key focus of any changes to the current regulatory structures should be on facilitating research for patient benefit rather than solely on making cost savings. The relatively small savings to be made through disbanding the HFEA and the HTA need to be balanced against the inevitable period of disruption and uncertainty, and any potential risk of loss of expertise, efficiency, effectiveness and coherence that could hinder research and practice and result in the loss of public and professional confidence. In our deliberations, we have also considered the fact that these areas of regulation and governance are not perceived to present the greatest barriers to research by our community. We would prefer the Health Research Authority (HRA) to be able to give priority to its work in supporting NIHR in its efforts to improve research governance in the NHS and to successfully taking on the data functions of the National Information Governance Board for Health and Social Care (NIGB).

3. After careful consideration, we see little benefit and significant risk in disbanding either the HTA or the HFEA and do not support either option one or option two. Where specific problems have been identified within the regulatory process, it is crucial that these are addressed; however we do not think that forcing change through structural reform is the best way to bring about these improvements. **We support retaining both the HFEA and the HTA, providing they work closely with the HRA and other regulators to further streamline the regulation, inspection and governance process for patient and public benefit. We consider this to be an enhanced version of option three, and believe that it is the most likely to deliver benefits, and the least likely to lead to a loss in professional and public confidence in research and practice.**

4. In terms of the improvements that we would want to be made to the process of research regulation in relation to the HFEA we regard that at a minimum:
Researchers should be able to use a single submission point to apply for all appropriate approvals and licences; and
Duplication in the current approvals process should be removed, especially in regard to the ethical approval of information given to patients.

5. We would emphasise that the HFEA and the HTA have very different regulatory approaches, which are crucial to the current and future success of each. We have therefore considered the impact of the different options on the HFEA and the HTA separately.

6. In regard to the HFEA, the Academy does not support splitting the research and non-research functions of the HFEA between the Care Quality Commission (CQC) and the HRA respectively. The key reasons for this are:

- The division of the regulation of research and non-research functions may lead to a loss of continuity that could hinder research and treatment.

- There are significant benefits to having a single visible organisation to provide a trusted source of information and advice for patients and the wider public, and a coherent policy and decision-making framework.

- Concerns have been expressed from within and outside the scientific community about whether the remit and expertise of the CQC qualify it to take on this scientifically and

ethically complex area.

- The HRA would need considerable time and resources to develop the necessary expertise and structures to be able to take on these research functions, which we believe would distract it from what we see as areas of higher priority.

7. Considering the HTA, we do not support transferring the functions of the HTA to the CQC, owing to concerns around the ability of the CQC to take on the wide remit of the HTA and the likely loss of the advisory role of the HTA along with its ability to govern in a risk-proportionate way. The Academy highly commends the partnership approach that the HTA and the HRA have taken to streamline the approvals process for research involving human tissue and reduce delays. We believe that this has been highly successful and would not recommend formal division of the regulation of research and non-research functions of the HTA, which would increase the regulatory burden on establishments, and may result in the advisory role of inspections being lost.

8. As outlined above, we do not support disbanding either the HFEA or the HTA, or separating the regulation of the research and non-research functions of the HFEA or the HTA. However, should the government decide to disband either the HFEA or the HTA the Academy would recommend transferring the research functions of the HFEA and the HTA to the HRA. In this eventuality we would want assurances that it would be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively.

9. There is wide agreement among our Fellows who carry out research in relevant areas that the current problems faced by researchers are best addressed through specific amendments to current research licensing processes, rather than through the transfer of functions. However, we do not think that the regulatory landscape for health research and practice should be static; scientific practice is constantly changing and regulation and governance needs to evolve with this. As such, we recommend that the functions and form of the HFEA and the HTA be kept under regular review, in line with guidance issued by the Cabinet Office. We would stress however that future reviews must prioritise the question of how to promote a regulatory environment that facilitates research and practice for public benefit and is responsive to changing patient needs.

Introduction

10. The Academy of Medical Sciences welcomes the opportunity to contribute to this consultation on proposals to transfer functions from the HFEA and the HTA. The Academy promotes advances in medical science and campaigns to ensure these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts in research involving human embryos and human tissue from hospitals, academia, industry and the public service, who have contributed to this response and who would be happy to provide further evidence.

11. The Academy is supportive in principle of Government's aim to reduce the number of NHS arm's length bodies in order to simplify the regulatory landscape and reduce costs, whilst strengthening the effectiveness of regulation in this area. In particular, we welcome the commitment to establish the HRA as a Non-Departmental Public Body (NDPB) to create a unified approvals process for health research, and promote consistent and proportionate standards for compliance and inspection.

12. Our response has drawn on previous work, particularly the Academy's 2011 report '*A new pathway for the regulation and governance of health research*' ('*Regulation and governance*'),¹ the evidence received on the HFEA and the HTA by the working group, and broad consultation with Fellows and other experts about the three options proposed. We have also worked closely with other research organisations, such as the Wellcome Trust.

13. We do not consider that the HFEA and the HTA should be treated as part of a 'package'. Although they both regulate some aspects of health research, they are concerned with widely different areas and have evolved very different regulatory approaches; and in these areas detail and specific expertise is critically important to the current and future success of both. We would highlight the problems with this approach as evidenced in the debates around their possible merger to form the Regulatory Authority for Tissues and Embryos in 2007. As such, where appropriate, we consider the impact of the

different options on the HFEA and the HTA separately.

Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA?

14. Option one states that *'all functions should transfer to the CQC except the HFEA functions relating to research that would pass to the HRA; and the HFEA and HTA be abolished'*. The Academy's 2011 *'Regulation and governance'* review noted that many people felt that significant progress had been made in the regulation of human tissue and human embryo research, and that compared with an area such as use of patient data, there was a much clearer regulation and governance pathway. However, at the time the Academy understood that the government intended to disband the HFEA and the HTA and transfer their functions elsewhere. The Academy recommended that in this event, the research functions of the HFEA and the HTA should be transferred to the HRA. Should the HFEA or HTA be disbanded, this remains the position of the Academy. However, within the current consultation document, option three allows for the retention of the HFEA and the HTA. In this context we do not favour option one for a number of reasons as detailed below.

Transferring the research functions of the HFEA to the HRA and the non-research functions of the HFEA to the CQC

15. Evidence collected during our *'Regulation and Governance'* review indicated that there was a broad view that the regulatory processes relating to research involving human embryos worked reasonably well and that the role of the HFEA in facilitating debate about use of human admixed embryos had earned it the confidence of researchers and the wider stakeholder community. While the HFEA has been subject to some criticism, it has nevertheless gained a considerable reputation nationally and internationally as a model for regulation in a sensitive, complex and rapidly changing field. It has played a key role in supporting people who need fertility treatment and has provided a robust regulatory environment that has enabled practitioners in the UK to pursue areas of research and practice that have been much harder to pursue elsewhere. This has involved an intimate knowledge of the more routine aspects of reproductive medicine, as well as the highly specialised nature of In Vitro Fertilisation (IVF) laboratories, especially those concerned with additional functions such as preimplantation genetic diagnosis, embryo cryopreservation and embryonic stem cell derivation. It has built and retained real expertise in the area, at both inspectorate and advisory level. In this context our key concerns are set out below in paragraphs 16–28.

The division of the regulation of research and non-research functions may lead to a loss of continuity that could hinder research and treatment

16. The functions of the HFEA are inter-related, especially the regulation of research and clinical practice, which has facilitated the translation of research into treatment. This reflects the area of regulation, where expertise in research and clinical practice is shared and often both are carried out by the same team, or at least with a substantial overlap. For example, practitioners offering treatment facilities are often also those performing cutting edge research, working in a 'bench to bedside' manner. The HFEA has been praised as an interface that helps to move research forward, and losing its combined functions could lead to a loss of continuity which would decrease benefits to patients and opportunities for research.

17. Importantly, through a single integrated licensing regime, the HFEA has created a clear ethical and legal framework. The majority of human embryos used in research are donated by patients having fertility treatment, either because the embryos are not suitable for use in treatment or because they are no longer required for treatment. The responsibility for ensuring that patients, donating embryos created using their gametes, receive the correct information given by an appropriate (competent) person lies with the 'Person Responsible' for the licensed research project. In practice, because the majority of embryos are obtained from a treatment centre, this duty falls on staff employed by the IVF treatment centre. By regulating both treatment and research centres the HFEA is able to ensure that patients receive the appropriate information by competent persons in order for the patient

to give or refuse consent to the use of embryos in research. Disassociating the regulation of treatment services from the use of human embryos in research could jeopardise this ethical and legal requirement.

18. Further, although it has been argued that the clinical technologies that the HFEA regulates are no longer novel and so no longer need to be subject to specialist supervision, many of our Fellows would emphasise that there is relatively little consensus as to what is meant by 'standard' IVF. Although there is widespread acceptance, based on experience, that current assisted reproduction technologies (ARTs) are generally safe, the evidence for this, particularly in terms of long term safety, is relatively weak when compared to other similarly well established clinical techniques.² The composition of media and additives used for IVF and intracytoplasmic sperm injection (ICSI) are frequently being modified by manufacturers or by individual teams of practitioners, with the aim of achieving higher rates of fertilisation and/or clinical pregnancy. Similarly, methods of choosing embryos of 'high quality' are continuously changing with new equipment or technology. However new equipment or technology, some of which may involve invasive techniques on embryos, is often introduced without a formal clinical trial process with patient consent, or follow up review of efficacy. It will take many years of follow-up to know whether these changes in methods have any effects on birth rates and the health of offspring. The need for increased oversight of the introduction of new ARTs is addressed further in paragraph 68. However, it is important to emphasise that deciding when a technique that is used in assisted reproduction research becomes routine clinical practice is not subject to clear demarcation, which would compound the risks of trying to separate these functions.

19. Transferring regulatory responsibility between two bodies would also be highly complex in practice. Effective protocols would have to be implemented to address the tensions in regulatory responsibility that would arise. This would be essential to ensure that regulatory gaps do not occur, not just leading up to and at the time of transfer of functions to the two bodies, but in perpetuity. For example, the production, storage and use of a 'permitted' embryo would be regulated by the CQC but then, should that embryo not be used in therapy but be donated for research, its storage, use and disposal would be regulated by the HRA. This would mean that consent forms designed and approved by one body would have to be agreed by the other. Further, the Register that the HFEA currently holds is a unique data collection containing information about every cycle of treatment carried out in the UK since the HF&E Act 1990. Although it is used primarily for regulatory activities, including the calculation of clinic fees and to advise a person about his or her genetic origins, it is also used for a range of secondary purposes, such as research into the long-term health implications of certain treatments. If responsibility for this data collection was split between the CQC and the HRA it would be critical to ensure that they worked together effectively to collect information and prevent duplication.

Benefits of having a single visible organisation to provide a trusted source of information and advice for patients and the wider public and a coherent policy and decision-making framework

20. There are great benefits to having one body that is statutorily responsible for all the duties that arise under the HF&E Act 1990 (as amended), from the provision of information to stakeholders, including patients and licensed establishments, to facilitating scientific, social and ethical horizon scanning. The HFEA has provided a single point of contact for communication around fertility treatment and research, which is known to patients and professionals as a source of impartial information and advice. Patients especially value having a single, trusted point of contact for information and to handle complaints when dealing with matters that could affect whether they have children and the health of these children. If the roles of the HFEA were split, it would be extremely challenging for the HRA and the CQC to jointly carry out these functions in the coherent way required. Similarly, if the functions were kept together, but subsumed within a larger organisation, it may lose the clear line of contact for support and advice, which is greatly valued by both patients and professionals.

21. It is also a significant benefit for one body to have a clear regulatory remit over the formulation, implementation and communication of ethical policy relating to the use of human embryos in research and treatment. The HFEA has acted as a source of proportionate and evidence based policy on issues which are often ethically and clinically

complex, drawing on advice given by the Authority's Scientific and Clinical Advances Advisory Committee (SCAAC) and Ethics and Law Advisory Committee (ELAC), and from public consultation. It has had a significant influence on policy internationally and aspects of its approach are replicated all over the world. It governs a key area of growth which is likely to become more complex over the next 5-10 years, with respect to methods, approaches, ethics and public perspectives or expectations: for example in relation to the genetic testing of preimplantation embryos and the transfer of mitochondrial DNA for the prevention of mitochondrial disease. There is a significant risk that this coherence in approach and policy would be lost if the functions of the HFEA were split between two or more bodies, and the proposals seem to indicate that there is already some confusion about responsibilities. For example, the consultation document notes that the HRA would *'provide a focal point for the ethical consideration of research'* but that the CQC would *'provide a focal point for ethical considerations of treatment licensing that arise from the Human Fertilisation and Embryology Act 1990'*.³ However it is unclear which body would have responsibility for taking into account public perspectives and making relatively rapid decisions about whether such techniques should be permitted in research or treatment and how they should be conducted and regulated, which illustrates the difficulty of dividing responsibilities in practice. Embryo research remains an extremely controversial field of scientific endeavour, which gives rise to differing, and often very strongly held, opinions. Neither the Board of the HRA nor the CQC was established with the remit to be responsible for the development of ethical policy. They do not currently have appropriate membership or structure, and likely would not have the legitimacy of the HFEA's ELAC committee. If the HFEA was disbanded it is unclear from the consultation documents where this important function would fall. We note that the functions outlined for the HRA in the draft Care and Support Bill do not include public dialogue.

22. There is a significant risk that public and professional confidence in research and treatment using human embryos would be damaged if the regulation of the non-research functions of the HFEA is transferred to a body which is not perceived as competent to take on these functions. The CQC was heavily criticised by the National Audit Office (NAO)⁴ in December 2011, and these concerns were reiterated by the House of Commons Committee of Public Accounts (CPA)⁵ in March 2012. The CPA report highlighted serious concerns about the Commission's governance, leadership and culture, and noted that it has *'a long way to go to become an effective regulator'*. Although we would hope that the situation would have significantly improved by 2015 when the transfer of functions is proposed to take place, we cannot be confident of this. Further, transferring the non-research functions of the HFEA to the CQC would take them into significantly new areas of regulation, which would require substantive new skills and expertise. We would highlight the reservations of the NAO that extending the CQC's role into new areas risks distracting the Commission from its core work of regulating health and adult social care, which would be detrimental to the overall health and well-being of patients and the wider public. In line with this, the CPA explicitly recommended that the CQC should not take on the functions of the HFEA and the HTA because *'it does not have the capacity to take on oversight of such a complex area, and the change would undermine its ability to focus on the improvements it needs to make in relation to its existing regulatory functions'*. In the annual accountability hearing with the House of Commons Health Select Committee in September 2012, the CQC themselves stated that they did not wish to take on the functions of the HFEA or the HTA. The CQC emphasised that they were already working with the HFEA and the HTA to share back-office costs, avoid duplication and share data and information. They stressed that should the government decide to transfer functions to them, they would need to ensure that the necessary expertise was put in place within the CQC to enable them to take on this new remit.⁶

23. Transferring the functions of the HFEA to the CQC is also likely to be highly complex in practice owing to the differing geographical remits of the HFEA and the CQC. Although the proposal is that the CQC would take on the non-research functions of the HFEA which extend to the whole of the UK, this would require the CQC to work closely with existing regulators in the devolved administrations, specifically the Regulation and Quality Improvement Authority in Northern Ireland, Healthcare Improvement Scotland and Healthcare Inspectorate Wales. This concern was also raised by the CQC in the recent annual accountability hearing with the House of Commons Health Select Committee. Further, the key benefit outlined in the consultation documents, that the transfer of functions to the CQC would lead to a reduction in the number of regulators who providers

have to deal with, would not extend to the devolved administrations because of the continuing role of existing regulators in these countries.

The HRA would need considerable time and resources to develop the necessary expertise and structures to be able to take on the research functions of the HFEA

24. The HRA is perceived by the Academy and others as an important step towards streamlining the regulation and governance of health research. The National Research Ethics Service (NRES) is a core component of the HRA, which reviews over 6000 research applications per year through its 80 Research Ethics Committees (RECs), providing an efficient and effective approach to ethics review. The HRA also has a key role in creating a unified approval process and promoting proportionate standards for compliance and inspection, which it achieves in partnership with a multi-agency team, including the Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health Research and the HTA. However, the HRA is a new body, not yet established as a NDPB, which is about to take on the challenging functions of the NIGB to become the single point for approvals for processing confidential information relating to patients. In our deliberations, we have considered the fact that these areas of regulation and governance are not perceived to present the greatest barriers to research by our community. We consider that the HRA should be able to focus on supporting NIHR in its efforts to improve research governance in the NHS and to successfully taking on the data functions of the NIGB.

25. The majority of the HFEA's work relates to the regulation of treatment, and research regulation is only a small aspect of its work: currently only 24 centres hold HFEA research licenses. However, at the HFEA the same members of staff that oversee the regulation of treatment also provide the functions necessary for research regulation. Although the number of research licence applications to the HFEA is low, the HRA does not currently have the breadth of scientific or ethical expertise to assess these. Although this could be developed over time, the HRA would need additional resources to ensure that the necessary expertise to deal with these applications was in place.

26. The HFEA also has regulatory licensing functions, which are qualitatively different in nature to the work of the NRES and REC's, and the HRA does not currently have the capacity to undertake these functions. We anticipate that if they were given the research functions of the HFEA, they would likely delegate the inspectorate function to another body. It is unclear whether this would deliver cost savings, or what impact it would have on the regulatory burden for research establishments. Although some principles of regulation within a quality management system are generic, currently HFEA inspections are undertaken by members of staff, who advise on the ethical, scientific and technical nature of the research projects, as well as inspecting premises facilities and equipment and governance and quality systems. Should these be delegated to another body, we are concerned that the advisory role of inspections, which is greatly valued by the research sector, would be lost. Further, concerns have been raised that as the field gets increasingly complex, the HFEA Compliance staff, who currently undertake inspections, will need additional scientific and technical expertise to understand more complex projects and to undertake effective evaluation of progress. Such concerns would be vastly amplified if inspections were delegated to the CQC, especially as the CPA report in March 2012 stated that CQC inspectors are already responsible for large and varied portfolios of providers, and that *'individual inspectors do not have sufficient support to develop the range of expertise and experience needed, and there is a lack of consistency in their judgements and in the Commission's approach to taking enforcement action'*.

27. Based on the reasons outlined above, transferring the research functions of the HFEA to the HRA is not our preferred option. However, as stated in paragraph 14, should the government decide to disband the HFEA, the Academy would support transferring its research functions to the HRA. In this eventuality, we would want assurances that that the HRA would be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively.

28. On balance, we see few benefits and many risks in splitting the research and non-research functions of the HFEA between the HRA and the CQC respectively. We see a number of benefits to keeping the functions of the HFEA together,

namely that it enables continuity between research and practice, which facilitates the translation of research into clinical practice. It also provides a trusted source of information and advice for patients and the wider public and a coherent policy and decision-making framework. We have concerns as to the ability of the CQC to take on this scientifically and ethically complex area and would prefer the HRA to concentrate on the parts of the regulation and governance framework that are causing the greatest delays to research.

Transferring all the functions of the HTA to the CQC

29. Our discussions with the research sector have not highlighted any specific problems with the HTA, which is widely regarded as an effective regulator. Comments regarding their activities in this area are very positive, with researchers praising the support systems for researchers, Designated Individuals and licence holders. This support includes training, a professional advisory network, regular communications and an effective inspection framework. Although the research community has in the past raised significant concerns, especially in regard to lack of clear guidance, there are now a number of secondary Codes of Practice which have been developed through an iterative process of consultation with the research community, and in general researchers find the Codes useful and easy to follow. Although the area which the HTA regulates is certainly less ethically, clinically and politically complex than that of the HFEA, the public is still concerned about the use of human tissue in research, especially with respect to issues of consent.

Concerns about whether the remit and expertise of the CQC qualify it to take on the functions of the HTA

30. Our concerns about whether the CQC will be equipped and appropriate to take on responsibility for publicly sensitive areas of research has been outlined in paragraph 22 in the context of the HFEA. The HTA regulates human tissue in a very diverse range of settings, which encompasses research, patient treatment, post-mortem examination, teaching, public exhibitions and approval for organ and bone marrow donations from living people. Transferring the functions of the HTA to the CQC would take them into new areas of regulation and would require new skills and experience.

31. We would also have similar concerns about the differing geographical remits of the HTA and the CQC, as outlined under paragraph 23 in the context of the HFEA. In regard to the HTA, this would require the CQC to take on the current remit of the HTA, which covers England, Wales and Northern Ireland, but also a UK wide remit for those functions that fall under the remit of the HTA as the competent authority for the EU Organ Donation Directive 2010/53/EU and the European Union Tissue and Cells Directives (EUTCD).

Specific risks of transferring the research functions of the HTA to the CQC

32. The role of the HTA as an advisory body, as well as licensing and inspecting premises, is highly valued by those it regulates. Although some principles of regulation within a quality management system are generic, currently HTA inspections are undertaken by members of staff, who advise on the scientific and technical nature of the research projects, and the requirements for informed consent, as well as inspecting premises facilities and equipment and governance and quality systems. We have already highlighted the concerns expressed about the large and varied portfolios of CQC inspectors in paragraph 26. The research sector would welcome assurances that if the HTA functions were transferred to the CQC, the advisory role of inspections, which is greatly valued by the research sector, would be retained.

33. The HTA is also widely perceived as a model of good practice in regard to proportionate and streamlined regulation, which responds in a balanced, practical way according to the terms of the Human Tissue Act (2004). For the HTA, research is not generally viewed as a high risk sector and is managed in a risk-proportionate way. There is concern amongst the research sector that if the research functions of the HTA were transferred to the CQC, as a body which has a statutory duty to monitor and report on safety and standards, it may increase a risk-averse culture to the use of human tissue, which will inhibit research that inherently involves some risk.

34. On balance, we see no benefits and many risks to transferring the functions of the HTA to the CQC, primarily because of concerns about whether the role and expertise of the CQC qualify it to take on the wide remit of the HTA, and the likely loss of the advisory role of the HTA and its ability to govern in a risk-proportionate way.

Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA?

35. Option two aims to 'transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.' This includes transferring the licensing of premises for removal or storage of relevant material for the Scheduled Purpose of research from the HTA to the HRA, which is considered in detail here.

Transferring the licensing of premises for removal or storage of relevant material for the Scheduled Purpose of research from the HTA to the HRA

36. As outlined in paragraph 14, the Academy's 'Regulation and governance' report recommended that the research functions of the HTA should be transferred via an appropriate mechanism into the HRA if the government intended to disband the HTA. However, within the current consultation document option 3 allows for the retention of the HTA, and in this context we do not favour option two for a number of reasons, which are set out below in paragraphs 37-41.

Transferring the licensing of premises for removal or storage of relevant material for the Scheduled Purpose of research from the HTA to the HRA would increase duplication

37. The HTA is widely regarded as an effective regulator, as detailed in paragraphs 29, 32 and 33. Importantly the partnership between the HTA and the HRA to streamline the approvals process for research involving human tissue and reduce delays is often put forward as an example of best practice. A HTA licence is not needed for storage of human tissue for a specific research project if it has been approved (or is pending approval) from a recognised REC (which is assessed by the NRES). Further, efforts between the HTA and the NRES to streamline the approvals process for research tissue banks is seen to have enabled the UK to become a world leader in the field. RECs can now give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue. This approval extends to specific projects receiving non-identifiable tissue from the bank and means that the tissue does not then need to be stored on HTA-licensed premises, nor does it need project-specific REC approval. This has benefited 200 HTA-licensed tissue banks.

38. In line with Government, we agree that the division of the regulation of the research and non-research functions of the HTA would increase the regulatory burden on establishments. A HTA licence is for the storage of human tissue for use in research, not the use itself. Transferring the research functions of the HTA to the HRA would redesign the licensing of human tissue according to the purpose of storage rather than the fact that it is being stored, which would increase the regulatory burden on the 200 organisations across three sectors that also engage in research activities including the post mortem sector, the sector using tissue for patient treatment and the anatomy sector. It would also set a precedent for other areas of regulation, which could mean more circumstances where a single activity, but for dual purposes, is regulated by two bodies.

The regulatory licensing functions of the HTA are qualitatively different in nature to the core work of the HRA

39. The HTA also has regulatory licensing functions which are qualitatively different in nature to the work of the NRES and RECs. The HRA does not currently have the capacity to undertake these functions, as outlined in regard to the HFEA in paragraph 26. There is deep concern that if the HTA inspectorate functions were delegated, the advisory role of inspections, which is greatly valued by the research sector, would be lost.

40. For the reasons outlined above and in paragraph 24, transferring the research functions of the HTA to the HRA is not our preferred option. However, as stated in paragraph 14, should the government decide to disband the HTA, the Academy would support transferring its research functions via an appropriate mechanism into the HRA. In this eventuality, we would want assurances that that the HRA would be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively.

41. We highly commend the partnership approach that the HTA and the HRA have taken to streamline the approvals process for research involving human tissue and reduce delays. We believe that this has been highly successful and would not recommend formal division of the regulation of the research and non-research functions of the HTA, which would increase the regulatory burden on establishments, and may result in the advisory role of inspections being lost if the HRA delegated this function to another body.

Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies?

42. Within option three, the '*HFEA and HTA retain their functions but deliver further efficiencies*', and the Department of Health proposes to create a duty to co-operate between them and the CQC. For the reasons outlined in detail above, after careful consideration, we support retaining the HTA and the HFEA. Where specific problems have been identified within the regulatory process, it is crucial that these are addressed. However, we do not think that forcing change through structural reform is the best way to bring about these improvements. The Academy's support for retaining the HFEA is conditional on closer relations between the HFEA and the HRA. With this caveat, we regard option three as the only option outlined in the consultation that will streamline regulation and reduce duplication whilst maintaining professional and public confidence in research and practice.

43. We consider this to be an enhanced version of option three; importantly it should not be taken as support for the status quo, and we put forward a series of measures as to how the process of research regulation in relation to the HFEA could be streamlined in practice in paragraphs 45-52. A further condition of our support is that the HFEA and the HTA should work with other relevant bodies to further streamline the inspection process where synergies exist, building on the current efforts of the HTA and MHRA, who have recently piloted joint inspections. The Academy believes that this would achieve the aims of the Academy's '*Regulation and governance*' review, by streamlining and improving regulation, without the formal transfer of the research functions of the HFEA or the HTA to the HRA.

44. We support retaining both the HFEA and the HTA, conditional upon the HFEA and the HRA working together to streamline regulation and reduce duplication for patient and public benefit. We consider this to be an enhanced version of option three, and believe it is the only option outlined in the consultation that will streamline and improve regulation whilst maintaining professional and public confidence in research and practice.

Streamlining regulation and reducing duplication between the HFEA and the HRA

45. At present, in order to gain approval to conduct research using human embryos, researchers have to seek research ethics approval from a recognised REC before they can apply for a licence. Only once this has been approved, and a 'Person Responsible' has been identified within the research institution to ensure that the centre and staff comply with the HF&E Act and Code of Practice, can the researcher submit a research licence application to the HFEA. On receipt of the research licence application and fee, the HFEA Compliance department arranges peer reviews of each research application using suitably qualified and independent experts in the field of reproductive technologies, infertility, embryology, genetics, and stem cells, to assess whether the research fulfils the categories for which embryo research is permitted: the importance of the research in the field; whether the research has been done before; and whether the use of human embryos is justified. If the peer review is successful, the HFEA initiates visits to the proposed research sites to review proposed project protocols, inspect research laboratories and to meet the research teams. The inspection team then prepare a report for the dedicated Research

Licence Committee (RLC) considering the application. In order to grant a research licence, the RLC has to be satisfied that the science meets the statutory tests (i.e. that the project of research is necessary or desirable for one of the legally permitted purposes and that the use of human embryos is necessary for that purpose) and that the practices used to carry out the research are ethically suitable. In determining these requirements the RLC takes into account the views of the Authority's SCAAC and ELAC committees.

46. We consider that it is possible to streamline this process and remove duplication whilst retaining the distinct functionality and expertise of the HFEA and the HRA, and propose a series of measures which we believe would achieve this. The core features of this are set out below in paragraphs 47-52.

Researchers should be able to use a single submission point to apply for all appropriate approvals and licences

47. The HFEA requires all research to be approved by a local ethics committee, and where the research involves obtaining embryos from fertility centres located within the NHS, this ethics approval is obtained from ethics committees regulated by the NRES. However, at the current time, the HFEA is not a member of the integrated research application system (IRAS), which was established to streamline the research application process by providing a single system for applying for the permissions and approvals for health and social care/ community care research in the UK. If the HFEA became a partner in IRAS it would streamline the approvals process by enabling researchers to make a single application to obtain a research licence through the HFEA and ethics approval through NRES. The HFEA has stated that it is already working with the HRA to move towards an integrated application process and we would urge this to be considered as a priority.

48. This will mean that the HRA will also oversee the handling of all applications to access patient data for medical research. Currently applications to access HFEA anonymised data for medical research are handled by the NIGB, via a Memorandum of Understanding with the NIGB's Ethics and Confidentiality Committee. The NIGB are already IRAS partners, and will shortly become part of the HRA. The HRA is already exploring with the NIGB how the HFEA application form has been integrated into their systems, to inform future developments. This will simplify the process for researchers who would need to apply to the NIGB to access any other dataset they want to link HFEA Register data to.
Duplication in the current approvals process should be removed, especially in regard to the ethical approval of information given to patients

49. One area of substantial duplication relates to patient information and informed consent. Currently patient information leaflets and processes to ensure informed consent are assessed by both the NRES and the HFEA. This can lead to delays, because if the HFEA asks for amendments to be made to this information after the researcher has already obtained REC approval, having made these amendments, the researcher has to go back to the REC to seek its approval to these changes. If the HFEA delegated responsibility for ensuring that the information given to patients meets the requirements of the HF&E Act 1990 (as amended) to the NRES, this would reduce duplication and could speed up the time for deciding whether a research licence should be granted or not. The HFEA has indicated that it would be supportive of this in principle.

The HFEA would retain responsibility for inspecting the research centre and for deciding whether a research project should be licensed

50. The information collected by the HRA, as outlined above, would then be automatically passed on to the HFEA. Responsibility for inspecting research centres and deciding whether a research project should be licensed or not would remain with the HFEA. This would ensure that role of the inspectors in advising on the ethical, scientific and technical nature of the research projects, as well as inspecting premises facilities and equipment and governance and quality systems would not be lost. It would also mean that the dedicated RLC would still be responsible for deciding whether or not to grant a research license, taking into account the views of the SCAAC and ELAC committees and comments received from the general public (via the HFEA website) on each research application.

51. We welcome the duty of cooperation between the HFEA and the HRA that is proposed under the draft Care and Support Bill. This should be used to ensure that researchers

receive a smooth and joined-up approach to research licence approvals and that there is clear accountability for progress. The two organisations should also seek to determine whether there are additional aspects of the research licensing process that may be streamlined, or which may benefit from closer sharing of expertise.

52. The Academy believes that if these measures were implemented it would achieve the aims of the Academy's 2011 review of the regulation and governance of health research, by streamlining and improving regulation, without the formal transfer of the research functions of the HFEA to the HRA. The HFEA has indicated that it would be willing to work with the HRA in this way.

Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse?

53. Significant savings have already been made by both the HFEA and the HTA since the review of arms length bodies was announced in July 2010.

54. As outlined in the Impact Assessment⁷, the HFEA is now located in the CQC and they share back-office functions, including HR and finance. The HFEA has consolidated its senior management team and proposed further efficiency savings, which would reduce staff levels from 86 FTE as of 2010/11, to 67 by 2014/15, a reduction of their overall budget by a quarter over that period. As a result of these efficiency savings, HFEA has reduced licence fees from October 2011. The HFEA is also working to ensure that licensed research centres located within, or affiliated to, a licensed fertility centre have combined inspection visits.

55. The HTA made efficiency savings of 14% in 2010/11 and estimates 31% in 2011/12. They do not currently have plans to co-locate with the CQC, but they aim to reduce their staff from 54 in 2010/11 to 44 from 2014/15 onwards. As noted in the Impact Assessment, the largest area in which the HTA expect to make efficiencies is in relation to inspections, and they have already piloted joint inspections with the MHRA to reduce the burden of regulation on establishments in the sector using tissue and cells for patient treatment. We understand that HTA is also working with the HFEA to move towards joint inspection visits for those research centres that are required to be licensed by both the HFEA and the HTA because the researchers are using human embryos to derive embryonic stem cells for therapeutic purposes.

56. We welcome this progress and understand that the HTA and the HFEA are currently undertaking work to provide further information on the efficiencies which could be realised under option three, and that these will be included in their response to the consultation. In particular, we believe further savings could be made by realising synergies where they exist, for example by continuing to streamline inspections between the HFEA and/or the HTA and other relevant bodies. This would also reduce the regulatory burden and facilitate research and practice. More effective co-operation between the HFEA and the HRA, as outlined in paragraphs 45-52, could also deliver overall reductions in cost through reducing duplication, although it has not been possible to quantify these at this stage.

57. However, we would stress that although delivering cost savings is important, it should not take precedence over facilitating research and practice for patient benefit, which is likely to deliver more cost savings in the long term. We would stress that the HFEA and the HTA

must continue to be sufficiently resourced to enable them to undertake their statutory duties effectively and ensure public confidence, and we would urge caution in using the estimated savings associated with options one and two in the Impact Assessment as a benchmark for delivering savings within option 3 as detailed in paragraphs 64-67. It will be important to ensure that any additional cost efficiencies can be made without reducing quality or putting patient or public safety at risk.

58. We believe that more effective co-operation between the HFEA and the HRA, and further streamlining of inspections between the HFEA and/or the HTA and other relevant bodies could deliver savings. We would welcome further initiatives to reduce costs; however, we would stress that although delivering cost savings is important, the HFEA and the HTA must continue to be sufficiently resourced to

enable them to undertake their statutory duties effectively, and ensure public confidence.

Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere?

Transferring the licensing of activities relating to the use of human tissue for human application from the HTA to the MHRA

59. The Academy believes that there may be merit in further considering transferring the licensing of activities relating to the use of human tissue for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 from the HTA to the MHRA. In particular, for researchers involved in stem cell research with a view to the eventual development of therapeutic products, devolving this function to the MHRA may reduce the number of regulators with whom researchers need to liaise.

60. Currently, if stem cells are to be derived from human embryos, a HFEA licence is required. The HFEA's remit includes the use of embryos in the derivation of stem cell lines, up until the point at which the embryo is 'dissociated' during the cell line derivation process, but does not extend to the regulation of the stem cell lines themselves. The HTA regulatory remit then begins and a HTA licence is required. This is because the HTA, under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, regulates the procurement, processing, testing, storage, distribution and import or export of human tissue and cells intended for human use; including stem cell lines for therapeutic application. No licence is required by the HTA for research carried out on stem cell lines not destined for human application, including human embryonic cell lines generated under a HFEA licence. During the derivation or processing phase, stem cell lines do not come within medicines regulation. However, once 'Master Cell Banks' have been created with a reasonable expectation of clinical utility in a medicinal product, they fall within the remit of the MHRA.

61. However, although the remit of the MHRA does not officially begin until there is an expectation of clinical utility, in practice, researchers are encouraged to involve the MHRA at an early stage because the manner in which stem cells are derived, cultured, stored etc. will affect their suitability for human application. For example, there is a distinction made between clinical grade and research grade cell lines: a clinical grade line will have been grown in traceable documented defined conditions in compliance with the European Tissues and Cells Directive, ideally in the absence of animal feeder cells, supplements, etc. As such, the HTA plays a very limited role in this regulatory process, and liaising with three regulators can lead to a lack of clarity as to the requisite standards required for human application, as regulated by the MHRA.

62. Consequently, devolving this function to the MHRA may reduce the number of regulators with whom researchers need to liaise and increase clarity. We would consider this to be worthy of detailed further consideration, and hope that other organisations will make more in-depth comments as to its relative advantages and disadvantages.

63. There may be some merit in transferring the licensing of activities relating to the use of human tissue for human application from the HTA to the MHRA, in particular, for researchers involved in stem cell research with a view to the eventual development of therapeutic products. We would support further detailed consideration of this transfer of function.

Do you have any comments on our assessment of the efficiencies associated with the different options?

64. The £3.8m saving associated with option one and two in the Impact Assessment has been based exclusively on the benefits of reduced salaries from ceasing to employ the Chair and Chief Executive of the HFEA and HTA (salary and remuneration), against the costs of redundancy and transition over a ten year period from 2014/15 to 2023/24. There has been no attempt to estimate the cost of the resultant disruption and the establishment

of specialist functions within the CQC and the HRA. The Impact Assessment notes that this is because at this stage it is not clear what the final organisational structures would be, or how organisations would operate and carry out their functions, as it would be up to the HRA and the CQC and other relevant bodies to decide.

65. There is wide agreement that the functions of the HFEA and the HTA should only be transferred if it can be done without decreasing the quality and effectiveness of regulation in these areas. However, it is unclear what the likely costs of retaining the expertise of these bodies within the CQC or the HRA would be. The functioning of the CQC is very different from that of the HFEA and the HTA and gaining these functions would take them into substantially new areas of regulation and governance, for example the development of ethical policy and person-centred decision making. Ensuring that the necessary expertise is retained would likely require separate Boards or subgroups to be established. However, the CQC is already a very large regulator, with approximately 1900 staff, and putting these structures in place may actually increase bureaucracy and costs over current levels. Further, the HRA would need to be allocated sufficient additional resources to ensure that it has the appropriate expertise to be able to deal with these research applications efficiently and effectively. It is important that the costs of implementing option one or two are taken into consideration, because these may significantly reduce the estimated savings put forward in the Impact Assessment.

66. There has been no attempt to quantify the benefits of streamlining registrations, licensing or inspections (or potential associated reductions in administrative burden for providers), or risk analysis as to whether these would be more likely to be achieved by disbanding the HFEA and the HTA or retaining them with further streamlining of processes. In addition, under options one and two it is acknowledged that licence fees to providers may increase (if Government decreases the current level of grant-in-aid) or decrease (if running costs fall); this uncertainty is likely to be a concern for industry and research institutes.

67. We would question whether a purported saving of £380,000 per annum is sufficient to overcome the risks acknowledged in the Impact Assessment, and outlined in detail in this response, such as loss of expertise through loss of directly employed staff and expert advisers and reputational mechanisms. We would emphasise that the proposals outlined in paragraphs 42-52 would deliver benefits to researchers and patients through streamlining regulation and deliver savings through removing duplication, without the risks associated with disbanding two bodies which have earned the confidence of the public and professionals.

Further views as to how functions might be undertaken in the future or other issues of concern

Increase oversight of the introduction of new assisted reproduction technologies

68. A key concern for some of our Fellows in the context of the HF&E Act 1990 (as amended) is the need for closer oversight of the introduction of new ARTs, especially in an increasingly privatised environment where potential parents are willing to go to great lengths to have a child. This should include a clear indication of their status in terms of the available evidence base to support their introduction, such as whether they have undergone a formal clinical trial process. More effective long-term monitoring of new ARTs for safety and efficacy *post hoc* is also necessary, to minimise the health risks to children and their parents. Achieving this will require improved ways of collecting and sharing data, to enable researchers to answer the kind of questions that follow-up studies seek to address, and to facilitate the collection of follow-up information from parents who have given the appropriate consents. For example, linking data on ART procedures to health outcomes, potentially through data linkage to other databases, would enable more specific research studies to be carried out.⁸ We would recommend that any future review of the HFEA should include an assessment of the HFEA's methods for incorporating and licensing new technologies, and appropriate follow-up of efficacy and safety.

Review the definition of 'relevant materials' in the Human Tissue Act (2004)

69. Evidence received during the 'Regulation and Governance' review and in the

preparation of this consultation response indicates that researchers consider the broad scope and application of the Human Tissue Act (2004) to materials such as urine, faeces and saliva to be the main barrier to research involving human tissue. Further, researchers cannot currently store samples that have appropriate consent in unlicensed storage facilities unless they have REC approval for a specific project. The cost of storage in a licensed facility makes keeping samples already used in one project prohibitive, even though they might be of value for future research. There is a strong belief among those we consulted that the current situation unnecessarily increases costs and bureaucracy and was not the intention of the Act, which was introduced to prevent inappropriate retention of body parts and whole organs, i.e. any repeat of events similar to those at Alder Hey.

70. We do not think that the current application of the Human Tissue Act (2004) presents a proportionate approach to the regulation of the use human tissue in research. Nor is it consistent for hair and nails to be excluded from the Act, whereas materials such as saliva and urine are retained. Respondents highlighted the advantages of the regulation of human tissue in Scotland, which is confined to post-mortem tissue. We think this approach is beneficial and believe that tissue from the living could be regulated effectively under REC approval and a broad consent model, which would mean that tissue collected from the living for research would not need a HTA licence for storage.

71. The HTA is obliged to regulate according to the terms of the Act and its remit does not extend to applying a proportionate approach to the range of materials within the Act's scope. It has previously drawn attention to the need to clarify the definition of 'relevant material' and amend the legislation. To address these issues and ensure a proportionate approach to the regulation and governance of the use of tissue from living subjects, we would support a review of the definition of 'relevant materials' in the Human Tissue Act (2004), as recommended in the *'Regulation and Governance'* report. In considering changes in the types of material included in the Human Tissue Act (2004), we suggest that an analysis of the impact of the Act on health research be undertaken using the approach taken in Scotland as a comparator.

72. We recommend that a review of the Human Tissue Act (2004) be carried out to determine whether the burden of regulation for the use of human tissue for research could be further reduced, for example, by bringing it into alignment with the Human Tissue (Scotland) Act 2006.

The future of health research regulation

73. There is wide agreement among our Fellows who carry out research in relevant areas that the current problems faced by researchers in relation to time delay and duplication of effort are best addressed through specific amendments to current research licensing processes, rather than through the transfer of functions. There is a clear perception that this is more likely to be cost effective and to bring about the desired changes within a reasonable timeframe. However, we do not think that the regulatory landscape for health research and practice should be static, and we do not support retaining existing structures where they do not facilitate research for patient and public benefit. Scientific practice is constantly evolving and we need to be prepared to change or create new systems to ensure that we continue to have an effective regulatory environment that not only prevents research that is unethical or scientifically unsound, but that also enables the development and translation of new technologies that respond to changing patient needs.

74. To ensure that the problems that we have identified are addressed and that the current regulatory structures and processes continue to evolve to maximise their effectiveness, we recommend that the both the functions and the form of the HFEA and the HTA be kept under regular review by the Department of Health. Key stakeholders should have the opportunity to input into these reviews, in line with guidance issued by the Cabinet Office.⁹ This would ensure external accountability for implementing change and also establish a clearer evidence base on which to consider the benefits and risks of any future reform. These reviews should continue to consider whether integration into the HRA, as opposed to simply closer alignment, would create the most effective regulatory structure for research and deliver the greatest benefits for patients. We would emphasise however, that future reviews must centre on the question of how to promote a regulatory environment that facilitates research for public benefit and not prioritise cost savings.

- 1 Academy of Medical Sciences. 'A new pathway for the regulation and governance of health research'. January 2011. <http://www.acmedsci.ac.uk/p47prid88.html>.
- 2 Medical research Council, 'Assisted reproduction: a safe, sound future'. 2004. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002393>. 5
- 3 Department of Health, 'Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority'. June 2012. Paragraphs 100 and 103. <http://www.dh.gov.uk/health/files/2012/06/Consultation-on-proposals-to-transfer-functions-from-the-Human-Fertilisation-and-Embryology-Authority-and-the-Human-Tissue-A.pdf>.
- 4 National Audit Office. 'The Care Quality Commission: Regulating the quality and safety of health and adult social care.' December 2011. http://www.nao.org.uk/publications/1012/care_quality_commission.aspx.
- 5 House of Commons Committee of Public Accounts. Seventy-Eighth Report, 'The Care Quality Commission: Regulating the quality and safety of health and adult social care.' March 2012. <http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1779/1779.pdf>.
- 6 House of Commons Health Select Committee annual accountability hearing with the Care Quality Commission, Tuesday 11 September. Uncorrected transcript of oral evidence, HC 592-i. Questions 129-135. <http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm>.
Concerns about whether the remit and expertise of the CQC qualify it to take on the non-research functions of the HFEA
- 7 Department of Health, Impact Assessment on the Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority. June 2012. <http://www.dh.gov.uk/health/files/2012/06/Impact-Assessment-Transfer-Functions-from-the-HFEA-and-HTA.pdf>. 14
- 8 Medical research Council, 'Assisted reproduction: a safe, sound future'. 2004. <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002393>.
- 9 Cabinet Office, 'Guidance on reviews of Non Departmental Public Bodies'. June 2011. http://www.civilservice.gov.uk/wp-content/uploads/2011/09/triennial-reviews-guidance-2011_tcm6-38900.pdf.

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Response 84 – PHG Foundation

1. The Foundation for Genomics and Population Health (PHG Foundation) is the successor body to the UK Public Health Genetics Unit. Its overarching purpose is to foster and enable the application of biomedical science, particularly genome-based technologies, for the benefit of human health. Among its specific objectives is the promotion of a social and regulatory environment that is receptive to innovation, without imposing an undue or inequitable public burden. The Foundation has a particular interest in the way that new technologies are translated from genetic and genomic research into health services and in their impact upon clinical care and public health.

Relevant experience in this area

2. The Foundation's remit is as an independent policy think-tank with the overarching aim of making science work for health. Our multidisciplinary organisation has developed an iterative process of working with stakeholders. Our work does not involve holding tissue samples or carrying out any of the activities regulated by either body; nor do we formally represent a particular stakeholder group or sector.

General comments

3. The PHG Foundation closely followed the progress of the Human Tissue Bill as it advanced through Parliament in 2003-4. The reason that we followed the Bill so diligently was because we felt that the main driver for the legislation was to be seen to remedy the wrongs that were so apparent from the Alder Hey incident, namely that the body parts of babies and young children were retained without the knowledge and consent of their families. By incorporating provisions regulating non-consensual testing of genetic material which applies to the whole of the UK, the Act went further than simply addressing unauthorised tissue holdings. In particular, we were concerned about the wider impact that the Act might have on genetic testing for medical purposes. This is because one of the Scheduled purposes requiring consent is where tissue is removed, stored or used for the purposes of "obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)" (Human Tissue Act, Schedule 1 Part 1(4)).

4. In particular, our fear was that the statutory requirement for a living person to give their consent for tissue to be used for this purpose might jeopardise the complex evaluation of competing benefits and harms that clinical geneticists or counsellors might invoke within a clinical encounter. We pressed amongst other things for a provision to be included in the Act to allow consent to be "deemed" by the Authority in certain circumstances (Human Tissue Act sections 7 and Section 45, Schedule 4 Part 2 para 9).

5. The PHG Foundation has no way of knowing how much this statutory provision has been used in practice, but we believe that insufficient account

may have been taken of this function, in future plans. We consider that the activity of 'deeming consent' is so important and clinically significant that it should be carried out by staff who not only have the expertise, but a secure understanding of the clinical implications of disclosing potentially sensitive information (which may raise distinctive ethical and legal challenges).

6. There are a number of other functions that are carried out by the HTA which seem to require specialist quasi-clinical skills: these include assessment for the programme of living donation. The remit of the HFEA also includes some sensitive functions that require specialist training, such as providing information to individuals who have been conceived through assisted reproduction.

7. Should these and other functions be transferred to the CQC, we consider that there is a substantive risk that the existing well-functioning regulatory system will be undermined, particularly as the CQC is still consolidating its expanded role. Although the proposed transfer of functions to the CQC might allow some members of staff to be retained and transferred, it seems likely that some loss of expertise will occur through planned redundancy. By contrast, retaining these functions within specialist regulators will in our view, enhance the existing expertise in these areas. Moreover, retaining these and other less sensitive functions within separate regulators, also serves to enhance public trust and confidence in these activities: in both these regulatory areas, the consequences of failure are high, and only relatively modest savings have been predicted from the transfer of functions from the HFEA and HTA to the CQC, and the reservation of the research functions for the HRA.

8. Overall, our view is that both regulators have gained expertise since they were set up, have demonstrably learnt from their mistakes, and that they are best placed to continue as statutory regulators for each sector. Although there may be arguments in favour of transferring the research functions to the Health Research Authority, as a body which has an overarching responsibility for research, we do not support the transfer of the residual functions of the HTA and the HFEA to the CQC for the reasons set out above.

9. If the HFEA and the HTA are retained as independent regulators, we consider that additional savings could be achieved by the following:

- Streamlining the application process to each regulator, and using a combined electronic application form which has a sieve to select relevant questions (such as the IRAS form for research ethics and research and development applications);
- Inspectors could co-ordinate and rationalise their inspection timetable to, where possible, arrange for visits to take place at the same time.

Response 85 – Human Tissue Authority

Human Tissue Authority's response to the Department of Health's Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

28 September 2012

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Department of Health's (DH) "Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority" which it was pledged would be undertaken in the document "Liberating the NHS: Report of the arms-length bodies review"¹ published in July 2010.
2. The HTA is committed to working with DH and other stakeholders to ensure that human tissue and organs continue to be stored and used safely, ethically and with proper consent, and that the bodies of deceased people are treated with respect and dignity. The HTA holds patient safety and public confidence as paramount and notes that the Ministerial Foreword to the consultation document stresses the Government's commitment to maintaining standards.
3. This response document provides information on the HTA and the range of activities it carries out. It also provides the views of the HTA on the options proposed in the consultation document, the views of a number of stakeholders and of HTA staff.
4. The response does not comment explicitly on the proposals as they relate to the Human Fertilisation and Embryology Authority (HFEA). It should be noted that while the DH consultation concerns both the HTA and the HFEA, these are two independent organisations charged with distinct remits and working with different groups of stakeholders.
5. **The HTA believes that of the options presented in the consultation document, option 3 would continue to ensure the safe and ethical storage and use of organs and tissue while delivering realisable efficiencies,**

¹ [DH consultation document](#)

without the risks associated with options 1 and 2. Therefore, the HTA's preferred option is option 3.

About the HTA

6. The consultation document provides an overview of the HTA at paragraph 29. As a statutory body the core of what the HTA does is laid down in three pieces of legislation. These are:
 - a. The Human Tissue Act 2004 (HT Act) and associated Regulations
 - b. Human Tissue (Quality and Safety for Human Application) Regulations 2007
 - c. Quality and Safety of Organs Intended for Transplantation Regulations 2012
7. Since the HTA came into being in April 2005, it has established itself as an effective and successful regulator. It has achieved this by developing a distinctive style of regulation that is underpinned by close working relationships with its stakeholders, and supported by a risk-based and proportionate approach.
8. The HTA's regulatory approach is made possible by its specialist and expert staff who provide high quality advice and guidance to licensed establishments, professionals and the public in order to raise standards more widely, ensure compliance with statutory requirements and maintain public confidence.
9. The HTA regulates establishments and activities in the following sectors, and this work is fully funded by licence fees:
 - a. Post Mortem
 - b. Research
 - c. Human Application (the use of tissues and cells for patient treatment)
 - d. Public Display; and
 - e. Anatomical examination (the donation and use of bodies for the teaching of medical students)
10. The HTA also regulates establishments and activities in the transplantation sector. This work is currently funded by DH.
11. At the time of writing, the HTA has a headcount of 47, which equates to 45 full time equivalents (FTE). The majority of staff are involved directly in the licensing and inspection of establishments and activities that support regulation such as the provision of advice and guidance, the development of regulatory policy, and investigating and overseeing Serious Adverse Events and Reactions (SAEARS) and Serious Untoward Incidents (SUIs). These activities ensure continued compliance with legal requirements and HTA standards. This work is funded by

licence fees,² which constitute 80% of the HTA's annual income. The remaining 20% is Grant-in-aid funding from the Government, which for the year 2012/13 totals £860,000.

12. The HTA licences 543 establishments across all of its sectors, and in August 2012 issued 35 licences to transplantation establishments under the Quality and Safety of Organs Intended for Transplantation Regulations 2012.
13. A small team works on the assessment of living organ donations, of which there are approximately 1,200 a year. Of this figure about 10% are classified as complex cases and require further assessment by a panel of HTA Authority Members. Each panel consists of three Authority Members. All 12 Members sit on panels on a rotation basis and are trained annually to carry out this statutory function. This work is funded by Grant-in-aid.
14. The HTA deals with approximately 2,800 enquiries a year. Half of these enquiries come from members of the public and the remaining half from licensed establishments and professionals. Enquiries cover areas as diverse as donating one's body to medical science to queries on the storage of tissue samples following a Coroner's inquest. Recently, the HTA has seen an increase in the number of enquiries received on umbilical cord blood banking, illustrating how the sectors with which the HTA works are rapidly evolving.
15. It will be important that the scientific expertise and knowledge that is required to answer such enquiries is not lost under a transfer to another organisation or organisations.
16. The HTA is supported by a very small team of staff who provide high quality business support functions, including Human Resources (HR), business technology, legal, finance, administration, project management and communications. For example, the HR function is delivered by just one person, and the reduction in staff in support roles over the last two years has contributed to the 27% efficiency savings that the HTA has made.
17. The Authority itself has eleven Members and a Chair. The Chair, Baroness Warwick, works two days a week for the HTA, and each of the other Authority Members work two days a month. By statute, the Chair and at least half of the membership must be lay, and Members currently include a transplant surgeon, an ethicist, a coroner, a pathologist and a Professor of Diversity in Public Health. The Authority meets six times a year and one of these meetings is held in public.

² In 2011/12 licence fee income totalled £3,120,000

18. The HTA's success to date is largely due to the manner in which it discharges its functions. The high opinion of stakeholders and the high standards of compliance throughout the regulated sectors are attributable to the specialist knowledge and skills of the HTA's people, the quality of the relationships that have been built and the focus on advice and guidance. These combine to add value and give the HTA its distinctive style of regulation which accounts in part for the high standards of compliance throughout the regulated sectors.

Indeed, Henny Braund, Chief Executive of the charity Anthony Nolan, recently stated in BioNews that:

*"We have a regulator [the HTA] whose board has learnt some pretty complicated detail about cells, laboratory techniques, medical practice, genetics, national and international law. In turn, the board is supported by an expert executive. Board members play an active role in sector working groups, for example in transplant, ensuring they can guide the organisation with a clear awareness of their stakeholders' evolving needs."*³

Similarly, Dr Archie Prentice, President of the Royal College of Pathologists (RCPATH), has stated:

"The HTA continues to reduce the burden of regulation whilst being proportionate and risk-based in its approach. The HTA's Histopathology Working Group has made much progress in addressing the concerns of the sector, whilst balancing them with those of the public and the requirements of the Human Tissue Act."

19. The HTA has always been committed to collaboration with other organisations, and continues to work to realise synergies with other bodies. The HTA carries out joint inspections with the Medicines and Healthcare products Regulatory Agency (MHRA) and will continue to strive to do so for the 15 establishments which are regulated by both organisations for Advanced Cell Medicinal Products. Significant work was undertaken during 2011 and early 2012 by the HTA, HFEA and the Care Quality Commission (CQC) to ensure that information held on establishments that are licensed by more than one of these regulators is available to the others. This aims to provide increased levels of protection for the public and improvements in clinical standards. Work is also ongoing with Clinical Pathology Accreditation (CPA) to scope the options available for joint working, which may initially involve a small number of establishments, to explore whether this could be expanded to include other establishments regulated by both organisations.

³ [Bionews article](#)

20. The HTA is widely acknowledged to be a highly effective and efficient regulator. In addition to its core regulatory role, the HTA is regularly called upon for its expertise by a wide range of groups and organisations. In the last year the HTA has worked with and supported the groups in the table below.

Organisations the HTA worked with and supported during 2011 and 2012		
Association of Chief Police Officers	Bereavement services	British Transplantation Society
Competent Authorities in other EU Member States	Coroners	Council for Healthcare Regulatory Excellence
EU Commission	Health Research Authority	Hillsborough Independent Panel
Home Office	Ministry of Justice	National Policing Improvement Agency
NHS Blood and Transplant	Nuffield Council on Bioethics	Patient organisations
Royal Military Police	Stillbirth and Neonatal Deaths charity	The three devolved administrations

21. The table above is not exhaustive, but gives an indication of the range of relationships the HTA has, many of which were instigated by the partner organisation as it required specialist knowledge and expertise to resolve or address sensitive and emotive issues. This is an example of the added value delivered by the HTA and diversity of the areas covered by such a small organisation.

22. Some of these relationships were established and developed by the HTA in order to ensure that tissues and organs are used safely, ethically and with proper consent. The regulatory approach taken by the HTA is based on advice, guidance and support; and through an active and ongoing stakeholder engagement program this approach has been improved and refined.

23. The HTA has worked with the media during crisis or potential crisis situations that have had the potential to damage public confidence, or to be accountable to the public by participating in public debate. Concerns on the removal of such support have been raised by Fiona Fox, Director of the Science Media Centre.⁴ In response to a potentially significant regulatory incident it may be difficult for a large organisation to have the expertise to be able to respond to the media quickly and seek to limit the potential damage caused to public confidence and

⁴ [Fiona Fox comment](#)

the organisation's reputation. This is particularly true of functions moving to an organisation that may have to handle such issues in parallel with a diverse and wide ranging remit.

24. The HTA is a proportionate regulatory body, and on occasion this means that robust and timely regulatory action has to be taken in order to prevent a breach of legislation or license conditions. A system of review is incorporated in procedures to ensure that there is constant learning and refinement.
25. Licensed establishments in the post mortem sector are required to report SUIs to the HTA within five working days of them having been discovered, and establishments in the human application and transplantation sectors should report SAEARs within 24 hours. This reporting allows the HTA to factor such incidents and events into the risk profile of each establishment, and allows the HTA to share knowledge to prevent such events from occurring elsewhere, or reoccurring at the same establishment.
26. The HTA has developed and is implementing an online portal to reduce the administrative burden on licensed establishments so they can view all the information relevant to their particular licence. The HTA continues to identify ways in which it can relieve the burden on those it works with, and this contributes to the organisation's supportive regulatory approach.
27. A number of the groups the HTA works with represent patients or the public more widely. Working with such groups to make sure there is public confidence in the way in which tissues and organs are used has been a key part of the success of the HTA. Continued dialogue with these groups, for example on the development of a model paediatric post mortem consent form, will be important under any of the three options presented to realise the Government's aim of "no decision about me, without me".

Options for consideration

28. The consultation document gives three options on the future of the HTA's functions. These are:

Option 1

Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the Health Research Authority (HRA); and abolish the HFEA and HTA.

Option 2

Transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and a limited number of functions that would transfer elsewhere; and abolish the HFEA and HTA.

Option 3

HFEA and HTA retain their functions but deliver further efficiencies.

29. The HTA (and many of its stakeholders)⁵ believe that option 3 is, subject to clarification of the further efficiencies envisaged, by far the best option for the regulated sectors and the public as a whole. It is the view of the HTA that this option would continue the effective and efficient regulation of human tissue and organs by the HTA, minimise the risks associated with the use of human tissue and protect, maintain and improve public confidence. The HTA therefore supports option 3.

⁵ See page 22 for stakeholder quotes and comments

The HTA's view on option 1

30. In the ALB review document published in July 2010, the option of transferring the HTA's functions to the CQC was detailed, and this was subsequently identified as the preferred option of the Government.

Benefits

31. Since the publication of the ALB review document in 2010, the HTA has been of the view that under any transfer arrangements, all of its functions should remain together. This is required to ensure that a consistent approach is taken to the regulation of appropriate and valid consent for the full range of activities in the HTA's remit, and to build on the work already done on ensuring public and professional confidence. There is currently certainty on where information can be obtained on all the HTA's functions, and separating them could cause confusion and uncertainty, undermining what has been achieved to date and increasing the risk of non-compliance.

32. It is of value to note that the HTA gives advice and guidance not only on the regulated sectors, but also on other matters relating to human tissue and organs, such as the analysis of DNA. This advice and guidance is provided to a wide range of stakeholders including members of the public, licensed establishments and the Government.

33. One of the reasons put forward in the consultation document for an overall reduction in the number of health ALBs is an envisaged reduction in bureaucracy, which will in turn reduce the burden on licensed establishments.

34. Whether or not there is a reduction in bureaucracy under option 1 will very much depend on how the transfer is undertaken.

35. The HTA believes that it is too simplistic to state that a transfer to a larger health regulator will, in itself, lead to a reduction in bureaucracy. Without knowing how the CQC will take on the functions of the HTA (for example, becoming integrated with existing functions or becoming a separate unit within the organisation), it cannot be said that transferring the HTA's functions to the CQC will reach the stated aim of reducing bureaucracy.

36. Indeed, if the benefits of the HTA's current regulatory approach are to continue, it is difficult to imagine how there could be a reduction in staff or major change in methodology on transfer. It should also be noted that the Government has no intention of altering the requirements of the HT Act, and therefore the burden will not be reduced by limiting the statutory obligations of an establishment. Rather it

is proposed under options 1 and 2 that the burden will be reduced by limiting the number of regulatory bodies in this area.

37. It was originally stated that a transfer to the CQC would result in cost savings,⁶ and therefore deliver greater value for money to the tax payer. This is not a discussion which is focussed on in the consultation document, and the HTA considers it important that sight of this original aim is not lost during any transfer.

38. There will be costs associated with closing an organisation and transferring its functions, and these have historically been above the level identified in scoping documents and impact assessments.⁷ The Impact Assessment for the transfer of the HTA's functions does not yet provide the detail required to allow a full cost-benefit analysis to be carried out. A proposal to merge the HTA and HFEA was rejected as recently as 2007,⁸ and an important factor in that decision was the costs such a merger would incur.

39. It would be disappointing if any potential transfer failed to deliver the cost savings envisaged, and came at a high price to licensed establishments and the taxpayer.

Concerns

40. The HTA notes the commitment in the consultation document to ensuring that any successor organisation has the necessary expertise and resources to carry out the additional functions for which it becomes responsible during any transfer.

41. The Health and Social Care Act 2012 requires the CQC to take on additional responsibilities, and these combined with the possible transfer of HTA functions, will pose a significant challenge to an organisation in a period of change.

42. During the two years since the publication of the ALB review document the CQC has sustained damage to its reputation, culminating in the Public Accounts Committee's Report of March 2012.

43. It will be important that any body taking on the HTA's functions is both credible to, and has the confidence of, licensed establishments and stakeholders more widely.

44. If option 1 is chosen, it will be important for the CQC to give regular reassurance to the public, professionals and the regulated sectors that they will continue to receive the same level of support, advice and guidance; and the envisaged benefit of less bureaucracy will be realised.

⁶ [Arms' Length Bodies Review](#)

⁷ [Public Accounts Committee Report](#)

⁸ [RATE debate](#)

45. The risks posed by option 1 require consideration and this is provided below. Steps will need to be taken to mitigate such risks, and assurances provided at each step of the transfer process. If the Government chooses to follow this option, the HTA will do all it can to ensure a successful transition and the continued effective and efficient delivery of services and functions.
46. The risk of a loss of expertise is highlighted in the consultation document and there is value in exploring a little further why this matters, and to whom. The feedback received by the HTA following inspections is consistently of a very high standard and it is regularly the knowledge and understanding of inspecting staff which is specifically commented on.⁹
47. The HTA has focussed on the importance of building a relationship of trust and openness between regulator and establishments, and a key facet of this has been the ability of the HTA's staff to discuss scientific and technical matters on an equal footing. The aim of this has been to ensure establishments receive the very best level of support, advice and guidance from the HTA, and that a culture of sharing best practice exists, promoting a rise in standards in each of the regulated sectors.
48. One benefit of a small organisation (such as the HTA) is that it can quickly respond to developments, and deliver a regulatory approach that is consistent, informed and appropriate. This is due to the fact that it can be quickly identified which person or team is best placed to address the issue and a decision made at senior level on whether further work needs to be commissioned. It may be more difficult for a large organisation to be able to provide this level of focus on small but significant matters, and for decisions to be made quickly when necessary. This may be made more difficult with multiple layers of management and when an organisation is responsible for a broad range of sectors that may have a high public profile.
49. The sector using tissue and cells for treatment is one of the more complex, fast growing sectors the HTA regulates because of its rapid scientific developments. By using the expertise of HTA staff and working with other agencies, such as the MHRA, the sector has been supported to help ensure that the UK is a positive environment within which emerging regenerative technologies can flourish.
50. Any regulatory body taking on new functions and seeking to build strong and appropriate relationships faces a significant challenge, and the HTA urges DH to explore how the CQC would seek to do this under option 1, prior to making a final decision. If this option is chosen, then reassurance should be given to licensed

⁹ In Quarter 1 2012/13, 99% of respondents considered the approach used by the HTA inspection team to be excellent (79%) or good (20%)

establishments and stakeholder organisations that they will continue to be inspected and receive advice and guidance from people with the specialist skills and knowledge required to do so. Part of this will be a continuation of the HTA's regulatory approach, which is based on strong relationships, advice and guidance, and proportionate regulatory action.

51. The HTA was created in part in response to the retention of organs without consent by a number of hospitals. This caused great distress to those families affected and widespread condemnation in the media and from the public more widely. Many of those affected are still in regular contact with the HTA to ensure that the risk of similar events occurring is not forgotten, and to act as a reminder that the reasons why the HTA was established have not disappeared. The advice and guidance the HTA has recently provided to the Association of Chief Police Officers and the Royal Military Police on retained human material is a timely reminder of the need for a regulator with expert and specialist knowledge.
52. Regulation must be proportionate and adhere to the right touch regulatory principles outlined by the Council for Healthcare Regulatory Excellence¹⁰ yet, if there is a loss of focus on why regulation is required or the harm it is intended to prevent, the risk of non-compliance will increase. There is also a risk that the transfer of the HTA's functions to a large and overarching body, with a different regulatory remit, such as the CQC, could lead to focus being lost.
53. In focussing entirely on the Human Tissue Act and Quality and Safety Regulations, Members of the Authority have been able to develop a level of expertise about the issues at stake. This in turn allows them to provide effective advice and challenge to the executive to continuously drive up standards and provide improved value for money. The HT Act also mandates that certain decisions relating to living organ donation can only be made by the Authority. There are approximately 120 living organ donation cases each year that must each be assessed by a panel of three Authority Members.
54. It is not yet clear what type of structure of governance the CQC would adopt if it were to take on the functions of the HTA. In order to ensure that the value derived from the current Authority is not lost, the HTA believes it is essential that a mixed professional and lay governance structure for human tissue matters continues within the CQC.
55. The consultation document notes that the CQC is an England-only regulator, whereas the HTA has responsibilities across the UK (with the HTA undertaking some functions on behalf of Scottish Ministers). It is not clear how a cross-UK solution would be delivered after the transition of functions.

¹⁰ [CHRE principles](#)

56. Under option 1 (and option 2) there will be a transitional period. This will be the period after the announcement of a transfer of functions, and before these functions actually being transferred. As work will need to be done to effect the transfer, there is a risk that focus will be lost on the primary duty of ensuring that human tissue and organs are stored and used safely, ethically and with proper consent. During this period work will need to be done by DH, in conjunction with CQC and HTA, to ensure that standards are maintained and there is clarity as to which organisation has responsibility at any given time.
57. The year following the date of transition will also pose risks as licensed establishments and the new organisation or organisations will need to forge strong working relationships, as well as rebuilding and inspiring confidence. If there is any confusion as to which organisation is responsible for a function, there will be an increase in the risk of non-compliance as advice and guidance may not be sought or accurately given, and SUIs and SEARS under-reported.
58. For option 1 to be successful the HTA believes the following reassurances would need to be in place:
- a. That there is sufficient focus by the CQC on the specialised regulatory remit of the HTA and access to expert advisors.
 - b. That effective governance arrangements are in place to oversee the effective provision of HTA functions, particularly board-level assessment of living donation cases, and accountability for these functions.
 - c. That there is sufficient strategic and operational expertise to support robust regulation.
 - d. That the regulatory approach of the HTA, based on advice and guidance, is maintained following the transfer of functions.
 - e. That the identity of the HTA is maintained to support public and professional confidence and their ability to access advice and guidance easily.
 - f. That the impact on licensed establishments and stakeholders is minimal and the transfer is seamless.
 - g. That there is the resource and expertise required to address challenging issues as they arise, and the ability to adapt processes and procedures accordingly.

Conclusion

59. Although this option keeps the HTA's functions together and therefore goes some way to ensuring public and professional confidence, the HTA is not able to support this option due to the risks it would incur.

60. If this option was chosen by the Government, the HTA would strive to ensure the successful transition and support future provision of functions in order to maintain public and professional confidence in the safe and ethical use of human tissues and organs. The HTA seeks additional reassurances about the effective and efficient provision of functions and how the risks of transition will be mitigated.

The HTA's view on option 2

Benefits

61. The HTA notes the view of a small number of stakeholders that there may be benefit in one organisation becoming the single regulator for the European legislation on blood and tissues and cells, meaning that the Human Tissue (Quality and Safety for Human Application) Regulations 2007 would become the responsibility of MHRA. While this might appear logical, questions have already been raised as to the likely change in the regulatory approach, and whether real benefits would be delivered.
62. It is of value to note that there are only 15 organisations currently regulated by the HTA and MHRA to develop regenerative therapies.
63. There are a small number of establishments which are regulated by both the HTA and MHRA for other purposes, including NHS Blood and Transplant (NHSBT), which is licensed by the MHRA for the work it does on blood donation, and the HTA for tissue and organ donation.
64. In June 2011 the HTA and MHRA worked together to draft a position statement on this proposal and concluded that there was not a strong case for such a transfer.
65. There does not appear to be a case for any of the other transfers of functions proposed under option 2.

Concerns

66. The HTA has maintained the position that its functions should remain together under any transfer, and believes the risks associated with fragmenting them are too great. For example, the risk of non-compliance due to confusion or uncertainty about regulatory remit and transition timescales.
67. Fragmentation would lead to an increased number of organisations having responsibility for consent provisions, and could give rise to inconsistencies and differing standards being applied.
68. This option is likely to prove most confusing to stakeholders and the regulated sectors. A benefit of both options 1 and 3 is that functions will be kept together, which gives the public, professionals and patients confidence on where to go for advice and guidance.

69. Although a number of transfer options are discussed in the consultation document, it is unclear whether these have been fully explored with the possible successor bodies, for example Arts Council England. Indeed, some of the bodies do not currently have the remit to take on all the functions identified under option 2. When it has been suggested that there may be a transfer to an organisation outside the DH family, there is a risk that there will be a lack of consistency in the regulation of consent and this should be considered seriously if this option is to be taken forward.
70. Under this option (and option 3) the functions of the HTA that relate to research remain with the other functions, rather than transferring to the newly formed Health Research Authority (HRA). Since the HRA was established in November 2011 the HTA has worked closely with it on a multi-agency programme of work to shape an effective national role for the HRA, within its remit to provide a unified approval process for research projects and to promote consistent, proportionate standards for compliance and inspection.
71. It may seem that the natural home for all regulatory responsibilities for research is the HRA. However, the HTA's function in relation to research (which is to ensure that premises at which human material for research is removed from the deceased and subsequently stored are licensed and meet the standards required by the HT Act, and that consent is in place) finds its best fit with other activities licensed by the HTA such as post mortem examination and transplantation, rather than with the HRA's primary aim of protecting and promoting the interests of patients and the public in health research.
72. Option 2 would prove even more complex than option 1 in regard to the jurisdiction of successor bodies in comparison with the HTA. Option 2 would require a great deal of exploratory work to be done with a range of organisations and it is questionable whether this could be done in the expected two year transition period.
73. There is also a concern about regulatory fit. Questions have been raised as to whether a hospital or other licensed establishment would consider themselves to be aligned to a number of the organisations suggested, and therefore be confident in seeking advice and guidance from them.
74. Such a significant change as proposed under option 2 is likely to increase the regulatory burden on establishments, if this is in part defined by the number of organisations they are required to work with.
75. The consultation document makes it clear that there are, as yet, no clear plans as to where the assessment of living organ donations should be transferred. The HTA runs this process effectively and efficiently, and has built strong relationships

with the transplant community and the 150 Independent Assessors who carry out interviews with donors and recipients on the HTA's behalf. Without HTA approval, living donations cannot take place; therefore, any disruption to this process could directly affect outcomes for patients.

76. A discussion of the possibility of NHSBT taking on this function is included in the consultation document, but quickly dismissed. The HTA shares the reservations about the possible perception of conflict associated with the independent check that a living organ donor's consent is freely given being undertaken by the same body responsible for increasing organ donations. This could damage public confidence in this important process.

Conclusion

77. Option 2 appears to create a less streamlined regulatory landscape, which is more complex for establishments and increases bureaucracy. In light of these factors and the increased risk of a decline in standards and reduced public and professional confidence, the HTA does not support option 2.

The HTA's view on option 3

78. Option 3 is the HTA's preferred option. The reasons for this are detailed in paragraphs 87 to 95 and this option is supported by many professional and patient groups as detailed below.

79. Option 3 retains all of the benefits of the HTA's current regulatory regime as set-out in earlier paragraphs of this response, while realising further efficiencies

Efficiencies

80. It is not yet determined what scale of efficiencies are envisaged under option 3. The HTA has made efficiencies of 27% from 2010/11 to 2012/13 and continues to review how it regulates and operates to provide value for money to licensed establishments and tax payers.

81. Further efficiencies are planned for 2013/14, and by 2015 the HTA will have refined regulatory processes further. This will include having reviewed the regulatory activity required from the Quality and Safety of Organs Intended for Transplantation Regulations in the light of experience over two years, and identified ways of operating that would lead to further efficiency savings. With the support of DH on more significant changes, further efficiency savings would be possible.

82. The HTA estimates that savings of 5 to 10% could be made in 2015, compared to 2013/14 levels (which already include savings of more than 30%, a saving of up to 37% from the 2010/11 baseline, as well as absorbing inflation). If the HTA remains a standalone body, it will continue to review ways of working and make efficiencies. This approach is embedded in the HTA's culture and there is a good track record.

83. The HTA has not focussed only on financial efficiencies, but has also sought to reduce the burden on regulated sectors. There has been a streamlining of the inspection process over the last two years and a move towards themed inspections. Themed inspections enable the HTA to focus resources on areas of higher risk in order to maintain and increase public confidence in the regulation of human tissue and organs, while also reducing the bureaucracy faced by licensed establishments.

84. Further efficiencies can be made by working even more closely with the CQC, HFEA, HRA and other regulatory bodies and agencies, to build on the HTA's reputation for collaborative work. The HTA is actively exploring different collaborative models with other regulators and agencies to assess whether there

is scope to provide even greater efficiency savings while still safeguarding the effective delivery of HTA functions.

85. For example, the HTA is working with the HRA to ensure researchers are supported in their work. The HTA has previously taken similar action with the National Research Ethics Service (NRES) through a Memorandum of Understanding, to ensure that advice and guidance on research regulation is clear, coordinated and consistent. This also ensures that mechanisms are in place to put researchers in touch with the most appropriate regulatory expertise.
86. The HTA notes the guidance issued by the Cabinet Office in 2011 on reviews of Non Departmental Public Bodies.¹¹ The triennial approach outlined in this guidance is welcomed by the HTA.

Benefits

87. The HTA considers that option 3 presents an opportunity to engage with DH with the aim of achieving efficiencies that are currently outside the HTA's control and are therefore in addition to those that would have happened anyway, notwithstanding the report of the ALB Review.
88. The HTA fulfils a valuable role in regulation that avoids other bodies taking on additional work by identifying areas which are suitable for collaborative working, and this results in efficiencies elsewhere. An example is how the HTA has absorbed the work arising from the Organ Donation Directive at minimal additional cost.
89. The joint working that the HTA is developing with other regulators, while not leading to cost reductions for the HTA, may help others to make efficiencies and pilots indicate that there are less tangible, but nonetheless significant, benefits for those being regulated, such as less disruption to their existing working practices.
90. Over the seven years of the HTA's existence, it has developed expertise and systems that have helped licensed establishments and led to efficiencies and increased standards in those establishments. The continuation of the HTA preserves this and avoids establishments needing to make costly changes to their processes.
91. There has been detailed discussion of the strengths of the HTA which may be lost in transition and it is of value to revisit these:

¹¹ [Cabinet Office report](#)

- a. A supportive and proportionate regulatory approach, based primarily on advice and guidance to ensure compliance with relevant standards.
- b. Specialist staff, with a strong commitment to their area of expertise and pride in the organisation, who are responsive to the requirements of the regulated sectors.
- c. A supportive and diverse Board, which provides strategic leadership and shapes the approach of the executive.
- d. A collaborative approach based on engagement and communication, as well as a strong record of joint working to reduce regulatory burden and costs.
- e. A clear and consistent focus on the primacy of consent.
- f. The ability and willingness to establish and maintain relationships with other government departments and organisations to ensure the safe and ethical storage and use of human tissue and organs, with proper consent.
- g. A continued aim of increasing public and professional confidence in the storage and use of tissue and organs by using the media and other communication channels to raise awareness of regulation in this often highly sensitive area.
- h. A strong track record of identifying and realising efficiencies.
- i. Developing a culture of confidence and trust in human tissue regulation amongst licensed establishments and other stakeholders.

92. Option 3 ensures these strengths are not lost, and can be built on. Any transition would be likely to lead to these diminishing and possibly disappearing, which would mark a backward step in the regulation of human tissue and organs.

93. The HTA continues to strive to increase the level of collaborative working it is engaged in with other regulatory bodies to reduce the burden on licensed establishments and the tax payer. Option 3 allows this to be delivered and refined, without the demands of a transition detracting from this.

94. This collaborative approach is already delivering tangible benefits in the form of information sharing and joint inspections, and more are planned for the next year.

95. The HTA's determination to deliver value for money, both to licensed establishments and the tax payer, is outlined at paragraphs 80 to 86 above, and this goal continues to be a key part of the HTA's objectives.

Concerns

96. It is noted that this option does not contribute to the stated aim of reducing the number of health ALBs. However, it would reduce the cost to licensed establishments and the taxpayer, as well as ensuring the regulation of tissue and organs remains transparent. The HTA believes that if it is possible to:

- a. maintain standards; and
- b. increase public, patient and professional confidence; and
- c. deliver further efficiencies,

without incurring the risks inherent to options 1 and 2. This must be given serious consideration.

97. The HTA is of the view that, if the efficiencies required by the Government under option 3 are so great that the organisation would in reality be unable to function effectively, then this option is not a realistic one. This is due to the fact that regulation would be weakened and there would be greater risk that the public's confidence in the safe storage and use of human tissue and organs with proper consent could not be maintained.

98. The HTA seeks further information from DH about the extent of the efficiencies required under this option.

Conclusion

99. The HTA supports option 3 as it ensures the safe storage and use of human tissue and organs with proper consent, while still delivering efficiencies for licensed establishments and the taxpayer.

Views of stakeholders

100. As identified above, the HTA has a wide range of stakeholders including licence holders, professional bodies and patient groups. It is acknowledged that there will be a range of views and opinions amongst stakeholders, which are likely to be detailed in the responses to the consultation. There has, however, been a significant number of representations made to the HTA directly expressing strongly held views on the options presented.

101. All the stakeholders who have contacted the HTA have been in favour of option 3, for a wide range of reasons. At the root of these has been the fact that the HTA is regarded as an efficient and effective regulator, which places consent and public and professional confidence at the centre of everything it does.

102. The HTA has received feedback from stakeholders that they are concerned at the prospect of being regulated by the CQC, with the following comments providing examples of this:

“We do not have the same confidence in CQC. It has not yet mastered its current remit. It does not listen and act on maternity issues in the same way that we have found you do.”

National Childbirth Trust

“The HTA has greatly increased public confidence in the proper collection, storage and use of human organs and tissue for public benefit. Independent Cancer Patients Voice members do not think it appropriate to de-rail the regulatory process by re-organisation or [relocating] the functions of the HTA. We are concerned that the high level of acceptance to researchers will be undermined and public confidence eroded if the process was managed by the CQC in which public confidence is very low.”

Independent Cancer Patients Voice

“I agree that being part of the CQC may create a very bureaucratic organisation, which could create conditions, which could allow another Alder Hey situation to occur, problems which other parts of the world continue to experience, with the usual attendant adverse media storm.

“I fully support the independence of the HTA if only because of the legal ramifications of the [Human Tissue] Act, some organisation has to enforce the laws embodied within the Act and I think this is best dealt with in the tolerant way, that it has been, by the present and independent HTA. Problems are more easily dealt with and accounted for by an independent HTA.”

Public Group Stakeholder

103. It is noted that in the consultation document DH commits to working with stakeholders during any transition. However, it will be important to consider how concerns about the CQC will be addressed particularly.

104. The HTA has been encouraged by the number of stakeholders who have been in contact to state their support for option 3 and for the HTA to remain an independent body, while realising further efficiencies. Comments of particular note include:

“The changes being proposed in the consultation document seem to create costly and cumbersome processes, and inevitably bring with them the risk of misinterpretation by transferring all or some of the HTA’s responsibilities to other bodies.”¹²

British Neuroscience Association

“The potential adverse effects, on the UK’s ability to contribute to (and generate income from) vital medical research, of a further failure of public confidence in regulation of human tissue storage and use is unquantifiable. The visibility and unambiguous purpose of the HTA since its inception have been invaluable in ensuring such confidence.”

Confederation of Cancer Biobanks

“The abolition of the HFEA and HTA could hinder progress and investment in research and development in life sciences in the UK and could adversely affect the country’s reputation as global leader in the emerging bio-science and medical fields these bodies regulate.

“In GE Healthcare’s experience, as a major commercial organisation that operates in areas regulated by both the HTA and HFEA, we have found both these regulators to be efficient, knowledgeable, transparent, and above all extremely helpful to us maintaining compliant operations.”

GE Healthcare

“Over the years I have witnessed and experienced the ethos and culture of the HTA. It strives for excellence, is dynamic and responsive to human need, in ways that few institutions can emulate.”

HTA Independent Assessor

¹² [British Neuroscience Association response](#)

Views of staff

105. The staff of the HTA have met to discuss the options presented in the consultation document on more than one occasion. The primary focus of staff has been that the HTA's functions continue to be delivered efficiently, effectively and economically and that the high quality regulatory approach they have been part of creating is not lost.
106. HTA staff also recognise the risks of transition and the delivery of functions by either the CQC or other organisations, and that this may compromise the safe storage and use of human tissue and organs and undermine public confidence.
107. Option 3 gained the support of the HTA's staff, and the focus was very much on the service which would be provided in the future by a successor organisation or organisations. The staff of the HTA do not believe they are the only people who can deliver a high quality service. However, they do wish to be assured that any transfer of functions would not lead to the loss of confidence and trust that has been so hard won.
108. The staff of the HTA are very proud of the work they do, how they do it, and the organisation they work for. Even if the Government's aim was to transfer every member of staff to the successor organisation, it is unlikely such a transfer would be realised and a certain amount of rebuilding would be required.
109. Maintaining a core of motivated, expert staff during any transition period may also prove challenging and, if either option 1 or 2 is chosen, it is recommended that DH makes provision for higher levels of staff turnover.

Conclusion

110. The HTA believes that of the three options presented, option 3 is the one which offers the greatest assurance to members of the public that their tissue and organs will be stored and used safely, ethically and only when there is proper consent in place. This is the reason why the HTA was established and the harm it was intended to prevent was that such activities took place without the consent of the person or their family. The risks associated with options 1 and 2, as outlined above, mean that sight of this could be lost and the confidence of the public would fall away.
111. There are many other benefits associated with option 3 and these are rehearsed throughout this document, alongside the risks associated with options 1 and 2. When balancing these risks and benefits it becomes clear that option 3 can realistically maintain public and professional confidence, while also ensuring that standards in the regulated sectors continue to rise, alongside realising greater efficiencies. The HTA believes therefore that option 3 is the best option for the public, professionals and licensed establishments. The HTA supports option 3.

Response 86 – Progress Educational Trust

Organisational Response by the Progress Educational Trust

This response is limited to comments on the Human Fertilisation and Embryology Authority and the response was formulated following a meeting between staff and trustees. A draft response was circulated to the Trustees for comment before submission.

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

1.1 We do not agree with the option to transfer HFEA functions to the CQC and the HRA, and to abolish the HFEA.

1.2 The nature of HFEA functions is such that, even assuming that they were transferred without impediment and with all of the necessary expertise transferred alongside them (both of which are very optimistic assumptions), it is likely that the HFEA would be recreated in all but name as a discrete unit within the CQC. One could argue that this has already taken place spatially (the HFEA having already moved into the CQC's offices), but for one organisation to be formally subsumed by the other would not, in our opinion, cut costs. Indeed, this exercise is likely to incur net costs because of the bureaucracy involved.

1.3 One argument that has been made in favour of transferring HFEA functions to the CQC is that because fertility treatment is now routine, it is therefore appropriate for it to be regulated by a generic body like the CQC, rather than by a specialist body like the HFEA. We have some sympathy with this view, but do not think it can be reflected meaningfully in regulation – except perhaps disingenuously via a form of deliberately engineered 'neglect', whereby it is hoped that HFEA duties will be lost from sight because the CQC has bigger fish to fry. The problem with shifting the HFEA or its functions into a bigger operation is the likelihood that it will be lost from sight. A dangerous corollary of this would be a loss of accountability.

1.4 Although this is an area in which procedures such as IVF are routine and have wide public support, a significant minority of people consider even IVF to be extremely controversial. It is therefore crucial that public confidence in the effective regulation of this area is maintained. It is an inconvenient truth that the CQC has an image problem, with public confidence in this body eroded following the recent care homes scandal.

1.5 Primary legislation in this area remains predicated upon a special moral status ascribed to the embryo, with the consequence that fertility treatment is the subject of deliberate regulatory exceptionalism. This arrangement is at the core of the Warnock settlement developed via the Warnock Report and the two HFE Acts. It should not be undone without due political contestation, addressing matters of morality well ahead of financial cost.

1.6 The HFEA's role is small and specialised and should be circumscribed, and a big organisation will simply have other priorities. If (as seems likely) public money continues to be tight, there will also be an irresistible tendency to move staff from the broader CQC into the CQC's HFEA-equivalent department when vacancies occur. This niche area will then be

vulnerable to getting staff at particular grades, solely because they are not useful elsewhere. By definition, they will be ignorant of the HFEA's role and its subject matter. Specialist work requires specialist staff.

1.7 Human resources at the HFEA have suffered since the announcement that it faced abolition. A number of staff have left and have not been replaced, or have been replaced by promoting other staff members who lack the requisite experience, expertise and gravitas.

1.8 The area the HFEA regulates is still developing apace, and provision needs to be made to cope with unforeseen developments, new breakthroughs and novel techniques. For example, the Government has commissioned the HFEA to run a public consultation on novel techniques for avoiding the transmission of mitochondrial disease, and if the law is changed to permit the use of these techniques in treatment, then the HFEA will be responsible for regulating their use.

1.9 If a development occurs with similarly far-reaching scientific, social and legal ramifications – say, the successful derivation of viable human sperm from induced pluripotent stem cells – will the CQC have sufficient resources to address this development? Or will the first question asked be what is going to be cut from the workload?

1.10 The areas which the HFEA regulates still capture the media's attention, often receiving front-page coverage in national newspapers. A press office with expertise in this field is needed, and a general press officer at the CQC without the necessary experience could easily exacerbate problems in the media rather than successfully managing them.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

2.1 Your consultation document outlines the considerable overlap between fertility clinics that are regulated by the HFEA, and centres that are regulated by the CQC. However, the savings that could be made by eliminating this overlap are likely to be limited, because fertility treatment is a sufficiently distinctive area of healthcare to require its own inspection regime. This remains the case, even if those who inspect a centre represent one organisation between them rather than two.

2.2 That said, an independent review of the inspection procedures by both organisations should be carried out, to avoid duplication where possible, to avoid potential conflicts and to streamline the processes of both the HFEA and CQC.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

3.1 We do not agree that HFEA functions relating to research should be transferred to the HRA, for two reasons.

3.2 First, embryo research and fertility treatment are fields that are connected in several respects. They both involve embryological expertise and they both involve the use of donated gametes and embryos, not to mention the challenge of encouraging donation of these gametes and embryos. There is also a category of translational work that exists

between laboratory research and clinical practice, making it still harder to distinguish the two (for example, if techniques to avoid the transmission of mitochondrial disease are legally permitted, they will pass through a translational phase). It is therefore illogical to separate embryo research and fertility treatment, when this has been performed by a single regulator for two decades.

3.3 Second, while we sympathise to some extent with the desire to reduce regulatory burdens upon researchers, there is no guarantee that the HRA will succeed in achieving this aim. The HRA is a new organisation still awaiting NDPB status, and while it was established with the aim of reducing regulatory burdens, it is too soon to tell whether it can deliver.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

4.1 There is an argument to be made against the existence of arm's-length bodies in general, on the grounds that by deriving authority from government while being separate from it, such bodies can never have accountability commensurate with the power they wield. According to this argument, all HFEA functions would sit better with central Government.

4.2 However, we do not currently have a political culture that would make this argument viable. The logical corollary of a reduction in the number of arm's-length bodies is an appetite on the part of Government for assuming rather than outsourcing responsibility, and for engaging in principled moral debate about relevant policies and practices. This appetite does not appear to exist. A desire simply to reduce costs and regulatory burdens is not sufficient to justify a return of functions to central Government, which is itself subject to cuts, and which has traditionally been slow in responding to issues arising in fertility treatment and embryo research. We are also concerned that staff at the Department of Health who have expertise in this area have been redeployed.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

5.1 We believe that the HFEA should retain existing functions but deliver further efficiencies by tighter focusing. This is because transferring these functions will not, in our opinion, lead to improvements in efficiency or effectiveness, whereas such improvements are eminently feasible if the HFEA remains.

5.2 Our small charity addresses the same areas which the HFEA regulates (fertility treatment and embryo research), and is almost as old as the HFEA. Like the HFEA, we were founded following the passing of the original HFE Act, while our precursor organisation (the Progress Campaign for Research into Human Reproduction) was founded in 1985 in response to the Unborn Children (Protection) Bill proposed by Enoch Powell. Over the past two decades, we have come to consider ourselves a 'critical friend' of the HFEA, supporting it or criticising it as appropriate based on our ongoing evaluation of its decisions and activities. We understand that some individuals and organisations are very critical of the HFEA (indeed, we offer several criticisms of our own below) but we do not believe that calling for the HFEA's abolition via a response to this consultation is the appropriate vehicle for this critical impulse.

5.3 Some of the frustration that individuals and organisations feel towards the HFEA is in fact sublimated frustration at the way its duties are defined in statute. The only honest and appropriate way to exercise this frustration is via Parliament. Inasmuch as the HFEA is a legitimate target of frustration, those who would like to see it abolished assume that its deficiencies are so severe that any alternative regulator would be better. From our perspective, this position is naïve. The CQC is a beleaguered organisation which the House of Commons' Public Accounts Committee has specified 'should not take on the functions of the HFEA at this time', while the HRA is a new and untested organisation. It would be foolish to rely on presumptions that these organisations will regulate in ways that are less competent and/or more objectionable than the HFEA.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

6.1 The HFEA could deliver savings by adopting a more minimalist approach to its statutory duties. The best way to achieve this would be to audit the current activities of the HFEA, compare them to the organisation's statutory duties, and pare back the activities accordingly.

6.2 For example, the HFEA recently launched a National Donation Strategy Group, with the aim of identifying and addressing impediments to gamete donation. While we think this is a laudable aim (indeed, our Director is a member of the group) it takes a generous interpretation of the HFEA's duty to provide information to see this as being within the organisation's statutory remit. This is especially the case, when one considers that the DH has to date funded the National Gamete Donation Trust to perform what is ostensibly the same work.

6.3 The HFEA could also deliver savings by developing a more rigorous and disciplined organisational culture. For several years now, we have ensured that we attend every London-based HFEA open authority meeting, and we also attend various other HFEA events. The impression given at these meetings is that the HFEA's organisational culture is, at least in some respects, poor. Authority Members' views are curtailed by the Chair and decisions appear to be rushed through. Our perception of these open meetings is that the fact that HFEA does not give a more professional impression of itself (whatever its shortcomings behind closed doors) suggests a lack of judgment and a poor understanding of public perception and a contempt for that public and sometimes the very Authority members themselves.

6.4 The phrase 'public purse' needs to be clarified in relation to the HFEA, because much of the organisation's income derives not from Government funding, but from licence fees. However, since these licence fees are passed on to the public in the form of fertility treatment fees, talk of the public purse is not entirely inappropriate. In fairness to the HFEA, there are restrictions on how it is permitted to use its cash surplus (which was revealed to be a remarkable £3.4million earlier this year), and perhaps these restrictions create perverse incentives for inefficient and ineffective use of money. But whether the blame lies directly with the HFEA or with the policies that restrict its spending, a situation where HFEA staff talk openly at public meetings of the need for 'high-burn activities' to reduce the organisation's surplus (as we have witnessed) is unacceptable and must change.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

7.1 We would like to see a reduction in HFEA activities via a more minimalist interpretation of the organisation's statutory duties, there are no functions as such that we think should be transferred elsewhere.

7.2 We entertained briefly the argument that the HFEA register of information might be better maintained elsewhere – for example the Health and Social Care Information Centre, as proposed in the consultation document – where there is appropriate technical expertise. We also considered this argument in light of the fact that no satisfactory answer has yet been given by the HFEA, DH or anyone else, to the question of who will manage new issues that arise, once people who were conceived with donor gametes after the era of donor anonymity ended are entitled to request information about the relevant donor(s).

7.3 However, on reflection we think it would be impracticable for the function of maintaining the register to be transferred elsewhere, because this function is not sufficiently discrete. The register incorporates data submitted by clinics to the HFEA, as a condition of their license, on a rolling basis. The register is also dynamic in its entirety, rather than being wholly or partially static – for example, a datum such as the number of genetic half-siblings that a donor-conceived person has, or the identity of such genetic half-siblings, will always be liable to change. Furthermore, the register contains data relating to both public and private sector fertility treatment, whereas the Health and Social Care Information Centre is dedicated to public health data. The handling of personal data and public health data requires very different approaches.

7.4 It remains the case that in 2023, the first people who were conceived with donor gametes after the era of donor anonymity ended will reach the age of 18. Consequently, they will be entitled in law to request that the HFEA, or its successor, provides them with information about the relevant donor(s). It is far from clear how and by whom the logistics of this, and the provision of any necessary counselling, will be managed and funded. This needs to be resolved.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

8.1 We do not accept the assertion (unsupported by any evidence) that 'the option of transferring functions to CQC except for HFEA-related research functions would avoid fragmentation of expertise'.

8.2 Even if fragmentation of expertise is technically avoided, there will doubtless be attrition of that expertise, because not all HFEA staff and advisers will want to work for another organisation – especially not an organisation with as poor a recent reputation as the CQC. Indeed, attrition of expertise has already been taking place for

two years at the HFEA, as a consequence of its uncertain future following the Government's review of arm's-length bodies. Several staff members have left and have not been replaced, or have been replaced by promoting other staff members who lack the expertise desirable.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

9.1 In our response to Q6 above, we refer to the fact that the HFEA's organisational culture is, at least judging by the impression given at open meetings, poor. Signifiers of this include the Chair's frequent and inappropriate jocularity when discussing serious matters (we do not wish for the organisation to be po-faced but it deals with many areas where such levity is completely misplaced), and also her lavish praise for staff members for simply doing their job is disproportionate.

9.2 The HFEA's recent Donation Review and related public consultation attracted criticism from a wide range of stakeholders, not simply because of the conclusion that was reached, but because of the way the review was conducted. An especially good example of HFEA conduct was the fact that one of its decisions following the review was released to the media before Authority members had even voted on it at the relevant public meeting, thereby undermining the credibility of the proceedings. If the HFEA is spared abolition (as we hope it will be), these issues must be tackled by its recently appointed chief executive, Peter Thompson.

9.3 Much criticism has been levelled at the current Chair of the HFEA, Lisa Jardine. Most recently, she has attracted criticism for her intemperate comments to the press regarding the HFEA's public consultation 'Medical Frontiers: Debating Mitochondria Replacement'. Given the sensitivity of the areas the HFEA regulates, its figurehead will always attract attention and criticism, but the point to be made here is that the chairmanship of the HFEA is emphatically not a role for a 'personality' – whatever their qualities, and however eminent they may be in their calling in other areas outside this one. The Chair is the public face of the Authority and not the Authority itself.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

10.1 We believe that the government has carried out the wrong consultation.

10.2 The Government should have ordered a detailed review of the HFEA's functions and activities – to establish what the organisation is currently doing which is over and above that required by statute – and combined this with a stakeholder consultation about overly bureaucratic and burdensome regulation and should have sought evidence not just opinion. The findings from this review should have formed the basis for securing much-sought-after cost savings. Additional benefits of this strategy would have been curbing of HFEA 'mission creep', winning buy-in from stakeholders, and improving the HFEA so that it is fit for purpose for years to come.

11. Can you provide examples of costs and benefits of these proposals?

See our responses to questions above.

12. Do you have any comments on the consultation Equality Analysis?

No.

Addendum

PET has organised two public events about the proposed abolition of the HFEA. Approximately 300 people attended the first event and 150 people attended the second.

At PET's first public event 'The End of the HFEA: Are We Throwing the Baby Out with the Bathwater?' in January 2011 we asked the audience to complete feedback forms. One of the questions we asked the audience was:

Should the HFEA continue to oversee assisted conception and embryo research?

The responses were as follows.

Yes	65
No	22
Don't Know	30

We also asked: Have your views changed as a result of attending this event? The responses were as follows.

More in favour of HFEA	29
Less in favour of HFEA	48
No change	34

At PET's second public event in September 2012 we asked:

Which of the Government's three options for the future of the HFEA gets your vote?

- [1] **All HFEA functions transfer to the Care Quality Commission except functions relating to research, that pass to the Health Research Authority. The HFEA is abolished.**

- [2] **All HFEA functions transfer, as set out above, but a limited number of functions transfer to organisations other than the Care Quality Commission.**
- [3] **The HFEA retains its functions, but delivers further savings.**

The responses were as follows.

1: Transfer HFEA functions to the CCC except functions relating to research	4
2: Limited number of functions do not pass to the CCC	11
3: The HFEA retains its functions but delivers further savings	38

The Progress Education publishes **BioNews** a digital weekly news and comment service covering assisted conception, human genetics and stem cell and embryo research since the announcement that the HFEA faced abolition we have published a number of related comment pieces from a range of authors. These are listed below.

BioNews Comment pieces

August 2010 The demise of the Human Fertilisation and Embryology Authority
http://www.bionews.org.uk/page_68168.asp

August 2010 Wither the HFEA and the fate of donor registers?
http://www.bionews.org.uk/page_69470.asp

The demise of HFEA – Don't lament - or celebrate - too soon, it may never happen
http://www.bionews.org.uk/page_68043.asp

How not to save money: Unscrambling the HFEA
http://www.bionews.org.uk/page_68208.asp

Sept 2010 Is the Human Fertilisation and Embryology Authority fit for purpose?
http://www.bionews.org.uk/page_70517.asp

Sept 2010 Who will look after donor conception if the HFEA goes?
http://www.bionews.org.uk/page_70062.asp

October 2010 Why we shouldn't abolish the HFEA
http://www.bionews.org.uk/page_71776.asp

May 2011 Gamete Donation Review - not the HFEA's finest hour
http://www.bionews.org.uk/page_94012.asp

Feb 2011 HFEA must address its 'misconceived interventions'
http://www.bionews.org.uk/page_89820.asp

March 2011 HFEA: time for rebirth or burial?

http://www.bionews.org.uk/page_89730.asp

March 2011 The error of our ways? The demise of the HFEA and the prevention of errors in assisted conception

http://www.bionews.org.uk/page_89753.asp

October 2011 Perhaps the Government is right to plan to abolish the HFEA

http://www.bionews.org.uk/page_110436.asp

Jan 2011 The end of the HFEA: Are we throwing the baby out with the bathwater?

http://www.bionews.org.uk/page_87217.asp

Feb 2012 £3.4 million is a heck of a lot of money!

http://www.bionews.org.uk/page_128416.asp

Feb 2012 An embarrassment of riches

http://www.bionews.org.uk/page_128398.asp

July 2012 Better regulation for fertility treatment: a review of the options

http://www.bionews.org.uk/page_156837.asp

Sept 2012 Quangoing, going, gone: what should happen to the HFEA?

http://www.bionews.org.uk/page_182787.asp

July 2012 Concerns about the consultation on the future of the HFEA

http://www.bionews.org.uk/page_159616.asp

July 2012 Who will look after donor conception if the HFEA goes?

http://www.bionews.org.uk/page_160885.asp

Response 87 – Belfast Health and Social Care Trust



Belfast Health and Social Care Trust delivers integrated health and social care to 340,000 citizens in Belfast and part of the Borough of Castlereagh. It also provides specialist services to all of Northern Ireland. With a staff of more than 20,000, it is one of the largest Trusts in the United Kingdom. The Trust is currently licensed by the Human Tissue Authority in 5 areas of activity:

- Post Mortem
- Human Application (use of Tissues and cells for patient treatment)
 - Bone Bank
 - Burns Unit
 - Stem Cell Bank
- Research

The Trust welcomes this opportunity to respond to the proposals within the consultation document, and is keen to ensure that the effectiveness of the existing regulatory model is not adversely affected by any changes to how the functions of the Human Tissue Authority will be carried out. (A separate response has been submitted detailing the Trust's views regarding the future of the Human Fertilisation and Embryology Authority)

- 1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA? Please explain why you think this.**

No.

The Trust believes that the HTA's regulatory functions should not be transferred elsewhere, but rather that this body should continue in its current role.

The HTA is an extremely efficient and effective regulator and has secured the confidence of professional staff within the Trust as well as patients and the wider public. The HTA has developed robust methods of ensuring regulatory compliance that are rigorous and challenging, but also responsive where

possible to the realities and challenges of providing and managing healthcare services on the ground.

The regulatory systems employed by the HTA, notably the proportionality of approach; provision of specialist advice and guidance (both in the context of scheduled site inspections, and on an ongoing *ad hoc* basis where queries or concerns arise within the Trust); and emphasis on minimising administrative and financial requirements have generated extremely positive engagement with the Trust across all of its licensed activities since the HTA was established.

It has been our experience that the HTA consistently demonstrates sensitivity to feedback from licence-holding organisations regarding its regulatory processes - adapting its working practices and providing additional guidance where required. This ongoing focus on self-improvement has ensured that the HTA remains fit for purpose and succeeds in supporting maximum regulatory compliance with minimum bureaucracy. We would be concerned that this highly beneficial approach to regulation would be jeopardised by the transfer of HTA functions to a large-scale, more generic organisation.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The Trust believes that changes to existing regulatory arrangements under the HTA could potentially impact upon public confidence in the standard and quality of licensed activities being carried out by organisations. The loss of well-established, widely recognised regulatory bodies could potentially undermine confidence of patients and the public in these often sensitive areas of healthcare provision.

As previously mentioned at 1 above, further clarity regarding the proposed approach between the CQC and RQIA within Northern Ireland would be helpful to allow a more robust evaluation of the transfer of regulatory functions.

The confidence of healthcare professionals working in these areas could also be adversely affected, with concerns that quality will be compromised (particularly at the initial stages of any newly implemented system) due to loss or dilution of specialist knowledge and expertise on the part of the regulators – both in terms of capability to assess organisations in site inspections and appropriately ascertain levels of compliance, but also to in terms of expertise and experience to provide meaningful guidance where concerns are identified by organisations on a day-to-day basis.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Please see separate BHSCT response dealing specifically with HFEA functions.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No. The Trust believes that the functions of the HTA should be retained within a single organisation. Division of these functions across a number of organisations will increase both the complexity of regulatory processes and increase the risk of non-compliance on the part of licensed organisations.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

The Trust believes that the HTA should retain its existing functions and continue in its ongoing work to produce efficiency savings. Collaborative working with other regulatory bodies, and continuing review of working practices are already evident on the part of the HTA. We believe that continuing to approach regulation in this way would allow for further efficiencies to be made whilst maintaining the valued systems and working relationships which have proven to be so highly effective to date.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

The process of transferring functions from HTA to other bodies would inevitably involve significant costs at the outset. Retaining functions within the existing organisation would clearly avoid this financial cost, and would allow existing processes regarding identification of more efficient ways of working to continue within the HTA.

7. Within the option of retaining the HFEA and HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No.

The Trust believes that any fragmentation of the HTA's regulatory functions is not a viable option. Retaining these functions within an organisation which already has an effective infrastructure and well-established working practices poses the least risk to ensuring ongoing compliance with legislative requirements and standards.

- 8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?**

No.

- 9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.**

The Trust believes that the HTA fulfils its function as an independent regulator in a manner that is both efficient and effective. The HTA's approach is particularly robust due to the specialist skills and expertise of their regulatory staff, and their continued focus on providing a supportive and proportionate approach to regulation in order to best enable regulated organisations to achieve and maintain compliance.

With regard to how such functions might be undertaken in the future, the Trust would be keen to see the minimisation of overlap with other regulatory and / or professional bodies being prioritised as an objective. Avoidance of duplication (for example in preparation for site inspections; ongoing routine requests from regulators for activity and performance data) should be prioritised to reduce the administrative burden on organisations. The ongoing liaison between HTA and CPA for example is an extremely welcome development which should be replicated in other areas where possible.

- 10. Do you have any other comments on the consultation proposals that you would like to share with us?**

No.

- 11. Can you provide examples of costs and benefits of these proposals?**

No.

- 12. Do you have any comments on the consultation Equality Analysis?**

No.

Response 88 – Institute of Biomedical Sciences



**RESPONSE FROM THE INSTITUTE OF BIOMEDICAL SCIENCE
ON THE DH CONSULTATION:**

**PROPOSALS TO TRANSFER FUNCTIONS FROM THE HUMAN FERTILISATION
AND EMBRYOLOGY AUTHORITY AND THE HUMAN TISSUE AUTHORITY**

The Institute of Biomedical Science (IBMS) is the professional body for biomedical scientists working in the United Kingdom. It represents approximately 20,000 members employed mainly in the NHS pathology, blood, and health protection agency services in the UK, private laboratories, research, industry and higher education. The majority of its members are regulated by statute by the Health Professions Council under the protected title of Biomedical Scientist.

Consultation questions

- 1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.**

The Institute of Biomedical Science (IBMS) has concerns about the proposal and the impact its implementation could have on the services that currently fall within the jurisdiction of the HFEA and the HTA. The Care Quality Commission (CQC) is an organisation with a broad over-arching remit, very different in nature from the HFEA and HTA, which in contrast have a focused remit and associated clear body of expertise. The IBMS has considerable concern that transfer of functions to the CQC could reduce current standards of governance. The experience of this organisation is principally in respect of the HTA and there is an appreciation of its effectiveness in executing its remit. The HTA is recognised for its understanding and experience of pathology and mortuary services and the relationship that has developed to ensure safe, respectful and ethical handling and disposal of human tissues. There is concern that loss of the expertise within a much larger quality organisation could lead to a reduction of effectiveness and public confidence.

- 2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?**

There is recognition of and respect for the inspection process used by the HTA. There is concern that transfer of the functions to the CQC could lead to less rigorous

inspection regimens, less frequent inspections and of greatest concern, a loss of credibility within the international community for standards in handling human material within the UK.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Yes; the establishment of the HRA with the purpose to protect and promote the interests of patients and the public in health research was a significant step forward in regulation of research activity. In view of the effectiveness of the HRA it is the IBMS view that all research should come under one body, which could lead to the reduction of research overheads and improve efficiency.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

The HTA has at its heart a confusion between regulating the ‘donation consent’ of human tissue (its prime directive) and its subsequent use as a human therapeutic product.

Tissue obtained/stored in a HTA licensed Mortuary form part of pathological diagnosis and are not destined for use as a therapeutic product.

Tissue obtained and subsequently prepared as a ‘Therapeutic Product’ should be controlled by the existing statutory body, the MHRA. The HTA has had to establish a regulatory system to control the use of biologic Therapeutic Products and as a consequence is duplicating a system already in place within the MHRA.

Such a transfer of function in respect of human material destined for therapeutic product preparation could be achieved without the dissolution of the HTA and as a consequence deliver an efficiency saving. Both organisations would operate under the Human Tissue Act.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

This option could be explored further: it is possible that the administrative and managerial responsibilities of the two organisations could be merged, however it is likely the cost saving would be insignificant. Any required cost savings would need to be realistic, achievable and not to the detriment of the services delivered by the two organisations.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

It is possible although savings are likely to be small. The two organisations were created with specific objectives and as such they discharge their respective responsibilities effectively and efficiently. An option would be to consider the transfer

of functions associated with 'Therapeutic Products' to the MHRA (see question 4 response).

- 7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?**

All research functions within the HFEA & HTA should be transferred to HRA. Within the HTA, all therapeutic cell use should be transferred to MHRA

- 8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?**

Cost saving will only be achieved on a significant scale by the amalgamation of regulatory bodies. The CQC would need to TUPE all non-management staff, as they alone will have the necessary regulatory experience to continue the inspection work. It is likely that saving would only be achieved in the higher management levels.

- 9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.**

The MHRA should consider the establishment of a Cellular Biologics section, handling the use of all therapeutic human cellular material, including blood (as it currently does), hospital transplant centres and the ATMP licences issued to Bio-Pharma and cell manufacturers. This would future proof regulatory work in Regenerative Medicine.

There is some concern at the statement that "much of the detail of how functions would be carried out by recipient bodies would be for those organisations to decide". Detailed and effective handover of functions (if such a decision is taken) is essential to maintaining a safe and effective regulatory service.

- 10. Do you have any other comments on the consultation proposals that you would like to share with us?**

In transferring some HFEA & HTA responsibility to the HRA, note needs to be taken of international (mainly USA) requirements for the use of human material in research. Human material is routinely exchanged all over the world and depriving UK research/ Bio-Pharma of human material has already had significant financial consequences.

- 11. Can you provide examples of costs and benefits of these proposals?**

This Consultation considers the functions of the regulators (para 162). This should have been the rationale for their original implementation many years ago. There now exists an opportunity to reduce cost and improve regulatory management by devolving responsibility. The CQC was not established with HFEA & HTA functions

in mind. The proposed options are still not addressing the functions of the regulators (para 162) and will not improve the current position.

12. Do you have any comments on the consultation Equality Analysis?

No. This concludes the response from the Institute of Biomedical Science.

A handwritten signature in black ink that reads "Derek Bishop". The signature is written in a cursive style with a large initial 'D' and 'B'.

Derek Bishop
President, Institute of Biomedical Science

Response 89 – Belfast Health and Social Care Trust Regional Fertility Centre



Belfast Health and Social Care Trust (The Regional Fertility Centre)

Belfast Health and Social Care Trust delivers integrated health and social care to 340,000 citizens in Belfast and part of the Borough of Castlereagh. It also provides sexual and reproductive healthcare services. It also provides specialist services to all of Northern Ireland. With a staff of more than 20,000, it is one of the largest Trusts in the United Kingdom.

The Regional Fertility Centre (RFC) which is based within the Trust offers a comprehensive fertility service including full investigation of male and female fertility problems. We are committed to providing an excellent service to all our patients in a supportive and caring environment.

Treatments and services provided include Ovulation Induction, Stimulated Intra-Uterine Insemination (IUI), In-Vitro Fertilisation (IVF) and Intra Cytoplasmic Sperm Injection (ICSI), Frozen Embryo Transfer (FET), Egg Donation, Sperm Donation and Embryo Donation, Semen Analysis and Sperm Storage.

The RFC is licensed and regulated by the Human Fertilisation and Embryology Authority (HFEA) in accordance with the Human Fertilisation and Embryology Act. We also have an accredited quality management system which is compliant with the requirements of ISO 9001:2008.

The RFC is fully supportive of the need to review and improve the regulatory processes to make NHS systems more efficient and welcomes the opportunity to participate in this consultation process however there are serious concerns about the impact that removing the HFEA will have on the fertility treatment sector.

1. Do you agree with the option to transfer all HFEA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA? Please explain why you think this.

The Trust believes that the Human Fertilisation and Embryology Authority's (HFEA) regulatory functions should not be transferred elsewhere, but rather that this body should continue in its current role.

The Human Fertilisation and Embryology Authority (HFEA) has since its inception provided a consistent four country approach in its role as an independent regulator focused on protecting patients and the public interest. The option proposed offers no assurance that dividing the functions of the

HFEA across 2 other organisations will replicate the current position. Furthermore the absence of any clarity about the Northern Ireland position is of grave concern. The scale and nature of regulatory activity appears to have been underestimated and the document is silent in respect of the implications for each country as regards to ongoing compliance with the HFEA Act. The HFEA is an extremely efficient and effective regulator and has secured the confidence of professional staff within the Trust as well as patients and the wider public.

It has been our experience that the HFEA has over the years developed an increasingly responsive approach providing prompt guidance where required and therefore has remained fit for purpose providing maximum regulatory compliance with minimum bureaucracy. It has become a much more listening organisation as it has matured. We would be concerned that this highly beneficial approach to regulation would be jeopardised by the transfer of HFEA functions to a large-scale, more generic organisation.

There is no evidence contained within this document which identifies how cost reduction would be achieved. Transferring function to the 'new' organisations increases risk and doesn't guarantee savings. Neither the CQC nor the HRA has the knowledge, networks or information systems contained within the HFEA and it would take a considerable amount of time and money for these organisations to develop the organisational memory required to deliver their new roles and responsibilities. Over the last twenty years the expertise the HFEA has accumulated means it is uniquely equipped to deal with highly sensitive and emotive issues that can arise during fertility treatment. In dividing the function across two organisations in fact will add to the short and medium term with duplication of effort whilst increasing risk. Option 3 where the HFEA retain its functions and deliver further savings, provides the only acceptable outcome.

The issue of increasing the risks to patients cannot be underestimated. The HFEA currently collects large volumes of data submitted by fertility centres which it uses to monitor outcomes especially with respect to multiple births, donor-conceived children and their genetic origin. The CQC does not have the expertise in managing these types of process and whilst they may develop the knowledge and systems this will contradict any view that savings will be released through disbanding the HFEA. Potentially this move could also expose patients and clinics to an increased risk of error or incident during an inevitable and potentially lengthy period of transition.

The dislocation of the research function from the treatment functions of the HFEA is misguided as this will lead to increased regulatory processes in order to ensure good governance. The advance in the technology developed through research in fertility treatment has led to ever improving outcomes and has had public acceptance and confidence. The HFEA has played a pivotal role both in its regulatory and public-facing presence to secure this position.

The HFEA has developed robust regulatory mechanisms based on their expertise arising from the implementation of the legal framework which was required once the

ability to create and use human embryos became a reality. These well-defined processes in developing policy, making licensing decisions has put in place safeguards which have enabled practitioners across the UK to pursue areas of research and practice that have been much harder to engage elsewhere. The nature of the fertility service frequently brings to the fore medical and ethical dilemmas i.e. the treatment versus the research challenges. When considering the types of issues the HFEA have had to manage e.g. 'saviour siblings' there appears to be little direction in regards to how these type of situations will be addressed, what interfaces will need to be put in place and which organisation would take the lead.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

The future impact of option 1 in the devolved countries e.g. in Northern Ireland is a major concern. The lack of clarity about which organisation/s will assume responsibility for the regulation and monitoring of the fertility services significantly increases the risks to the patients through lack of consistency, a protracted period of transition and the further fragmentation of the regulatory functions for both treatments and research.

As previously mentioned above, further clarity regarding the proposed approach between the CQC and RQIA within Northern Ireland would be helpful to allow a more robust evaluation of the transfer of regulatory functions.

The confidence of healthcare professionals working in these areas could also be adversely affected, with concerns that quality will be compromised (particularly at the initial stages of any newly implemented system) due to loss or dilution of specialist knowledge and expertise on the part of the regulators – both in terms of capability to assess organisations in site inspections and appropriately ascertain levels of compliance, but also to in terms of expertise and experience to provide meaningful guidance to professionals and more importantly the public.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

As stated above the dislocation of the research function from the treatment functions of the HFEA is misguided and demonstrates a lack of understanding of the role currently fulfilled by the HFEA. In a devolved country this will lead to yet further increase in the regulatory processes in order to ensure good governance. Stringent criteria applied without variation across the four countries linked to an understanding of the clinical service provides assurance in support of research which cannot easily be replicated in a four country approach.

4. Do you think that some HFEA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No. The Trust believes that the functions of the HFEA should be retained within a single organisation. Division of these functions across a number of organisations will increase both the complexity of regulatory processes and increase the risk of non-compliance on the part of licensed organisations. Option 3 where the HFEA retain its functions and deliver further savings, provides the only acceptable outcome.

5. Do you believe the HFEA should retain existing functions but deliver further efficiencies? Please explain why you think this.

The Human Fertilisation and Embryology Authority (HFEA) has since its inception provided a consistent four country approach, it has been an independent regulator which has focused on protecting patients and the public interest. In the current financial landscape it is imperative that the HFEA should review its expenditure patterns and implement contingency savings plans and be able to demonstrate productivity. However the overriding role of a regulator must be about protection of the public and there is no evidence to suggest that fragmenting the organisation, its well established systems and processes would secure any reduction in costs and it may perhaps lead to a reduction in protection.

6. Do you think that retaining functions with the HFEA could deliver savings to the public purse? If so, please explain how and quantify.

The process of transferring functions from HFEA to two other bodies would inevitably involve significant costs at the outset and therefore option 3 would allow the HFEA to examine its existing processes in order to identify more efficient ways of working.

7. Within the option of retaining the HFEA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No. The Trust believes that for all of the reasons outlined above that the organisation should remain intact as division of any of its functions across other organisations would not be to the benefit of the public or the professionals who provide fertility services.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

No

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

The Trust believes that the HFEA fulfils its function as an independent regulator in a manner that is both efficient and effective. The HFEA's approach is particularly robust due to the specialist skills and expertise of their regulatory staff, and their continued focus on providing a supportive and proportionate approach to regulation in order to best enable regulated organisations to achieve and maintain compliance.

With regard to how such functions might be undertaken in the future, the Trust would be keen to see the minimisation of overlap with other regulatory and / or professional bodies being prioritised as an objective. Avoidance of duplication (for example in preparation for site inspections; ongoing routine requests from regulators for activity and performance data) should be prioritised to reduce the administrative burden on organisations. The development of a liaison between HFEA, ISO and CPA for example would be a welcome development.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

As previously mentioned above, the lack of clarity regarding the proposed approach between the CQC and RQIA within Northern Ireland made it extremely difficult to make a more robust and balanced evaluation of the transfer of regulatory functions

11. Can you provide examples of costs and benefits of these proposals?

No

12. Do you have any comments on the consultation Equality Analysis?

No

Response 90 – UK Accreditation Service



Dear Sirs

Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

Thank you for the opportunity to comment on the above consultation. I am responding on behalf of the United Kingdom Accreditation Service (UKAS), which is the sole national body recognised by Government for the accreditation, against recognised standards, of organisations providing calibration, testing, certification and inspection services. UKAS is appointed as the national accreditation body by The Accreditation Regulations 2009 (SI No 3155/2009) and operates under a Memorandum of Understanding with the Secretary of State for Business, Innovation and Skills, on behalf of government as a whole.

As the national accreditation body, UKAS does not have a strong view on the options presented for the abolition or retention of HFEA and HTA. However, whatever the organisational structure of these organisations, UKAS considers that considerable economy and efficiency gains are available from the greater use of UKAS accreditation in the regulatory framework for those organisations regulated by the HTA and HFEA.

Many of the organisations/laboratories that are licenced by HTA also have UKAS accreditation, through its subsidiary Clinical Pathology Accreditation Ltd (CPA). CPA has considerable expertise in this field and CPA assessors already visit most of the laboratories inspected by HTA. We are convinced that the greater recognition of CPA accreditation of these laboratories in the regulatory process would provide considerable benefits for the laboratories themselves, in terms of reducing the number of inspections required, and the regulator, by reducing the number of inspections they need to make and by allowing them to target their inspections at the higher risk establishments.

In fact, trial joint assessments are already taking place so that HTA staff can witness the assessments carried out by CPA and consider how they can be used to address HTA requirements. These trials are progressing well and considerable synergies are being identified.

Similar opportunity exists for CPA accreditation to replace separate HFEA inspections with a similar reduction in costs for the laboratories concerned and in the costs to HFEA in operating the licensing regime.

The CPA process requires organisations to demonstrate, through audit or other evidence backed up by scrutiny on a site visit that the procedures they have in place are being adhered to and are delivering the desired outcomes. CPA accreditation therefore provides confidence in the competence, impartiality and consistency of accredited organisations.

CPA accreditation of pathology laboratories is taken into account in the CQC registration process. We see no reason why a similar approach could not be adopted for laboratories dealing with human tissue, fertilization and embryology.

Furthermore, UKAS and CPA have a good track record of working closely with Government, to ensure that the accreditation provided in any specific area addresses the regulators' needs and can be regarded as a reliable indication of a laboratory's compliance with its regulatory obligations. Currently, UKAS accredited laboratories support the regulatory activities of Government departments and agencies in a number of fields including drinking water testing, food safety testing, asbestos sample testing, forensic science and DNA testing for the National DNA Database.

Whilst accreditation is delivered to agreed standards, there is a considerable degree of flexibility in targeting the accreditation process to meet a specific need.

CPA accreditation could therefore play a greater role in all three of the options proposed. Under options 1 and 2, if HFEA and HTA functions were transferred to CQC, CPA could carry out inspections on behalf of CQC. Under option 3, if HFEA and HTA retain their functions but are expected to deliver further efficiencies, CPA could carry out inspections on behalf of HFEA and HTA. Under all options, we believe that the benefits of scale of CPA operations would enable it to carry out these inspections at considerably lower cost to the laboratories whilst still achieving the required level of assurance. There would also be savings for CQC (or HFEA and HTA) from not having to carry out the routine inspections themselves.

I hope these ideas are of interest to you and, if you would like further information on how UKAS and CPA could contribute in this sector, please let me know.

Yours faithfully

External Affairs Manager

Response 91 – Care Quality Commission



Care Quality Commission
Finsbury Tower
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www.cqc.org.uk

28 September 2012

Consultations on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

Thank you for the opportunity to comment on this consultation. The proposals have been considered by the CQC Board and they have agreed that at present we are not in a position to make a decision on these proposals. Our priority is to focus on becoming a more effective organisation, delivering our core functions and implementing the functions recently added to our remit, including Healthwatch England and Joint Licensing with Monitor.

These functions are complex and technical. A transfer of functions would require significant restructuring of the governance for CQC. Consequently the Board believes that the potential benefits for CQC are by far outweighed by the potential risks involved for CQC.

We recognise the rationale of grouping these regulatory functions within CQC given that they all relate to protecting and improving quality and safety in health and social care. Consequently we will continue to work with the HFEA and the HTA in pursuit of more efficient and coordinated regulation by:

- increasing mutual understanding of our respective approaches
- identifying where alignment of inspections might be possible; and
- setting up mechanisms to share information.

We will also continue to work with the Department, the HFEA and HTA to see whether there is any potential to further reduce overhead costs, such as those already achieved with co-location of the HFEA and CQC London offices.

The Board would be happy to reconsider these proposals at a later date if required to do so.

I would of course be happy to discuss these matters further.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'David Behan'.

David Behan
Chief Executive

Response 92 – Bioindustry Association

Established in 1989, the BioIndustry Association (BIA) is the trade association for innovative healthcare focused bioscience enterprises. BIA members include emerging and more established bioscience companies, pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector. Our members are responsible for over ninety per cent of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation will lead to better outcomes for patients, to the development of the knowledge-based economy, and economic growth.

The BIA welcomes the Department of Health's consultation on the future of the HTA and the HFEA and the opportunity to consider the three options set out in the consultation document as part of the Government's drive to reducing NHS administrative costs and the number of arm's-length bodies. We would like to thank the Department for holding a consultation workshop on 19 September which offered the opportunity for helpful discussions with a wide range of stakeholders. The BIA response to this consultation was developed in light of these discussions and comments received from its members.

After consideration of the proposed options, we believe that options 1 and 2 will not bring better value to the regulated sectors and the public, and there are wider implications beyond making cost savings.

We are concerned about the risks associated with the transfer of the HTA and HFEA functions and the abolition of these bodies. Both the HTA and HFEA are well-established authorities and have developed a proportionate regulatory approach which has been improved through ongoing stakeholder engagement. The proposal to split certain functions of the HTA and HFEA between the Care Quality Commission (CQC), the Health Research Authority (HRA) and other organisations carries a risk of losing core staff and expertise which would impact on services provided, in addition to the need for the new regulator to establish and maintain relationships based on trust and confidence. Furthermore, we have serious concerns about the CQC taking on these additional responsibilities in light of the findings in the Public Accounts Committee Seventy-Eighth Report published in March 2012. Clearly the public lack confidence that the CQC is an effective regulator.

Therefore the BIA's preferred option is option 3: the HFEA and the HTA retaining their functions but delivering further efficiencies. We understand that option 3 was a popular option at the workshop on 19 September and is supported by the Wellcome Trust, non-commercial research organisations and patient groups as well as by the HTA and HFEA.

It is recognised that both the HFEA and HTA have made significant efforts in reducing their costs over the last two years. The HFEA now shares premises and back office functions with the CQC. The HTA has made efficiencies of 27% by reducing staff in support roles and estimates that further savings will be made over the next year by reviewing its operational activities and refining regulatory processes. The HTA relocated with the Medicines Healthcare products Regulatory Agency (MHRA) at 151 Buckingham Palace Road in London; this will be particularly helpful in ensuring synergies to improve the regulatory environment for the research and development of regenerative medicine therapies.

It should be noted that option 3 is 'not a do nothing option' and it is important to ensure that an independent review is conducted and that both the HTA and HFEA are made accountable to provide further efficiencies and savings.

We look forward to continuing the dialogue with the Department, regulatory authorities and interested parties to simplify the governance of research involving human tissue to the ultimate benefit of patients and the life science sector in the UK.

Yours faithfully,

Dr Christiane Abouzeid

Head of Regulatory Affairs

¹ The Care Quality Commission: Regulating the quality and safety of health and adult social care (<http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1779/177902.htm>)

Response 93 - The Wellcome Trust

Key Points

- This consultation is an important opportunity which highlights the need for effective and proportionate regulation around human tissue, embryology and fertility.
- In reviewing the three options presented, the Wellcome Trust broadly supports Option 3, and we propose an enhanced version of this option that seeks to further streamline the regulatory pathway and has the potential for significant cost savings in the future. We do not regard this option as maintaining the status quo, but as a positive step towards regulatory improvements that should be subject to further review in the future.
- We consider that Options 1 and 2 present risks that outweigh the potential benefits, specifically the potential for loss of expertise and specialist function within the HFEA and HTA, and potential corresponding impacts on researcher and public confidence in the regulatory system.
- It is essential that further steps are taken towards a unified approvals system for research projects, based around the Integrated Research Application System portal and with further integration of the licensing and approvals processes. The Health Research Authority should become the focal point for advice and guidance on research regulation to provide clarity in the system, connecting researchers with genuine expertise either within or outside the HRA. We also suggest that a review of the relevant parts of the legislation be undertaken to identify where changes could be made for the benefit of patients and research participants, such as the approach to regulation of tissue from the living.
- Whatever the decision, it is vital that the public bodies concerned are sufficiently financed and resourced to be able to carry out their functions adequately and maintain confidence in the regulatory system.

INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to respond to the Department of Health's consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA). The HFEA and HTA fulfil functions that are central to the effective regulation of research and treatment involving human tissues and cells. We support the Government's efforts to streamline the regulatory environment, as it is vital that these functions are delivered in a way that supports an effective, proportionate and cost-effective regulatory system, which facilitates research while protecting the safety and rights of patients and securing economic benefits that will help make the UK more competitive. We urge the Government to look at all options to achieve this and consider all wider implications including those outside of purely financial considerations. As a research funder our response focuses on the implications of the options for research within the wider context of clinical practice.

2. This response sets out our view on each of the options in turn, before presenting

our view of the best way forward. We have developed this response by consulting with researchers and other relevant stakeholders with experience of working with the regulatory system, and have worked closely with other research funders and the Academy of Medical Sciences to develop a shared position based on broad principles.

CONSIDERATION OF THE PROPOSED OPTIONS

Question 1: Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Question 3: Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

3. Option 1 as set out in the consultation document proposes to transfer HFEA and HTA functions as described in question 1 above, and abolish the HFEA and the HTA. We broadly support the principle contained within this option of closer integration between the HFEA's research functions and the HRA, as it is in line with our view that the HRA should become a focal point for research approvals and a source of advice and guidance for researchers.

4. However, we also have several concerns about this option. Chief among these is the potential risk posed by the abolition of the HFEA and HTA. A common theme emerging from the evidence we have collected is that both the HFEA and HTA have established strong reputations not only as effective and proportionate regulators, but as 'brands' working in scientifically and ethically complex areas and that inspire confidence among researchers, patients and the public. We are concerned that to abolish these bodies and transfer their functions elsewhere, even with the goal of retaining core staff and keeping their functions together as much as possible, risks losing their long-established specialised expertise and functional cohesion.

5. Furthermore, the proposal to split the HFEA's functions by transferring its research functions to HRA, and the rest of its functions to the CQC, carries a risk of losing cohesion between the HFEA's clinical and research functions. The rapid emergence of new techniques, such as preimplantation genetic diagnosis and techniques to avoid mitochondrial disease requires a joined-up approach between the regulation of research into these new techniques and the oversight of clinics which offer current and emerging fertility treatments. The cohesion between research and clinical oversight is also vital in order to inform policy debates around emerging issues such as egg donation for research, and so proposed division of the HFEA's functions carries concerns regarding the loss of such an approach.

6. The HFEA has also established a strong reputation for its advocacy and public engagement work around the scientific, ethical and social aspects of new areas of fertility and embryology research and treatment. Abolishing the HFEA and splitting its functions between other organisations carries the risk of losing specialised expertise, with the potential for further impacts on public confidence. There is a further risk that moving these functions to a larger organisation such as the CQC would risk diluting the focus on functions such as communication, public engagement and advocacy. Even with guarantees to retain these functions as far as possible in their present form, we are concerned that the ongoing pressure on arm's-length bodies to make savings would risk compromising these functions in the future.

7. With regard to the HTA, we have obtained evidence from researchers about the HTA's strengths in regulation, inspection and stakeholder engagement. The HTA has a very good reputation among researchers for its approach to regulation, its willingness to engage with its stakeholders and its provision of consistent, high quality advice from experts within the organisation. We are therefore concerned about proposals to abolish the HTA and move all of its functions into the CQC, as the loss of the HTA's particular strengths and expertise would be likely to impact on the excellent service provided to researchers and other stakeholders in the regulation of human tissue for research, patient treatment, post-mortem, public display and education purposes. Further, any loss of the HTA's strong communications functions would risk a loss of professional and public confidence.

8. Another significant concern with option 1 is the capacity and expertise of the Care Quality Commission to take on these additional functions. We consider that to broaden the remit of the CQC in this way, particularly in light of the recent highly publicised concerns about the CQC's performance and governance, would risk damaging public confidence. In particular, we make reference to the House of Commons Public Accounts Committee report on the CQC from March 2012, which stated that "we have serious concerns about the leadership, governance and culture of the Commission." It also recommends that:

"The Commission should not take on the functions of the Human Fertilisation and Embryology Authority at this time. The Department is proposing to transfer to the Commission the functions of other organisations, including the Human Fertilisation and Embryology Authority, which regulates IVF services. In our view, the Commission does not have the capacity to take on oversight of such a complex area, and the change would undermine its ability to focus on the improvements it needs to make in relation to its existing regulatory functions."¹

9. Furthermore, in recent oral evidence to the House of Commons Health Committee, the outgoing Chair of the CQC, Dame Jo Williams, expressed reluctance on the part of the CQC to take on any functions from the HFEA or HTA, suggesting that the CQC does not have the expertise to do so.² Additionally, since the CQC regulates care in England and Wales only, to take on these additional functions would require them to extend their remit to the other devolved administrations. We feel that to require the CQC to take on additional functions despite concerns within the organisation about their ability to do so does not inspire confidence in the proposals to transfer additional functions into the CQC.

10. Finally, we point to significant savings already made by the HFEA and the HTA in efforts to cut costs, and the fact that they both already share premises with other organisations; the HTA with the Medicine and Healthcare products Regulatory Agency (MHRA), and the HFEA with the CQC, with whom they also share some back office functions. We suggest that the proposals set out in Option 1 would require significant upheaval for all of the organisations concerned, with associated costs of reorganisation. The HTA, HFEA and CQC regulate within three separate legislative frameworks with three different regulatory approaches. While some synergies may be possible, it is likely to be difficult to merge these regulatory functions to any significant extent, restricting the cost savings possible through reorganisation of this kind. The projected savings set out in the consultation document are between £3.7 and £3.8 million over ten years; we question whether this level of saving is an effective balance to the cost of such a reorganisation, especially when placed against the potential risks to expertise within the regulatory system and public confidence set out above.

Summary of position on Option 1

11. With all of this in mind, we do not feel that the CQC is best placed to take on any functions of the HFEA or the HTA at the present time, and that the proposed abolition of these bodies represents a risk to the effective and proportionate regulation of these sectors, and to public confidence. While we support the principle of integrating the HFEA's research functions more closely with the HRA, our concerns mean that we are unable to support Option 1.

Question 4: Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

12. Option 2 of the consultation proposes a similar model to Option 1, with the additional proposal that certain other functions that could be transferred to other organisations with which they might offer a 'better fit'. Our concerns outlined above regarding the abolition of the HFEA and HTA, and the capacity of the CQC to take on additional functions, also apply to Option 2. We have additional comments on Option 2 and the proposals regarding specific functions, which are set out below.

Public display of human bodies or tissue

13. The Wellcome Trust holds an HTA licence for the public display of human bodies or tissue due to exhibitions held in the Wellcome Collection that involve the display of human tissue. From our experience of organising such exhibitions, we have some concerns regarding the HTA's applications process for such licenses. The storage of tissue for the purpose of public display represents a small proportion of the HTA's overall licensing activity; figures from the HTA's website show that of the more than 800 organisations that have been granted HTA licenses, just 15 have been granted a license for public display (as of September 2012). The Wellcome Collection has noted that the application forms and inspection processes are orientated more towards research and clinical activities; for example the format and terminology of the application forms are not suited to public display, with many sections of the forms not being relevant and making the application process administratively burdensome. It has also been noted that the disproportionate administrative burden, along with the costs of licensing, is potentially a disincentive to smaller museums from mounting exhibitions or displays that include human tissue.

14. With these issues in mind, there is potentially a case to consider transferring the function of regulating the storage of human tissue for public display to a body other than the HTA. The consultation document suggests this function could transfer to Arts Council England (ACE); however, there is some doubt as to whether ACE has the capacity or the technical expertise to take this function on, and there is not another obvious organisation that would have the capacity and expertise to do so. We are therefore unable to support the proposals set out in the consultation document with regard to public display of human bodies or tissue. We have, however, spoken to the HTA of our concerns and they have expressed willingness to review the situation with a view to making improvements. We therefore feel that there is scope to address concerns around the regulation of human tissue for the purpose of public display without transferring the responsibility away from the HTA. Given the HTA's experience of regulating public display we feel that they will be well placed to carry out a review to identify possible improvements.

Register of treatment cycles, patients, donors and offspring ('the register')

15. The proposals under Option 2 highlight the register held by the HFEA of treatment cycles, patients undergoing treatment, the outcome of all treatment cycles, the details of all live births, and all gamete and embryo donors. This register is held by the HFEA in accordance with the requirements of section 31 of the Human Fertilisation and Embryology Act 1990, and is a valuable resource with considerable importance for research.

16. Section 33 of the 1990 Act allows access to these data for the purposes of research, subject to the granting of a licence to do so. The Ethics and Confidentiality Committee (ECC) currently advises the HFEA on these applications³. As the research functions of the ECC are to be transferred to the HRA, we would seek clarification as to whether the advisory function on section 33 will also be transferred to the HRA. We consider that this approach would maintain cohesion around the use of sensitive and confidential patient information in research, and ensure that the proper safeguards are in place for its protection.

Licensing the storage of tissue for the specific Scheduled Purpose of research

17. Within the discussion of Option 2, the consultation document notes that "among those holding an HTA licence for the storage of tissue for a Scheduled Purpose is a discrete group that stores tissue only for the purpose of research." An option is therefore proposed to separate licensing storage of tissue for the specific purpose of research and transfer it to the HRA, while transferring the licensing of tissue storage for other Scheduled Purposes to the CQC.

18. While we would support efforts to integrate the licensing of tissue storage specifically for research more closely with the HRA, we feel this proposal carries risks that outweigh these potential benefits. As discussed earlier (see paragraph 7, above), the evidence we have gathered from researchers shows that there is strong support for the HTA in its current form; those regulated by the HTA speak very highly of the Authority's approach to licensing, and their willingness to engage with stakeholders and provide advice. Correspondingly, there is little appetite for splitting the HTA's functions in this way, and concern that to do so would risk diluting the effectiveness of the HTA's approach.

19. Moreover, the HRA currently approves research projects whereas the HTA licences sites for tissue storage for specific purposes, including research. This fundamental difference in regulatory approach means that limited benefit would be achieved by integrating the research functions of the HTA into the HRA. The HTA and HRA have already worked together to simplify the system for researchers, for example through the establishment of Research Tissue Bank status⁴. We therefore consider that transferring functions away from the HTA as suggested in this option would actually add complexity to the regulation of human tissue storage, since those storing tissue for research and other scheduled purposes could be forced to apply to several different organisations if storing tissue for multiple purposes. Furthermore, anecdotal evidence from researchers in organisations that have an HTA licence only for research suggests that they would see no benefit from dividing the HTA's licensing activity in the manner outlined in Option 2. This, coupled with our concerns previously expressed over the CQC, mean that we are unable to support this proposal.

Summary of position on Option 2

20. We consider that Option 2 carries the same potential disadvantages of Option 1, with regard to the capacity and expertise of the CQC, the abolition of the HFEA and HTA, and the splitting of the HFEA's functions. In addition, the proposal to split the functions of the HTA carries further risks, outlined above, and would produce a fragmented and complex regulatory environment. Therefore we are unable to support Option 2.

PREFERRED OPTION AND PROPOSED ALTERNATIVE MODEL

Question 5: Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Question 6: Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

21. Given the concerns with Options 1 and 2 outlined above, and the evidence gathered from our discussions with researchers and other research funders, we consider there is a strong case to be made for retaining the HFEA and HTA in their core forms. However, we are keen to stress that this should not be an option to retain the status quo and it is vital that this option is used to deliver further streamlining to improve the regulatory environment.

22. We consider the following changes are essential to create genuine improvements in the regulation of the research sector:

- **Research licensing by HFEA must be integrated in the Integrated Research Application System (IRAS)** to produce a truly unified approvals system for research projects. The IRAS system has already demonstrated that approvals can be streamlined between different organisations and the full potential of this must be exploited. We would like to see a system where IRAS acts as a single 'portal' for all research applications, which would then be directed to the appropriate regulators, with the HRA maintaining oversight of the application so that researchers experience a seamless process.
- **Greater streamlining could be achieved in the approvals process for HFEA project licences** without compromising the protections in place. Currently projects are reviewed by both a Research Ethics Committee within remit of the HRA and also by the HFEA's Research Licence Committee. We envisage that duplication within this process could be reduced, for example review by a single committee with appropriate expertise. This review could be delegated to the HRA by the HFEA.
- **The Health Research Authority should become the focal point for advice and guidance on research regulation** to provide clarity in the system. It is important that coordinated and consistent guidance is provided across the organisations and that mechanisms are in place to connect researchers to the most appropriate expertise whether within or outside the HRA, for example in the HTA and HFEA.

We consider that these improvements would be best delivered through Option 3 led by the Health Research Authority, in collaboration with the HFEA and HTA and other

regulators. A legal duty of cooperation between the bodies and clear accountability for improvements will be important to ensure timely progress is made.

23. We also consider that, in order to effectively implement these improvements, **the relevant aspects of the legislation should be reviewed to identify where changes could be made without compromising the protection of patients and research participants**. Areas that we consider need to be reviewed include:

- The Human Tissue Act currently regulates the storage of **tissue from the living**. We consider that tissue from the living could be regulated effectively under Research Ethics Committee approval so that tissue from the living collected for research would not need an HTA licence for storage. This could lead to significant streamlining of the regulatory pathway.
- The legislation around **public display of human tissue** is currently not proportionate to the risks involved in this sector and would benefit from revision.

24. In addition to the need for further streamlining and changes to legislation, we recognise the need for the delivery of further efficiency savings. We propose an 'enhanced' version of Option 3 which we consider will facilitate the regulatory streamlining discussed above and also produce further cost savings; our proposed model is set out below.

25. We propose that the functions of the HFEA and HTA should remain distinct and with their own identity, but that many of their back office functions could be combined. The licensing functions of the HTA and HFEA would need to remain separate for the reasons discussed throughout this response, but the inspectorate functions could be combined to deliver greater efficiencies.

26. The model we propose for the HFEA/HTA is analogous to that employed by a number of London councils: the so-called 'Tri-borough' councils of Westminster City Council, Hammersmith & Fulham and the Royal Borough of Kensington and Chelsea were formed in 2011 by combining services and management functions, with a single chief executive overseeing the two councils of Kensington and Chelsea, and Hammersmith & Fulham. Externally, the three councils remain single authorities, but the combining of services and management functions has already saved £7.7 million and is on track to deliver savings of £33.4 million by 2014-15.⁵

27. We feel that this model could be applied to the HFEA and HTA, by retaining both as external facing regulatory bodies with separate boards in order to retain specialised expertise and public and professional confidence. However, management functions could be shared between them, with the potential to deliver positive cultural change in addition to significant cost savings while streamlining regulatory functions. The HTA has demonstrated positive leadership and ongoing improvements, and there are clear benefits to extending this approach. In this system it would be vital for the HTA and HFEA to work actively with the HRA towards greater integration of the regulatory functions for research discussed earlier. This model would solve some of the problems previously identified in efforts to integrate the regulatory functions of the HFEA and HTA more closely. During discussions to establish a single Regulatory Authority for Tissue and Embryos (RATE), the Wellcome Trust and the Medical Research Council issued a joint statement highlighting shared concerns with proposals to form a joint regulator. Chief among these were that the proposed regulator's remit would be too broad and its resources too stretched, and that to create a single regulator for such a broad area would place too much reliance on the

expertise of a small number of professionals. Retaining the HFEA and HTA as separate expert bodies, with the appropriate expert committees and panels would avoid these problems by retaining an appropriate level of capacity and expertise. Another potential difficulty around RATE was the difference in the HTA and HFEA's methods of regulation, with the HFEA issuing project licenses while the HTA issues licenses to premises storing tissue for research. The solution we have provided avoids this difficulty by integrating only the shared functions of the organisation.

Final comments

28. We stress, once again, that we see this solution very much as a direction of travel for greater streamlining and cost saving, rather than an argument for the status quo or the 'least worst' option – and that it does not preclude further structural changes, including a greater role for the HRA, further down the line and subject to review. The regulators themselves have expressed their recognition for the need to review the regulatory system and identify opportunities to simplify and cut costs, and we are keen to support this process, as are the other non-commercial research organisations with whom we have developed a consensus around the principles of Option 3.

29. Finally, we urge Government to consider the broader issues around the review of arm's length bodies, including those beyond financial savings that we have highlighted in this response. The regulatory pathway for research requires bodies that are independent, appropriately resourced and financed, and possessed of adequate expertise to ensure that regulation is fit for purpose, promotes the interests of patients and inspires confidence in professionals and the wider public.

¹ Public Accounts Committee (2012) –Seventy-Eighth Report: 'The Care Quality Commission: Regulating the quality and safety of health and adult social care'

<http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1779/177902.htm>

² <http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm>

³ <http://www.nigb.nhs.uk/s251/eccfrequently>

⁴ <http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/research-tissue-banks-biobanks/>

⁵ 'Tri-borough One Year On: Delivering our promise to improve lives and make public funds go further' http://www.lbhf.gov.uk/Images/Tri-borough-one-year-on-June-2012_tcm21-172864.pdf

Response 94 – British Association for Tissue Banking

Thank you for seeking the views of the British Association for Tissue Banking in considering the proposals to transfer functions from the HFEA and HTA. We circulated our membership to encourage consideration of and responses to your consultation process.

The BATB is an association of professionals working in tissue banking. Currently membership does not include professionals in reproductive tissue banking. We are not a policy making body, our role is to enhance education and training for our membership and provide a forum for discussion of common areas of interest of policy and practice.

However we acknowledge views of individual professionals and tissue banks. Our responses relate to the functions of the HTA only.

To facilitate your process we have completed your pro-forma.

Leicester Bone & Tissue Bank

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	The opinion of the members is that HTA functions should not be transferred. The views expressed are that the HTA has matured into an appropriate and competent regulatory body for tissue banking. The inspection process is evolving with a thematic approach after several rounds of general inspections. Efficiency has increased and the focused role for this area of activity is of benefit for enhancing the practices of tissue banking. Time resources have been invested by tissue banks in developing the necessary relationships and meeting the standard framework that has been set out. Concern is expressed that amalgamation into a larger body would reduce focus, diminish communication and dilute expertise.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	The impact of such a change includes the demand for further resources, human or otherwise, to manage any such change, especially if the standard framework for the inspection process is changed. Members are concerned about the reduced availability of resources at this time.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	Not applicable
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	The current function should be retained.
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	Yes. Efficiencies have been delivered since the start up position
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

See above.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The members are of the view that the current function should be retained.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

Our primary concern relates to the function of the HTA. Members have noted the ongoing efficiencies. A question has been raised in relation to the costs of the premises currently occupied by the HTA.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Response 95 – BOC Healthcare

Introduction

BOC Ltd currently hold a licence awarded by the HTA which allows us to store human tissue samples under The Human Tissue Act 2004 (HT Act) and associated Regulations and Human Tissue (Quality and Safety for Human Application) Regulations 2007 at our facility in Thame, Oxfordshire. This is a commercial enterprise offering customers a facility in which to place back up samples for both the research and therapeutic sectors. This is a relatively new facility and enterprise for our company and we have plans to develop further and into other sectors currently regulated by HFEA and HTA. Therefore we welcome the opportunity to comment on the proposals regarding the future of these establishments as changes to the functions will have impact on our current regulatory relationships and future regulatory strategy.

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

From our perspective although we can appreciate the benefits of transferring the functions from the current regulators to CQC in regards to general running costs, we are concerned that the expertise and skills currently held within the HTA and HFEA may be lost or diluted. The CQC was established under the Health & Social Care Act – and although personnel will be experts in auditing, monitoring compliance etc they are unlikely to have the scientific knowledge required for the specialised areas surrounding the use of human tissues and fertility samples. Experts from HTA and HFEA will have to be transferred to the CQC and retained to work exclusively in these areas rather than spread into other sectors that the CQC monitor. If not this could lead to diluting the resource and expertise available in these sectors.

In regard to our specific facility the proposal would currently result in the requirement for our facility to be inspected by the CQC only. This would remain the same in foreseeable future business plans, therefore could be an advantage both in licence costs and alignment of regulatory requirements.

However, in certain circumstances a facility may need to have two inspections (one from the HRA for research and one from the CQC) which would result in additional costs. In addition if the HRA and CQC failed to co-ordinate sufficiently with one another there is a risk of a disjointed approach to the regulation of licence establishments that are required to hold a licence with both establishments. There is currently no indication as to what level they must co-operate with one another.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

Under the proposed option our establishment would require an inspection from the CQC in a similar manner to that by the HTA currently therefore the changes

are unlikely to result in a change in regulatory costs. However, it may be possible to increase the services/functions under the CQC licence that would currently require a separate licence from HFEA. Therefore future costs may be reduced. Without knowing the likely licence fees that would be established by the CQC it is not possible to quantify the impact.

However, I can envisage that in other establishments two licences may be required which would result in an increase in regulatory costs.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

I think that HFEA functions relating to research should only be transferred to the HRA providing there is sufficient expertise within the Authority to compliment the current Regulatory Body (HFEA).

One clear advantage is that it would bring the assessment of research and ethical decisions surrounding this sector into one group allowing more communication and worksharing which may even lead to quicker, easier assessments.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

If the CQC and the HRA are deemed the competent body, and the HTA and HFEA are abolished, I think that they should regulate all associated functions (in the way the HTA and HFEA currently do). Fragmenting the system further may well lead to aspects of the uses of human tissues being overlooked. The HTA has done a substantial amount of work in gaining the trust of the public since its establishment, following on from the organ retention scandals etc., and there is a risk of this work being undone

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Ideally yes. Personnel within the HFEA and HTA are experts in their fields. Skills/expertise may well be lost following disbandment which would counter act the cost reductions that are hoped to be gained by the abolishment of the HTA and HFEA. Training and development of the new or transferred personnel to the CQC could reduce the envisaged savings.

If the HFEA and HTA were able to deliver further efficiencies it would put them in a more favourable public light.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Not Comments

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

No, I think they have evolved as all encompassing regulatory bodies ensuring all aspects of human tissue use is covered. Where possible these functions should be retained together,

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

Efficiencies need to be implemented. I feel the best way forward would be to keep the HTA and HFEA in place however bring them under the umbrella of the CQC which would streamline duplicated aspects of the two authorities and subsequently highlight areas where further savings could be made.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

No comments

10. Do you have any other comments on the consultation proposals that you would like to share with us?

No comments

11. Can you provide examples of costs and benefits of these proposals?

No comments

12. Do you have any comments on the consultation Equality Analysis?

No comments

Response 96 – Breast Cancer Campaign

About Breast Cancer Campaign

Breast Cancer Campaign specialises in funding innovative world-class research to understand how breast cancer develops, leading to improved diagnosis, treatment, prevention and cure. We are one of the leading specialists in breast cancer research right across the UK and Ireland. We are currently funding 111 research grants worth over £18 million in 36 centres of excellence across the UK and Ireland.

The Breast Cancer Campaign Tissue Bank

The Breast Cancer Campaign Tissue Bank (BCCTB) is a unique collaboration between four leading research institutions to create a vital resource of breast cancer tissue for researchers across the UK and Ireland. The Bank safely and consistently stores tissue samples donated by patients from across the UK and makes these available to scientists in the UK and Ireland to study how and why breast cancer develops and spreads, and to devise the best possible treatments. Researchers within the four institutions who make up the Bank have contact with the HTA and we have consulted with these researchers in developing this response.

Response to Consultation Questions

Breast Cancer Campaign welcomes the opportunity to respond to the consultation on the future of the Human Fertilisation & Embryology Authority (HFEA) and the Human Tissue Authority (HTA). This response focuses specifically on the future of the HTA rather than the HFEA.

Q) Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Q) Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Q) Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

We believe that the most appropriate option at the present time is Option Three and that therefore the HTA should remain as a separate body. We do not support the transfer of the HTA's functions to the CQC. Breast Cancer Campaign has analysed in detail the three proposed options for the future of the HTA and has

consulted both Campaign-funded researchers and scientists working in the Tissue Bank. While we believe it might be possible to consider moving the functions of the HTA to a different body in future - such as the Care Quality Commission (CQC) or the Health Research Authority (HRA), we do not believe that this should happen at the moment.

Our reasons for supporting Option Three include:

The potential for the loss or dilution of expertise that would result from a merger with the CQC. It has taken time for the HTA to develop and establish its reputation and it is not clear at this stage that there is sufficient guarantee of this expertise being maintained if the HTA's functions were transferred to the CQC or elsewhere. This expertise of those in the HTA stretches across the whole organisation, from those carrying-out inspections to senior management and it is not apparent from what has been proposed how that would expertise would be preserved.

We are not reassured that a move of the HTA's functions would result in sufficient value for money to justify such disruption and that actually it might result in greater costs in the longer term if the result of a transfer is a loss in knowledge and understanding. There is also the potential that a move could result in a reduction in the efficiency of inspections and delays for those wishing to undertake vital breast cancer research, for example, if an over-cautious approach was adopted by the new inspectors who lacked experience and expertise.

We are concerned about the preparedness of the CQC to receive the HTA's functions. With the CQC currently struggling to meet its existing targets, it is questionable whether this is the time to be transferring the HTA's responsibilities to the CQC. The move would not only lead to an increase in workload but would also drastically change the remit of the CQC- with their current focus on care rather than research. Indeed, the current Chair of the CQC herself, when questioned by the Health Committee earlier this month, indicated that the organisation does not have the expertise to take on these functions.¹

Lack of clarity about where the functions of the HTA would sit following proposed move to CQC. It is difficult to ascertain how the HTA's functions might be transferred to the CQC as the consultation provides little detail on this. For instance, is it proposed that the structure of the HTA would remain largely intact albeit sitting within the CQC or would the HTA's roles and responsibilities be divided within the existing structure of the CQC? While Breast Cancer Campaign does not support the transfer of the HTA to the CQC, if this option were chosen we believe it would be advantageous to keep the HTA largely intact within the CQC structure to ensure minimal disruption for researchers who need to use the HTA to gain licenses for their research.

Opinion of Breast Cancer Campaign Tissue Bank Grant holders

Professor Louise Jones, Breast Pathologist at the Barts Cancer Institute at Barts and the London School of Medicine and Dentistry; Professor Andrew Hanby, Professor in Cellular Pathology, at the Leeds Institute of Molecular Medicine; and Dr Valerie Speirs, Reader in Cellular Pathology, at the Leeds Institute of Molecular Medicine said the following about the HTA:

“Since the establishment of the HTA, we have developed a good relationship with them. We have seen numerous rounds of inspections, all of which have been very constructive. The inspectors are extremely experienced and their visits allow them to impart their advice and expertise, thereby improving our existing practices. Our main concern about any potential change to the HTA, whether it is moved in full to another body like the CQC or its existing functions are divided up between a number of different organisations, is the possible loss of experience and knowledge as a result of this and the negative impact this could have on the research community. We are also wary of any separation of the licensing of tissue storage for research from the licensing of tissue storage for other purposes as it is highly likely that this could result in an increased workload and additional cost for those wishing to undertake research using tissue.”

Q. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

At this time we believe that Option Three is the preferred option and that none of the HTA's functions should be transferred elsewhere. However, we believe that with wider changes underway to research organisations, there is an opportunity to review the location of the HTA's functions once there is greater clarity about the roles and responsibilities of the HRA.

¹ House of Commons Oral Evidence taken before the Health Committee. *Annual accountability hearing with the Care Quality Commission, 11 September 2012.*

Available at:

<http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc592-i/uc59201.htm>

Response 97 - Christian Medical Fellowship

The Christian Medical Fellowship (CMF) has over 4,000 doctor members and around 1,000 medical student members and is the UK's largest faith-based group of health professionals. A registered charity, we are linked with like-minded colleagues in more than 90 other countries. Our doctrinal beliefs and ethical values are outlined on our website: <http://www.cmf.org.uk/>.

CMF regularly makes submissions on ethical and professional matters to Government committees and official bodies. All submissions are on our website (www.cmf.org.uk/ethics/submissions/).

Consultation Question 1:

Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

CMF does not support this proposal. We are concerned that this option is being driven primarily by a desire to reduce costs, it is not primarily to improve regulation:

'Option 1, our preferred option, is based on the aim of making additional savings in relation to overall costs of the regulating bodies by reducing the number of regulators in the field, and of reducing the burden of regulatory activity and associated costs on providers.' (consultation paper, p46)

The splitting of individual HFEA functions will lead to a fragmentation of the roles currently undertaken by the HFEA, which will lessen the quality and effectiveness of oversight of assisted reproduction technology (ART) regulation and embryo research.

We disagree with the key objectives stated in the consultation paper:

1. That this option (and indeed the second option) will: *'Strengthen the effectiveness of regulation in this area'* (consultation paper, p12).

The HFEA has had experience over many years (longer than the CQC and HRA) in regulating and inspecting clinics and in oversight of data collection. Neither the CQC nor the HRA have this level of expertise. Neither has the specialist knowledge, expertise and experience in most of the areas that the HFEA regulates. Indeed, as the consultation paper acknowledges, several of the current duties of the HFEA would be completely new for the CQC (such as the data registers): *'and would require new skills and experience as well as an extension of their focus on service providers to include more work in particular areas on the individual needs of patients.'* (consultation paper, p50).

The CQC already has several different roles and adding to these will confuse its duties further, increase its regulatory burden and stretch its capabilities.

2. We disagree with the objective that: *'A reduction in the total number of regulatory bodies provides an opportunity for the regulators that remain to clarify their roles with providers and where possible reduce the regulatory burden on providers'* (consultation paper, p12).

The most important role of HFEA in overseeing research and data collection and regulation of ART activities at clinics is both clear and well established. This proposed option would not lead to a reduction in the number of overseeing bodies that would be involved in regulating the current activities that the HFEA carries out. Instead, it is likely to be more confusing and overly complicated if the DoH also has to take on some specialist oversight roles and/or contract them out to others.

If one of the drivers behind this option is to reduce the regulatory burden, it would suggest that pursuing this option is likely to lead to increasingly lax regulation over a specialist area that requires tight control and oversight (see our comments at Q2).

Reducing the regulatory burden on research bodies for the (assumed) benefit of the wider economy (consultation paper, p7) would be at the expense of reducing regulation over the creation, use and storage of human embryos and admixed embryos. CMF strongly opposes reducing the regulation of research using human embryos, as well as the storage of gametes and the oversight of ART. Human embryos and gametes are not the same as other body tissues. Embryos are nascent human lives, deserving of special treatment and protection, as specified in the HFE Act. It is imperative that there is particularly tight regulation of all embryo research.

The consultation paper acknowledges that the CQC does not have to monitor compliance regularly and is left to itself to make decisions on when to monitor. It has to ensure that any action it takes is targeted and is proportionate to the risk, which exacerbates our concern that the CQC will not regularly monitor research (as the HFEA currently does, at least every two years) unless there is a specific reason or request to do so.

Consultation Question 2:

Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

For donor conceived people who choose to seek information about their genetic heritage, the answers they receive have the potential to change their lives dramatically. The HFEA has a duty to keep registers, in order to record every treatment cycle, patient, gamete/embryo donor and all resulting offspring. The Human Fertilisation and Embryology Act 1990 also sets out the circumstances in which identifying information held on this register may be disclosed to third parties. On the whole, the HFEA has carried out this important duty reasonably successfully.

Transferring oversight and regulation of this sensitive and essential duty would represent a significant new activity for CQC, unlike any other it currently carries out.

The Department of Health suggests it may therefore have to contract out this service to an external provider which would introduce another layer of complexity and cost, one which is avoidable by retaining the HFEA. Contracting out to another body (or more) would introduce the strong possibility that important personal data might be lost, mislaid, inaccurately collected or not even collected at all.

We also question whether a transfer of duties, and consequent cutting of costs, will hinder essential research into the long-term health implications of fertility treatments.

Consultation Question 3:

Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

See comments above.

Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

N/A

Consultation Question 5:

Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

We support this option. There are options to reduce costs (including reducing salaries) while at the same time benefitting from the expertise and long-term experience that the HFEA has in the following areas:

Regulation of ART treatment cycles;
Regulation of creation, donation, testing, use and storage of human embryos and admixed embryos;
Licensing and regulation of the donation, procurement, testing, processing, preservation and distribution of gametes;
Collection of data on children born of donated gametes and ART;
Ensuring the welfare of child born from treatment;
Regular inspections of clinics.

Consultation Question 6:

Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

N/A

Consultation Question 7:

Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The following functions of the HFEA are best served by the HFEA, as a specialist and experienced body:

Regulation of the creation, use and storage of human embryos and admixed embryos;
Licensing and regulation of the donation, procurement, testing, processing, preservation and distribution of gametes and embryos;
Regulation of data on children born of donated gametes and IVF;
Ensuring the welfare of children born from treatment;
Regular inspections of clinics.

However all policy functions and decision-making activities of the HFEA would be best transferred to Parliament and then to the Department of Health. For example, the setting of compensation for donors of gametes, decisions on recipients of ART, and on the welfare of the child etc should be transferred to Parliament which would have overall responsibility for setting policy such as remuneration limits, in consultation with stakeholders and the general public.

Consultation Question 8:

Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

N/A

Consultation Question 9:

This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

N/A

Consultation Question 10:

Do you have any further comments on the consultation options that you would like to share with us?

N/A

Response 98 – Christian Action Research Education (CARE)



Christian Action Research Education (CARE) is a well-established Christian social policy charity providing resources and helping to bring Christian insight and experience to matters of public policy. CARE is grateful to the UK Department of Health for the opportunity to respond to this consultation. It welcomes the Government's intention to promote public consultation, understanding and discussion on this topic.

Not all questions will be answered.

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.
10.	Do you have any other comments on the consultation proposals that you would like to share with us?

1) Points of agreement

1.1 CARE agrees with the following objectives of the proposed reforms, namely to:

- a) **Reduce complexity of the regulatory landscape.** There is scope to simplify and streamline the institutional landscape and improve efficiencies. This is in light of the emergence of many arm's-length bodies which have evolved over time and have very similar and/or closely related interests.
- b) **Strengthen the effectiveness of regulation in this area.** As advances in technologies and techniques develop there is a need to ensure that adequate and effective legal provisions are in place to ensure public confidence and protect health and safety.
- c) **Clarify the regulatory landscape for service providers.** Helping to refine and reduce the number of regulatory bodies provides the opportunity to reduce confusion and duplication in terms of finance, function and regulation.

2) Democratic decision making

- 2.1 Like many organisations CARE recognises the important ethical issues presented by advances in assisted reproductive technologies. Consequently regulatory procedures concerning such technologies must be informed by ethical debate which is both transparent, democratically accountable and reflects diversity in terms of both moral and religious thought.
- 2.2 Whilst it may be difficult to define what is meant by ethical expertise, the need to improve ethical discourse surrounding these issues is of paramount importance. The work and activity of the HFEA has played a role in this discourse but there is room for improvement. In our opinion, weaknesses have emerged in this area on the part of the HFEA. The proposals currently being considered by the Department of Health could potentially help to address these weaknesses.
- 2.3 Commenting on the proposed merger of the HFEA and HTA in the 2007 report of the Parliamentary Joint Committee on the Human Tissue and Embryos (Draft) Bill, Sir Ian Kennedy is quoted as saying that “in all such amalgamations history tells us that very often you go back to ground zero”¹⁹. In many respects this is what we believe is required in order to resolve the current state of affairs which sees a regulator making significant political and ethical decisions whilst neither possessing the democratic mandate or ethical expertise to do so.
- 2.4 The HFEA does not adequately regulate new developments and seems to excessively support scientific research, without corresponding weight being given to other views and considerations. Absence of any minority reports often indicates a unanimous decision being made on issues of profound importance.
- 2.5 The primary rationale of the 1990 HFE Act was “the special status of the embryo means regulation of both research and treatment continues to be appropriate and desirable. In addition we recognise that regulation of IVF treatment provides assurance and protection to patients”²⁰. From this one learns that the primary purpose of the HFEA is to maintain respect and protection for the human embryo, whilst its *additional* responsibility is to regulate IVF treatments afford assurance and protection to parents.

¹⁹ House of Lords House of Commons Joint Committee on the Human Tissue and Embryos (Draft) Bill Session 2006–07. Human Tissue and Embryos (Draft) Bill Volume I: Report. p.27, para. 67.

<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169.pdf>

²⁰ House of Lords House of Commons Joint Committee on the Human Tissue and Embryos (Draft) Bill Session 2006–07. Human Tissue and Embryos (Draft) Bill Volume I: Report. p.34, para. 105.

<http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169.pdf>

- 2.5 It is noted that Baroness Mary Warnock has subsequently expressed her regret over the use of the phrase “respect for the embryo” in the original report which led up to the 1990 legislation. She perceives that the term leads to certain absurdities²¹. In response the House of Lords Committee emphasised the respect shown to embryos by ensuring that “research on embryos is carried out only if there is no alternative available and it is necessary or desirable to achieve one of the permitted purposes”; thus the HFEA must decide whether embryo research is warranted.
- 2.6 This seemingly admirable requirement becomes interesting when one considers that since 1999 when a central record of licence committee decisions has been maintained, the HFEA has refused only one application for a research licence. This refusal was then accepted upon appeal²². In its defence it has been argued that the HFEA has worked with applications to ensure that the necessary requirements were fulfilled. Consequently, submission of project applications which would not be considered suitable for licensing tends not to occur²³. One can view this from one of two perspectives. First, this is effective regulation in action helping to direct and control scientific advancement within a defined framework. Alternatively, it can be considered to make a mockery of any form of regulatory control which is in effect adapted to suit the needs of the science research community. Whilst seeking to work with science is necessary and essential, surely a sign of effective regulation would be that a fair share of applications were accepted and some rejected?
- 2.7 We believe that this scenario demonstrates the close proximity of the HFEA with the interests it seeks to regulate. This is a far from satisfactory position to operate in and we therefore proposal change is required.

3) Membership

- 3.1 The composition of the HFEA does not adequately reflect the wide spectrum of views within society. Eighteen members of the HFEA are selectively appointed to only represent certain views and that they have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.
- 3.2 The Warnock Report commended that “if the public is to have confidence that this is an independent body, which is not to be unduly influenced by sectional interests, its membership must be wide-ranging”. In reality, the HFEA has excluded from its membership those who wish to protect the embryo.
- 3.3 In reality it is our opinion that the HFEA is an unelected body set up to implement the regulations of the 1990 HFE Act and is therefore fulfilling an undemocratic mandate. This point was made all too clearly when the then Chair of the HFEA, Baroness Deach, suggested to the House of Commons Science & Technology Select Committee in 2002 that the HFEA was making ethical decisions to save Parliament direct involvement. In reply, Bob Spink MP questioned the Baroness’s reply by saying “How can it be democratic if you are preventing the democrats, the

²¹ Stem Cell Research: Select Committee Report, HL Deb 05 December 2002 vol 641 cc1311-53, 1327

²² Hansard (2008), Reply to House of Commons Written Parliamentary Question tabled by Jim Dobbin MP and answered by Minister of State for Public Health, 29th January 2008, (2007-08), col. 342
<<http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080129/text/80129w0037.htm#0801303000050>> [accessed 14th September 2012]

²³ Hansard (2008), Reply to House of Commons Written Parliamentary Question tabled by Jim Dobbin MP and answered by Minister of State for Public Health, 29th January 2008, (2007-08), col. 342
<<http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080129/text/80129w0037.htm#0801303000050>> [accessed 14th September 2012]

Members of Parliament who are elected to make difficult decisions on behalf of society as a whole, and protecting them from having to make such complex, fundamental decisions?”²⁴

- 3.4 Both the Houses of Lords and Commons, as the bodies representing the UK members of society, should be more involved in the decisions which have to date been considered by the HFEA.

4) The Future

- 4.1 In terms of the three options put forward by the Government, we would be broadly supportive of decisions taken to implement options 1 or 2. We see the opportunity to revise the responsibilities of the HFEA in particular and see value (not only in fiscal terms) in transferring functions to the CQC.
- 4.2 Considering the HFEA's dual role in licensing and regulatory powers, CARE is of the opinion that the licensing and inspection responsibilities should be separated from regulatory responsibilities.
- 4.3 The regulation of new technologies in the fields of biotechnology and reproductive should instead take place in a context which draws upon the collaborative expertise from across the academic disciplines, the general public and Parliament. Regulatory decisions on ethical import should ultimately be taken by Parliament. A parliamentary committee such as the House of Commons Science and Technology Select Committee is already well placed to monitor developments in this area, helping to initiate and lead on wider discussion of issues, before they proceed further.
- 4.4 Concerning licensing powers, initially it would seem logical for these to remain the remit of the HFEA. Nevertheless, noting that ninety percent of HFEA licensed centres are also regulated by CQC or are in premises that CQC registers; it would seem to make good sense to consider the transfer of licensing functions from the HFEA to the CQC as part of the merger process currently being considered. Moreover, the technical practicalities of IVF could be dealt with adequately by a body such as the CQC.
- 4.5 The demise of the HFEA affords the opportunity to make the case for some kind of national bioethics committee with inclusive membership and whose function would be to inform and advise on the ethics of new developments but not to create policy. This national bioethics committee (or future equivalent body), should include individuals representing very different viewpoints, thereby better reflecting the rich and diverse society in which we live.
- 4.6 It is noted that within Europe, the UK is currently in the minority of those countries which do not have such a committee in place. Views have been expressed that the HFEA is not adequately placed to handle both the regulation of human embryology as well as the ethical considerations of the latest technology advances²⁵. This opinion is even supported in part by a former interim chief executive of the HFEA who acknowledged that the authority, whilst it seeks to take into consideration the ethical ramifications of decisions it makes, is not primarily an ethics committee²⁶.
- 4.7 A possible model to emulate can be seen in the case of France where an updated regulatory authority in the form of the French Biomedicine Agency has been established to work alongside

²⁴ House of Commons Science and Technology Select Committee 2002. Minutes of Evidence 24 April 2002, Session 2001-2002 <http://www.publications.parliament.uk/pa/cm200102/cmselect/cmsctech/791/2042402.htm>

²⁵ House of Commons Select Committee on Science and Technology. (2005). *Human Reproductive Technologies and the Law: Fifth Report of Session 2004-05* (HC 7-1). London: HMSO.

<<http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf>>

²⁶ Doran, A. 2007. "Balancing trust with progress: Why regulation of assisted reproductive technologies (ART) and embryo research works in the UK" in James, M. (ed.) *Comparative Approaches to European Bio-Regimes and Regulations*. London: BioCentre, pp.10-11.

the 20 year old national ethics committee. One distinct advantage that this presents is the technical business can be the domain of the regulator whilst the ethical policy issues can be addressed by the committee.

4.8 New and improved approaches should be considered which aim to inform, educate and engage the general public in decision-making relating to what should be acceptable. This could also be part of the remit given to a national bioethics committee.

11. Can you provide examples of costs and benefits of these proposals?

12. Do you have any comments on the consultation Equality Analysis?

Response 99 – Hull York Medical School - Individual

CONSULTATION QUESTIONS	
1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.	No: I agree with option 3, that the HFEA remain where it is.
2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?	There would be little change from what happens at present; I think this would convey a sense of reassurance, born of the HFEA's long experience of overseeing this area of medicine.
3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.	No. I think they should stay with the HFEA. I have held an HFEA Research Licence for 20 years, since the HFEA was established and the research has always been inextricably bound up with general HFEA regulations and with IVF clinics. This is apparent if one looks at the Code of Practice, Section 22 which deals with <i>Research and Training</i> where the issues to be addressed are overwhelmingly concerned not with the actual laboratory research but with wider concerns, including: the purposes of the research, prohibitions, consents, the distinction between human gametes, embryos and stem cells, the donation of gametes and embryos for research purposes, genetic research, secondary research, storage and anonymity. These concerns date from the Parliamentary debates which preceded the Act in the early 1990s where a glance at Hansard at the time shows that about 90% of the debates were concerned with the <u>general</u> question of research on human embryos. The HFEA is considered to be the highest profile 'QUANGO' and much of this attention has revolved around its research function. As a Research Licence Holder and Person Responsible and former Inspector and HFEA member, I can testify to this. I dread to think what would happen if all this were swallowed up by the CQC – which, anecdotally, would apparently struggle to cope.
4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?	No. The HFEA has always come out well in terms of accountability, Parliamentary approval and its role in safeguarding the public interest. It is also much admired internationally; something I have observed as a member of the HFEA's Horizon Scanning Panel. I see no reason to hive off its functions; they are all so intertwined.
5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.	Efficiencies are always possible, but after a period in which I felt there was some 'over-regulation' by the HFEA (in this, I consider the HFEA was merely reflecting the rise of the so-called 'Audit Society'), it has adopted a more

	realistic regulatory culture, informed by the risks involved
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify. I doubt it, since the HFEA costs the public purse so little – around 75% of its income comes from a levy on the cycles carried out in the IVF clinics – about 80% of which are privately funded. In other words, most of the HFEA's costs are funded by infertile couples; something I have always considered to be totally unjust but unlikely to change.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why? No – as I have indicated. I think the HFEA is unlike any other such body.
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment? No - As I indicated, leaving the HFEA where it is would be cost-neutral.
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know. I've always felt that the HFEA should do more for infertile couples – i.e. adopt a <i>consumers' champion</i> function, by, for example, scrutinising fertility treatments of doubtful efficacy.
10.	Do you have any other comments on the consultation proposals that you would like to share with us? No
11.	Can you provide examples of costs and benefits of these proposals? No
12.	Do you have any comments on the consultation Equality Analysis? No

Response 100 – Medical Research Council



The Medical Research Council (MRC) is a UK-based non-governmental organisation funded by a grant-in-aid by the UK tax payer. The mission of the MRC is to improve human health through supporting the delivery of world class medical research.

Summary of response

1. The MRC welcomes the review by the Department of Health of the role of the HFEA and HTA and commends the detailed consideration of the current position and the three options set out in the consultation.
2. The MRC strongly supports the need to continue progress towards a harmonised and risk-proportionate framework for regulation of medical research which maintains effective protections for participants in approved research while removing unnecessary delays and duplications.
3. In this regard the objective of changes to the current system must be to ensure a continued evolution towards a more streamlined and 'joined-up' system of regulation. From discussion with researchers, the priority is to reduce the time to gain the full range of approvals required as well as to minimise duplication of information sought or contradictory requirements from reviewing bodies. In this way benefits to patients arising from research may be introduced more quickly.
4. It is our view that Option 3 provides the best model to facilitate this *providing that*:
 - o There is a single application point and a unified process to return outcome of licence and approval applications

- It is mandatory for all bodies involved in providing licences or other aspects of governance approval for research to cooperate with each other and to delegate shared functions to a single body ie one of the existing regulators and bodies involved in that function;
 - The legislative framework is reviewed, in particular in relation to the current requirement for licensing of premises for storage and use of human tissue for research
5. This will allow the evolution of a framework for continued integration of the diverse facets of research regulation, facilitating a harmonised system for application, review and response for legal, regulatory and governance requirements for research proposals.
 6. The MRC recognises that both the HFEA and HTA are well respected and effective regulators. The fundamental difficulties in the regulatory environment do not relate to the operation of these Authorities but reflect the complex legislative framework that applies to medical research in Universities and the NHS which clearly can result in an inhibitory effect on delivery of research by academic and commercial groups in the UK.
 7. The MRC has consulted with partner research organisations: there is a consensus that there is an urgent need to review this framework– specifically to consider whether the requirements of the Human Tissue Act 2004 remain proportionate.

Response to Consultation Questions

Option 1

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

- MRC does **not** support this option.
- The basis for the proposed transfer of research functions from HFEA to HRA is noted, and the MRC has concluded that there would be merit in aligning review of research projects involving embryos with NHS Research Ethics Committee review of those projects. However, this could be achieved without transfer of operations to HRA
- However, the two major drawbacks of this approach outweigh this, these drawbacks are:
 - the move of research licensing for human tissue use into a large organisation that does not have research expertise and
 - the separation of clinic licensing from research licensing in relation to embryos
- In relation to human tissue we do not consider that the case is made that the Care Quality Commission (CQC) is best placed to oversee storage and use of human tissue for research purposes. We have strong concerns that this function would be subsumed into the large volume of work the CQC undertakes in regard to clinical care and service delivery. The HTA has had a very effective role in supporting research institutions in high quality governance of tissue collections. This has been of great benefit and there is a significant risk of losing this expertise and risk-proportionate approach in a larger organisation where this function would be a relatively minor activity.
- The HTA works within the requirements of the Human Tissue Act 2004 and has established itself as an effective and risk-proportionate regulator within the requirements for licensing of that Act. It is the view of the MRC (and many partner research organisations) that the substantive issue in relation to use of

human tissue for research purposes is that the legislation itself is not proportionate to risks. The costs for research institutions and the HTA in resources and fees required for licensing for premises, in particular using small samples of tissue from the living are, in our view, not justified. There is no evidence that these measures provide significant additional protection over and above the consent requirements of the Act and effective governance within research institutions.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

- There is a risk that a disproportionate approach to regulation of tissue for research by CQC would lead to some organisations becoming less supportive of conducting such activity. If this were to occur it would be of considerable detriment as the UK develops approaches to encourage patient participation in research and facilitate access to tissue resources
- Requiring providers of fertility services to engage with a second regulator for research purposes may be a disincentive for some less research active clinics to become involved with research. Patients at those clinics would thus lose the opportunity to take part in research projects, should they wish to do so.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

- A strategic area for MRC support is regenerative medicine, which includes research on development of stem cells from embryos. We consider that this option has high risks of leading to further complexity and delay in approval of work which aims to deliver safe and effective therapies through stem cells.
- In relation to research projects that involve human embryos it would be beneficial to have stronger coordination on ethical review between the HFEA and the NHS REC system through HRA. This could, however, be achieved by HFEA and HRA being mandated to provide a single joint review of relevant ethical issues. Researchers

in this field do not support a separation of clinical and research functions as research projects are linked to clinics providing clinical services and creating embryos initially for clinical purposes. Separation of regulation risks creating an artificial barrier between clinical and research uses with the unintended consequence of greater complexity in gaining approvals.

- In the current framework there has to be a choice between separation of governance of research according to the modality used (tissues or embryos etc) or separation by purpose eg research from clinical. At present we have more confidence that HRA will facilitate coordination across research sectors with HFEA and HTA than that bringing another body into the equation (CQC) will deliver effective coordination across clinical and research governance sectors.
- It is also important to consider the role of the HFEA in curating the data register: separation of clinical from research licensing may reduce the impetus on clinical service providers to provide timely and appropriate information for the register which is a critical resource for research into effects of these treatments

Option 2

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

- The MRC has considered carefully whether this would be the optimal approach as a framework for functional integration of research functions into the HRA. Although it could provide a mechanism for improved coordination, we have concluded that the risks of separation of research from regulation of related clinical activities outweigh the potential benefits.
- As described below we further concluded that the benefits sought in terms of delivering a streamlined and harmonised approach with appropriate protections for participants would be best delivered by

retaining the current Authorities in a framework that progresses in several key areas of action.

- We do not consider that functions should sit with any other body at this stage. Such transfer could only occur by moving research functions into CQC, which may not be the most appropriate body, or by separating clinical and research functions which is not seen as a desirable step.
- It is important that there is improved alignment of responsibilities across regulators, we support HRA being the key body in effecting this alignment
- As discussed above, the MRC considers there is a compelling need to review legislation relating to human tissue storage and use. If such review concluded that licensing was not appropriate for research uses, it is possible that clinical applications of tissue, for example as cell therapy or transplant under the relevant EU Directives, could transfer to MHRA which has expertise in assessment of safety and efficacy of therapies. However, such a move could only be considered if there were no longer a requirement for licensing for any research purposes – otherwise the difficulty of separation of clinical and research licensing would remain.

Option 3

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

- **Yes**, the MRC supports this option. As well as sharing of such functions, retention of the existing bodies offers an opportunity to retain their skills, expertise and reputation in the sectors they regulate while putting in place mandates for cooperation with other bodies, such as HRA and MHRA.
- In order to deliver an improved system of research regulation one of the most important requirements is that applicants can submit a single unified application for legal, ethical and governance approvals. The MRC commends the work of NRES and now HRA in delivering IRAS as a tool to facilitate this. This work should now be

developed such that all approvals can be applied for through a single portal.

- The next step to deliver efficiency in regulation is to provide a single response to the research applicant – which coordinates replies and requirements from any relevant regulator. This system should also ensure that any contradictory requirements are resolved between bodies before the applicant receives the single response. This will ensure that, should amendments to the proposed research, information sheets or consent be required, applicants can have confidence that these meet with approval from all of the bodies of relevance to their project or premises.
- This streamlined coordinated system with a 'one-stop shop' for applications and feedback will address many of the functional difficulties with the current system.
- Although this structure will optimise what is possible under current legislation, the MRC supports the need for a review of legislation, in particular that related to human tissue, which we consider mitigates against a risk-proportionate and harmonised approach. The MRC is very willing to assist the Department in scoping the nature of such a review if this is approved.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

- Efficiencies should occur in several domains. The consultation has highlighted the need for financial efficiency and this could be delivered by further integration of back-office functions as well as consideration of joint review committees with HRA as appropriate. In addition, the option of shared Chair and Chief Executives should be considered as these posts are seen to represent a major cost in the assessment provided. Indeed, it may be that these roles could be extended to include other relevant bodies, provided sufficient support was available to effectively deliver.
- The costs of inspections for research purposes could be reduced by ensuring that joint inspections are conducted – this function could be delegated to existing bodies with expertise in *inspection* with the

regulatory authority providing the standards against which such inspection occurs as well as ensuring a risk-proportionate approach is maintained. This would provide efficiencies both for regulators conducting inspections but also for inspected institutions which would only be required to prepare for a single inspection. Preparation for inspections is resource intensive for research institutions, whether academic or commercial sector.

- Improved efficiency in delivering research regulation and approvals will also save public and charitable funding – the current duplications and delays mean that the system can take many months for researchers to navigate – this delays the start of funded research and uses considerable resource in terms of funded staff. There are also concerns that the current regulatory processes and related legislative framework are perceived as a disincentive to the Life Sciences industry investing in the UK. Thus, delivering a more effective system for regulation will provide financial efficiencies in public funding of research as well as a constructive environment to support commercial investment.
- As above, we submit that there should be a review as to whether the licensing function of the HTA in relation to research purposes is necessary. Removal of the need for licensing for some or all research purposes involving human tissue would deliver further cost savings for the HTA. However, this is not the prime reason for our support for such a review – which we consider is required to assess the proportionality of this approach

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

- Within this option there is scope to coordinate some functions much more closely with the HRA – in particular in relation to ethics review of projects submitted to the HFEA and requests for access to data held on the HFEA register.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

- The costs of transferring functions appear relatively low in the consultation document, there is a risk that the real costs of transition were option 1 or 2 to be pursued would be higher than estimated.
- The significant costs of Chair and CEO salaries could be reduced as above.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

- As set out above we consider that amending the roles of the regulatory bodies will not fully resolve the issues impacting on delivery of medical research in the UK. For this reason we support the need for a review of relevant legislation and governance requirements.
- The MRC is very willing to discuss further with the Department and with the HRA implementation of the proposed 'one-stop shop' for research approval applications.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

- No further comments.

11. Can you provide examples of costs and benefits of these proposals?

- Please refer to question 6.

12. Do you have any comments on the consultation Equality Analysis?

- We do not have comments in this regard.

For any further questions or comment please contact:

Head of Clinical Research Support and Ethics

Research Programmes Group

Medical Research Council

Response 101 – British Fertility Society



British Fertility Society

Response to the
Department of Health

Consultation on proposals to transfer functions from
the Human Fertilisation and Embryology Authority
and the Human Tissue Authority

28 September 2012

Contents

	Page
Introduction	3
Overview	4
• Key Considerations	4
• The Legal Framework for Assisted Conception in the UK	5
• The Regulation of IVF in the UK	5
• The Regulation of Embryo Research	11
• The Register of Assisted Conception Information	15
• Information to Donors and Donor Conceived People	17
• Responsibility for Policy Development	18
• The Management of Change	19
Response to the Consultation Questions	21
Appendix	26

INTRODUCTION

1. This document represents the response of the British Fertility Society (BFS) to the Department of Health consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).
2. The British Fertility Society is a multi-disciplinary organisation representing professionals with an interest in reproductive medicine. The objectives of the society are to:
 - Promote high quality practice in the provision of fertility treatment;
 - Provide a common forum for members of various disciplines having an interest in the science and treatment of infertility;
 - Promote high quality scientific and clinical research in the causes and treatment of infertility;
 - Provide professional leadership in the provision and regulation of infertility services; and
 - Promote the increase of NHS funding for and equity of access to fertility treatments.
3. The regulation of assisted conception is therefore of interest to members of the BFS, and our comments are limited to the proposals on the future of the HFEA.
4. This document has been prepared by The Executive Officers and is submitted by the BFS Honorary Chairman whose contact details are:

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5. Further information on the BFS and the process followed in the compilation of this response is an Appendix.

OVERVIEW

Key Considerations

6. In compiling this response, the BFS has been guided by the following:

- The strong support of BFS members for the provisions of the HFE Acts and the importance of regulation in this area and an expectation that the level of regulation will remain the same;
- The fact that many BFS members believe that routine IVF is now well established in clinical practice and therefore should be regulated no differently from other medical procedures;
- The evidence that a dedicated regulator for IVF – a well-established, routine procedure, operated to high standards of quality and safety – is no longer justified and may be detrimental to good medical and laboratory practice;
- The recognition by BFS members that the regulation of embryo research needs some specific oversight to recognise the “special status” of the human embryo;
- That many BFS members involved in embryo research, suggest that a ‘one-stop shop’ is needed to replace the current system which requires researchers to go through different routes to obtain ethical approval and a research license – a system which is unnecessarily complex and inhibits embryo research in the UK;
- That before decisions are taken on the best location for the Register of Assisted Conception Treatment, an urgent review is needed to deliver a more streamlined data collection system;
- That the establishment of CQC and the HRA, provides the scope to simplify the current over complex regulatory enforcement framework to the benefit of patients, researchers and practitioners (a key aim of the Coalition Government);
- That BFS support for change is heavily dependent on the effectiveness of the regulatory frameworks established by the CQC and the HRA and on the process for managing the transition, areas not addressed in the consultation document.

7. These considerations are described more fully in the following sections.

The Legal Framework for Assisted Conception in the UK

8. The Human Fertilisation and Embryology Act 1990 and its revision of 2008 has been instrumental in providing clarity and assurance to patients, researchers, the medical profession, and the public about the practice of ART and embryo research in the UK. In addition, the EU Tissues and Cells Directive set standards for quality and safety to minimise risks of errors, contamination, and accidents in the laboratory, and these requirements are incorporated into UK law.
9. BFS members fully support the current legislative framework and the need for regulation in this area, which is essential to the continued maintenance of patient and public confidence. They also recognise the part that the Human Fertilisation and Embryology Authority (HFEA) has played in establishing a credible regulatory framework and providing high quality information for patients. However, many BFS members believe that the continuance of the HFEA as a stand-alone regulator of assisted conception and embryo research can no longer be justified, and may have unwanted adverse effects in marginalising the sector, as well as creating inefficiencies. The proposed transfer of functions to the Care Quality Commission (CQC) and the Health Research Authority (HRA) is an opportunity to alleviate these effects.
10. It is commonly suggested, not least by the HFEA, that the 'HFEA brand' is essential to public and patient confidence in the sector. Many BFS members have stated that it feels more credible to suggest that the current high reputation of the sector is due to the strength of the legislative framework and the direct experience of patients receiving high quality treatments. Regulation plays a part in this, but in other European countries with a thriving sector this is provided by a generic healthcare regulator. The BFS would contend that it is the Act that has established Britain's reputation worldwide and has been imitated elsewhere, rather than the HFEA, which hasn't.

The Regulation of IVF in the UK

11. There are good reasons why IVF has been regulated by the HFEA to date, including the ethical and moral sensitivity surrounding it in the 1980s and 1990s, the limited knowledge of risks and adverse outcomes and anxiety about the welfare of children born through IVF. On the whole, the HFEA has addressed these issues well. However, BFS members have now provided a number of arguments that support the need for change in the way the sector is regulated.

The Case for Mainstreaming Regulation

12. IVF is now a well-established procedure in the UK and worldwide. This is well illustrated by the following table extracted from data produced by the European Society for Human Reproduction and Embryology (ESHRE).

Table 1: ART in European in selected European countries in 2008¹

Country	Cycles/million women 15-45	Cycles/million population	% Newborns Conceived through ART
United Kingdom	4066	825	1.9
Belgium	13069	2687	3.9
Denmark	12712	2450	4.6
Finland	9291	1698	3.1
Norway	9287	1778	-
Sweden	9288	1751	3.3
The Netherlands	6382	1290	2.4

13. It should be noted that there are less cycles of treatment carried out in the UK per head of population, and a lower percentage of newborns conceived through IVF, than in a number of other European countries with comparable ethical approaches. There is also no evidence of increased risk in these countries. Indeed, the HFEA has cited Scandinavia as a model of good practice in relation to elective single embryo transfer.
14. This demonstrates that IVF is flourishing in parts of Europe in the absence of a specialist regulator and casts doubt on claims that HFEA's regulatory oversight is essential to confidence in the UK sector.
15. Many BFS members feel that the creation of the HFEA, with its broad range of responsibilities was very much a reaction to the concerns of the day. It is very unlikely that a specialist regulator for IVF would be established today given the everyday medical nature of the treatments and the Government's clear emphasis on streamlining regulation.
16. There are also significant downsides to separate regulation of IVF. These include costly regulatory overlap between the HFEA and the CQC and a less immediately obvious marginalising effect on both patients and staff, particularly in (but not limited to) NHS organisations.

Regulatory Overlap

17. Both private and NHS clinics licensed by HFEA and registered with CQC have reported to the BFS significant duplication between the two regulators. One clinic estimated the overlap to be as much as 60-70%. Examples of overlap at inspection include the Quality Management System, complaints, incidents, audit, staff competency and training, staff interviews and patient interviews. This is unnecessarily disruptive and costly to clinics (many of which are Small and Medium Enterprises (SMEs)). The same clinic was inspected by both regulators with only a 5-6 month interval.

¹ Ferraretti AP, Goossens V, de Mouzon J, Bhattacharya S, Castilla JA, Korsak V, Kupka M, Hum Reprod. 2012 Sep;27(9):2571-2584. Epub 2012 Jul 10

18. Of course BFS members recognise that the focus of the two regulators is different but there is also considerable cross over. CQC inspection is generally patient centred, and emphasis is placed on patient pathway, care and facility. The HFEA's focus is on embryology and laboratory practice. However, the clinics who have spoken with BFS, report that both HFEA and CQC have covered consent, patient treatment and the provision of treatment and outcomes information. Both regulators interview patients and staff, both employ very similar processes of self-assessment against standards and both require similar evidence in support.
19. Both the HFEA and the CQC operate incident reporting systems, creating further duplication through two separate reporting routes. The HFEA require reporting of incidents relating to loss or damage to embryos, hospitalisations and breaches of confidentiality. CQC may also require some of these to be reported to them but their main interest is in any significant incidents that happen to patients whilst in the care of clinics.
20. It seems self-evident to many BFS members that there are clear synergies between the CQC and the HFEA on regulatory and licensing functions. In particular, the six main areas of the CQC's Essential Standards of Safety and Quality are equally relevant to assisted conception:
 - *Personalised care, treatment and support* – individual needs, health promotion, day to day care;
 - *Involvement and information* – appropriate information giving methods, consent forms;
 - *Quality and Management* – internal control, complaints, incidents, records;
 - *Suitability of staffing* – recruitment, qualifications, training, manpower;
 - *Suitability of management* – capability, structure, monitoring, finance;
 - *Safeguarding and safety* – facilities, standard operating procedures, medicine, equipment;
21. The HFEA has acknowledged that unnecessary regulatory overlap is a burden (although they do not acknowledge its extent) and have a commitment with CQC to coordinate activities better through greater partnership, with the objective of introducing a single regulatory regime for assisted reproduction centres. This is welcome, but it will do nothing to address the problems of marginalisation described in the next section.

The Benefits of Integration

22. Effective regulation should provide a lever for improvement to the benefit of patients, for example by lending support to a case for extra resources on staffing or training. However, the consistent experience of many BFS members working in NHS IVF clinics is that this does not happen.

“Over the past few years, I have conducted investigations on behalf of a number of large NHS hospitals where a common contributory factor to the problem appeared to be a lack of engagement by hospital management because they saw the assisted conception service as regulated differently and there was a sense that they were excluded because it was not seen as part of their domain.”

Dr. Allan Pacey, University of Sheffield.

23. BFS members have reported that regulating IVF separately from other types of mainstream healthcare has led to a culture in which IVF patients within an NHS setting are seen as different from the general patient population. The impact, in large NHS organisations, is that senior management and Board members display limited or no interest in the HFEA inspection process or outcomes in stark contrast to the priority given by Trust Boards to the outcome of CQC inspections. Integration of IVF/assisted conception into a single process of registration and regulation would ensure the Executive level responsibility and Board level accountability applicable to all other acute services. This would facilitate greater executive level ownership of the quality and safety standards that pertain to this area of clinical practice.
24. The generic systems of audit and governance that apply to the safety and quality of clinical practice in other areas of complex medical interventions for example blood transfusion, transplantation, major trauma and intensive care are equally applicable to assisted conception. Many BFS members have argued that integration of regulation under the CQC would be a key enabler for assisted conception services to benefit from these systems and more importantly their supporting infrastructure and the accountability framework that underpins them.

IVF treatment is an established part of clinical practice and has been undertaken for over thirty years. Whilst its social profile is not doubted and the specifics of gamete and embryo handling require particular expertise, generic systems of quality and safety used in other areas of clinical and laboratory practice are equally applicable to assisted conception. The continued consideration of ART as a unique and discrete area for the purposes of regulation and quality assurance is neither necessary nor best serves the interests of patient care”

Richard Kennedy, Medical Director at UHCW NHS Trust

25. All BFS members believe that a regulatory regime should bring clear benefits to IVF patients. They should not be stigmatised by being seen as ‘different’. Were we starting today with a blank sheet of paper, we would be designing a single healthcare regulator that included assisted conception. Many BFS members are of the opinion that we now have an opportunity to bring regulation of IVF into the modern age through the proposed transfer of the HFEA’s functions to CQC. This is reinforced by

considerable scepticism about whether the level of change needed can be achieved whilst keeping the HFEA as a stand-alone regulator.

Arguments for Retaining the HFEA

26. There has been an active debate within the BFS membership, and with other stakeholders, about the case for retaining the HFEA. Some BFS members would prefer to see the HFEA retained, although the need for further efficiencies is recognised by almost all. The complete absence of proposals in the consultation document about how regulation of the sector would operate post HFEA has made it difficult to give whole hearted support to any option. And the concerns raised by the Public Accounts Committee among others about the readiness of CQC to take on additional functions, raise questions at the very least about the proposed timetable for change.
27. Nonetheless, many BFS members consider the arguments deployed for retaining the HFEA to be seriously flawed.

Risks & Incidents

28. In her evidence to the Public Accounts Committee on 25 January 2012, arguing the case for retaining the HFEA, the HFEA Chair, Lisa Jardine described IVF as “the sharp pointy end of risk in our society”. She went on to say that “By the time there has been an incident in IVF there is a baby in the wrong mother or a baby with the wrong donor.... The public believe we [the HFEA] regulate in such a way that this is unlikely to happen”²
29. Incidents in IVF are in fact very rare. Following an incident in Wales in 2009, in which a couple were told that their last frozen embryo had been mistakenly implanted into another patient, Alan Doran, then Chief Executive of the HFEA, put the issue of incidents into proportion:

“Out of more than 50,000 cycles of treatment, 0.5 per cent resulted in an incident. Very few of these incidents are as serious as the one at IVF Wales. It is impossible to eliminate human error. We strongly encourage clinics to report all incidents and near misses, so that we can help them learn from their mistakes and to spread best practice across the sector.”

30. There will always be adverse incidents in healthcare, but these are no more likely to occur in the IVF clinic than elsewhere. Risks in IVF are now well understood by practitioners, explained to patients and well managed with professional bodies (eg the British Fertility Society, the Association of Clinical Embryologists etc) who publish guidelines for good practice as well as provide education and training of persons engaged in the profession.

² House of Commons Committee of Public Accounts: The Care Quality Commission: Regulating the quality and safety of health and adult social care. Seventy-eighth Report of Session 2010–12 HC 1779

31. When the HFEA was first established, hospitals did not have the same level of clinical governance as they do today. In addition, in assisted conception units, there is a strong focus on ISO quality management systems and strategies for improving patient safety. This includes assessing how patients could be harmed, preventing or managing risks, reporting and analysing incidents, learning from such incidents and implementing solutions to minimise the likelihood of them reoccurring. As mentioned at paragraph 19 above, CQC already has an incident reporting system in place. Merging this with the system currently run by the HFEA would both remove duplication and provide an equivalent level of assurance to patients.

Patient Confidence

32. Patient confidence stems from the protections in the HFE Act and patients' direct experience of clinics providing high quality, patient-centred, care. It is not linked to the identity of the regulator. It is the view of many BFS members that patients associate the HFEA 'brand' with the HFEA's per cycle fee and with the 'find a clinic' facility on the HFEA's website, but little else. They want to know that there is regulation, but there is no evidence to suggest that they will lose confidence if regulation is provided by CQC. The fact is that 90% of HFEA licensed clinics in England are already registered with CQC, with CQC already proving a focus on patient safety and quality.
33. As shown in Table 1 above, the assisted conception sector is thriving in Scandinavia and elsewhere in Europe, with regulation under the European Tissue and Cells Directive provided by generic regulators. In Denmark, which has the highest percentage of newborns conceived through ART, the Danish Medicines Agency took on the role of competent authority under the EU Tissue and Cells Directive. In March 2012, this merged with the Danish National Board of Health to form the Danish Health and Medicines Authority, of which inspection and licensing of assisted conception clinics is one small element.

Loss of Expertise

34. As acknowledged in the DH Impact Assessment, some BFS members are concerned that the transfer of HFEA functions to the CQC may result in a loss of expertise. However to others this feels like a non-issue as most HFEA staff will follow the transfer of work. CQC staff are also expert in standards-based inspection processes. Avoiding loss of expertise should be a priority for those managing the transition but is not a strong argument against change.

Provision of Ethical and Policy Advice

35. This is addressed in more detail at paragraphs 70-74 below. Rather than seeing the continuance of the HFEA as necessary to address future policy and ethical issues surrounding assisted conception, there is a strong

argument for these to be considered in a broader forum than the HFEA. Regulatory policy issues would naturally fall to the CQC, as they do at present.

Competence of the CQC

36. This is a shared concern of many BFS members, which needs to be taken seriously by DH. However, the majority of clinics we have spoken to who are registered with the CQC have confidence in the rigour of their inspection processes. The real issue, as with any organisational merger, is the effectiveness of how the transition is managed in practice (see paragraph 75 below). Some BFS members have expressed concern that the CQC does not have competence in the inspection of laboratories. However, we would expect that, in taking on the HFEA's functions, the CQC would engage staff with this expertise from the HFEA or elsewhere

Readiness of the HFEA to Make Changes

37. As noted in paragraph 25 above, many BFS members are sceptical about whether the level of change that the HFEA needs to deliver can be achieved whilst keeping the HFEA as a stand-alone regulator. We note that the HFEA say that they have put in place an efficiency programme that has reduced their costs by 30% since 2009 and have plans to make further savings. However, these savings have happened only as a result of the pressures brought about by the Arms' Length Body Review. Moreover, the BFS has been concerned that some of these efficiencies have had little impact in clinics and patients given the £3.4M HFEA cash surplus reported in the press in February 2012.
38. Were option 3 of the consultation proposals implemented, it is hard to see where the impetus for further change would come from. In dialogue with the HFEA the BFS has over the years suggested efficiencies to aspects of regulation, including (i) the regulation of embryo research; (ii) the process and extent of data collection; (iii) the provision of information to donor conceived people; (iv) concerns about 'regulatory creep'; and (v) the development of standards and policy. However, largely these suggestions have fallen on deaf ears.

The Regulation of Embryo Research

Background

39. There are currently 23 active research licences awarded by the HFEA in 17 Centres. Approximately eleven are related to the derivation of embryonic stem cells from embryos, four to embryo culture, three to preimplantation genetic diagnosis, two to the fertilisation process, one for chromosomal analysis of embryos, one for vitrification techniques and one for research on hybrid embryos. There are no applications pending. Only

two licences are for private/commercial centres: the remainder are from established academic departments. Fourteen of the centres that hold a current licence also held a licence in 1994. Thus they have had successful annual inspections/reports for 16 years. The typical profile of a centre undertaking embryo based research in the UK is a University linked department with a longstanding record of successful progress in this field and a low risk assessment by the HFEA.

40. By comparison, NRES currently receives about 500 applications a month. The scale of embryo research in the UK is thus relatively very small.
41. Prior to the Human Fertilisation and Embryology (1990) Act, medical research (including research involving human embryos), was conducted following approval from a local research ethics committee and with funding from bodies like the Medical Research Council (i.e. they would not fund unethical research).
42. In 1991, local research ethics committees were newly established and were largely autonomous bodies and arguably did not have the appropriate skill to enact the legal requirements of licensing research on human embryos in the HFE (1990) Act. Therefore, from 1991 onward it was wholly appropriate that the HFEA should take on the function of licensing research on human embryos and therefore providing support to local research ethics committees to approve medical research in this area.
43. The extent to which the HFEA was efficient and effective in its licensing of human embryo research during this time is a matter of debate to many BFS members involved in research. However, although the regulatory system for approving medical research in the UK developed enormously, the licensing of human embryo research did not. By the year 2000, and the establishment of the Central Office for Research Ethics Committees (COREC), researchers wishing to use human embryos in research had to manage two very different and sometimes contradictory systems in order to achieve this. This included, and still includes, two different application forms, documents such as protocols and CVs being requested in different formats. Similarly, throughout the research, separate progress reports and final reports had to be submitted to different timescales and in different formats, leading to an inevitable duplication of effort.
44. Some researchers have reported to the BFS that they have chosen not to propose projects using human embryos because of the unnecessary complexity of obtaining ethical approval and a research license through different routes. There is evidence to suggest that this bureaucratic complexity has inhibited rather than enabled the UK to be at the forefront of medical research involving human embryos.

“There are too many regulatory authorities for stem cell research including the HFEA and therefore consolidation of the regulators will in the long run be important to remove barriers for development of

regenerative medicine applications. For human embryo research I do think this responsibility would be better with not being within the HFEA as investigations for using human embryos in research has broadened over the years and would be better served by a body with a broader remit and viewpoint. However it will be important that patients have confidence that if they donate their embryos for research that there is proper oversight.”

Professor Harry Moore, Department of Biomedical Science, The University of Sheffield

45. The BFS has heard from one researcher that the involvement of the HFEA in regulating research is having negative effects on the ethical review system:

“The current system of duplication undermines the ethical review system such that ethics committees which are properly constituted may defer to the judgement of the HFEA rather than give applications full independent scrutiny”

Professor Richard Anderson, University of Edinburgh

46. In recent years, the national research infrastructure has been strengthened with the establishment of the National Research Ethics Service (NRES) in 2007 and, following the report by the Academy of Medical Sciences in January 2012, the establishment of a new independent Health Research Agency (HRA).

The Health Research Authority

47. After reading the arguments in the consultation document, the majority of BFS members support the proposal to transfer to the HRA the HFEA functions relating to research other than inspection.
48. This support is contingent on an understanding that a way will be found to create a ‘one stop shop’ for all research applications to put an end to the damaging bureaucratic complexities of the current system. This should start with a single application and conclude with a single approval.
49. The BFS believes that the IRAS application system is sufficiently generic to allow the integration of key questions about any embryo research that will then initiate ‘behind the scenes’ action by the HRA to assess these applications, perhaps by one or two ethics committees that have received specific training and have the specific support to do so.
50. The BFS first proposed this idea in 2005 (using the then COREC form) and it is disappointing that this was never taken forward.

NRES Consideration

51. The BFS understands that NRES research ethics committees already consider research outside the NHS where the law requires it. For example research involving patients who lack capacity to give informed consent or research involving ionising radiation. There would therefore be nothing to prevent embryo research applications being considered by NRES committees.
52. The requirement for embryo research applications to be considered by a local research ethics committee is a HFEA policy requirement and in retaining the safeguards, we understand that DH would expect HRA to continue to require review by a research ethics committee using NRES research ethics committees.

Inspection and Licensing

53. The BFS understands that the HRA would not wish to undertake the inspection of embryo research laboratories as they do not have this expertise. Most BFS members would support the transfer of this function to the CQC or to another appropriate body. This has the advantage of reducing possible fragmentation in the system.
54. Because the inspection process for centres engaged in embryo research is not specific - it follows the general principles of quality management - it could be undertaken by anyone with appropriate inspection skills
55. The HFEA has said in its response to the consultation that:

“..regulatory processes and legislation that govern embryo research in the UK are necessarily dependent on those governing fertility treatment; as the majority of embryos used for research in the UK are donated by couples undergoing fertility treatment.....As such, there is merit in having a single integrated licensing regime which governs the processes by which all gametes and embryos can be procured; the length of time for which they can be stored; and which ensures that appropriate information is provided to embryo donors and that all required consents are in place before embryos can be used in research.”

It should be noted that the need for a link between clinical and research regulation does not apply to other areas of medical research. Some BFS members have commented that in practice the HFEA is rigid in ensuring that there is separation of research and clinical practice with, for instance, strict rules on clinicians who undertake research not being involved with that patients' clinical treatment. The 'continuity' link is an idea that the HFEA has often quoted but has no ethical or practical foundation elsewhere.

56. The HFEA has also suggested that there would be an increase in inspections if research functions were transferred to the HRA. However, although the HFEA usually now carries out treatment and research licence inspections at the same time, the processes are in fact completely

separate. Separate documentation is required, different personnel are involved, there are different reports and different licence committee decisions to respond to. BFS members would therefore challenge the HFEA's assertion that transfer of functions to the HRA "would make the regulatory regime more complex (and duplicate administrative costs) not less."

"Embryo based research in the UK appears to be flourishing because of a very small number of high profile projects. Clinical embryology research is minimal and insignificant in the international context. In the NICE Guidelines on Fertility 2004, of the 100 areas of practice reviewed only one related to an embryology procedure (assisted hatching). The literature on assisted hatching was reviewed by a Manchester group in 2003. It contained 23 randomised trials, all of which were outside the UK. The lack of research in clinical embryology is regrettable. It does not appear to be because of a lack of interest by UK practitioners but is certainly not encouraged by the regulatory environment."

Professor Alison Murdoch, Newcastle University

The Register of Assisted Conception Information

57. The key issue for the BFS is the need for simplification of the process for collection of data and an end to the collection of information by the regulator which is not needed either for regulatory purposes or to meet the requirements of the HFE Act.
58. The requirements for the Register of Information are set out in the HFE Act and there is a duty on the HFEA to hold this information. There is currently no clear remit to provide feedback to clinics, and the database to which individual clinics contribute is not readily interrogated by them. The HFEA has however made some moves very recently to provide centres with individualised "profiles" and recommendations with regard to success rates and multiple births. However, this has not been welcomed by all BFS members who cite this as an example of ongoing 'regulatory creep':

"The HFEA now includes clinical performance, in terms of pregnancy rates as part of their quality assessment, and intends to notify clinics if their rates drift outside the expected ranges. This is not useful to centres, who are required to monitor their key performance indicators as part of their quality systems, and who are therefore likely to have this information before they are informed by the HFEA. Moreover Centres will be expected to provide a plan to the HFEA as to how they intend to address such a problem, despite the fact that the HFEA is not an expert body, and therefore not qualified to comment on the likely efficacy, or appropriateness of any plan. This is not only unhelpful, but also puts further negative pressure on centres, and is a prime example of regulatory creep, as there is nowhere in statute, or the regulatory framework that suggest or implies this is part of the remit of the regulator."

Dr Sue Avery, Director of Assisted Conception, Birmingham Women's Healthcare Trust

59. The BFS has identified a number of systemic faults with the Register that have evolved over the years, and along with other stakeholders proposes a major review of its content and structure. This has been written up as a publication currently under review and a draft copy is attached to this response for information.
60. Some of the recommendations made about the register are consistent with current practice but some will require fundamental changes. This includes:
- *Simplifying the reporting and recording of data* For a single treatment cycle, it is currently necessary to complete and submit up to 6 separate data forms to the HFEA. All clinics use a single record for each patient/treatment provided. This mismatch of data recording is unnecessarily complicated and it would be more appropriate if data were held by the HFEA and clinics in a similar format.
 - *Taking full advantage of electronic technology.* For instance, separate forms are needed for donor insemination and IVF treatments and for treatment outcomes. The advantage of digital technology is that a single database format can be created that can be used to input data from all treatment types. This would use 'drop-down' choices since most fields contain mutually exclusive entry options. This single form would include all the data needed for each treatment.
 - *Removing inconsistencies between different licensed treatments:* The data collection processes have evolved over many years. This has not always been associated with transparent explanation or consistency. For instance, in 2009, following the inclusion of gamete "processing" into the portfolio of licensed procedures, new forms were introduced relating to sperm processing for insemination and gamete intrafallopian transfer using partners sperm. Although this requirement also led to the need for some unlicensed centres to apply for and attain HFEA license, the data collection is a simple annualised form relating to cycle numbers and success rates. No patient identifying information is requested. This brings into focus the inconsistency in data collection between licenced treatments and demonstrates the need to review.
 - *Addressing regulatory creep* Over recent years the HFEA has expected clinics to complete various new forms, sometimes unheralded (e.g. monthly donor sperm procurement form) and without any clear explanation of why the information is sought. The implications for clinics are not taken into account other than a

presumption that if the HFEA asks for data then data must be supplied.

61. The BFS has identified savings that could be achieved through an improved data collection process and would expect to see these passed back to the clinic as a fee reduction. It is noteworthy that these discussions began over 10 years ago but during that time the data collection has continued expanding much to the frustration of many BFS members. One clinic has calculated recently that staff spent a staggering total of 5 hours 20 minutes inputting data on the HFEA's electronic data collection system (EDI) during just one cycle of a single patient's successful treatment.
62. BFS would support the siting of a reformed Register either by the CQC or by the NHS Information Centre (IC). The arguments given in the consultation document for transferring ownership of the Register to the IC are compelling, but we do not know enough about the IC to say if this is workable. The question of who maintains the Register is less critical to BFS than having an effective Register that is fit for purpose.
63. We have discussed options for siting the Register with NHS Connecting for Health, and recommend that DH does the same. Possible solutions could involve overall management of the Register by the National Back Office, who already handle very sensitive data, (eg witness protection information and the database of HIV infected individuals), and the IC who could hold the data and bring to bear their expertise in managing large databases and in data analysis. An options appraisal may be the best way forward.
64. There is also a strong case for developing an information standard for the Register. This would be a formal document approved and issued by the Information Standards Board for Health and Social Care, defining technical criteria, content, methods, processes and practices. Information standards are helpful in giving assurance on the management and use of databases, and can be particularly valuable where data is sensitive. For example, a standard is currently being developed for the HIV and AIDS Reporting System.

Information to Donors and Donor Conceived People

65. Many BFS members support the view in the consultation document that the provision information to donors and donor conceived people is not a regulatory activity and therefore does not belong with either the HFEA or the CQC.
66. The view of most BFS members is that this should instead be a fully professional service, providing mediation and origin counselling similar to that established in post adoption services. This was first suggested by the

BFS in 2005 following the announcement about the removal of donor anonymity:

“The BFS believes it is essential that clinics are able to inform donors about the likely route by which donor conceived people may make contact with them. It is disappointed that the UK government currently has no plans to fund mediation and origin counselling similar to those established in post adoption services.”³

67. Others have highlighted concerns about the HFEA's current approach:

“The current care that is given to post adoption services could be applied to post donation care – currently there is no clear pathway which has raised concerns amongst both patients and healthcare professionals. For example, I have worked as a counsellor seeing people who are considering gamete/embryo donation or offering to be donors for many years now as well as having active links with people who are donor conceived. These key stakeholders are increasingly sharing their concern about the inadequacy of the HFEA policy in relation to the collection of full biographical information about donors which fails to recognise that parents who want to share this information with their children from a young age need all the information requested of donors. The HFEA made a decision that only demographic and medical information was mandatory so that much of the information that children and parents need will be missing.”

Jennie Hunt, Senior Accredited Member, British Infertility Counselling Association

68. BFS Members do not have strong views on which organisation would be best placed to run a Post Donation Care Service. DH may wish to consult BASW's Project Group on Assisted Reproduction (Progar) and/or the British Infertility Counselling Association (BICA) who are better placed than BFS to advise on this.
69. To avoid the risk of fragmentation, the contracting out of the Post Donation Care Service may be better undertaken by CQC than by DH. Care would need to be taken to ensure proper governance around the transfer of data, ensuring that people only see the information they need to know. However, there is no reason why this should not be technically possible.

Responsibility for Policy Development

70. The HFEA derives its policy role from two statutory functions in the HFE Act – a duty to advise the Secretary of State and a requirement to

³ BFS Press Release: Fertility specialists welcome sperm and egg donor campaign but call for more action in time for change in law in April 2005, 26th January 2005

produce a Code of Practice (which by its nature requires the development of regulatory policy, eg advice on clinics on how to comply with the law and how compliance will be measured). Some BFS members have argued that the HFEA has gone beyond its statutory remit in developing policy in areas that relate to neither of these functions. The HFEA's work on donor remuneration and donor recruitment are two such examples of regulatory creep mentioned by BFS members.

71. The DH Arms' Length Body Report of 2010 makes clear that:

“Setting policy is the role of the Department of Health not arm’s-length bodies, although arm’s-length bodies will often have a role in policy development and implementation determined by the Department of Health”

72. Some BFS members argue that the HFEA is not an expert body and is not constituted as such. Nor is it appropriate for the HFEA as a regulator to make policy other than on regulatory issues, in the same way that we would not consider asking the police to make the law. There is a conflict in a situation where the body that has to implement the rules also makes them.

73. The House of Commons Science and Technology Committee inquiry into Human Reproductive Technology, which reported in March 2005, made a similar point:⁴

“...the current regulatory model, which provides the HFEA with a large amount of policymaking flexibility, should be replaced with a system which devolves clinical decision making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight. Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety.”

74. BFS members consider that the public interest in many of the policy and ethical issues currently considered by the HFEA, would be better and more democratically addressed through a properly constituted DH advisory group.

The Management of Change

75. This is a critical issue not addressed in the consultation document. Responses from BFS members have shown that there is not enough information regarding the options that could be put in place, especially for the devolved governments. The absence of information about how the functions of the HFEA will be exercised by the CQC and the HRA, whilst

⁴ House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, Fifth Report of Session 2004–05, Volume 1 HC 7-I

understandable, means that BFS support for the transfer of the HFEA's functions is contingent on a number of factors:

- that there is complete openness by the regulators around planning for the transition and that stakeholders are fully engaged in this process in line with Coalition objectives on government transparency.
- that expertise will follow function so that the CQC is properly equipped to take on HFEA functions that are new to it (eg inspection of IVF laboratories).
- that the transfer of HFEA functions to the CQC results in a single inspection leading to registration with the CQC that would include a licence for assisted conception.
- that a single fee is levied by CQC to cover registration and licensing.
- that the transfer of the HFEA's functions on licensing of embryo research will create a 'one stop shop' for all research applications.
- that the remit of the HRA will be extended to cover research licence applications from outside the NHS.
- that a major review of the Register of Information is undertaken and that cost savings are passed on to clinics.
- that the on-line Find a Clinic Guide continues under the new arrangements.
- that CQC engages stakeholders in the development and drafting of the Code of Practice required under the HFE Act.
- that a suitable provider will be found to undertake the provision of information to donors and donor conceived people.
- that, although the HFE Act is already UK law, proper account is taken by regulators of other relevant laws in devolved countries, for example Scottish family law.

RESPONSE TO THE CONSULTATION QUESTIONS

1. **Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.**

Yes. As discussed in the Overview section [paragraphs 11-25 above], many BFS members are of the opinion that:

- There are no compelling reasons to continue to regulate IVF as a distinct category of treatment, and some serious downsides to continuing to do so.
- There are good reasons why IVF has been regulated by the HFEA to date, including the ethical and moral sensitivity surrounding it in the 1980's and 90's, the limited knowledge of risks and adverse outcomes, and anxiety about the welfare of children born through IVF. Today, however, IVF is a well-established, routine medical procedure.
- Integration of regulation under the CQC would be a key enabler for assisted conception services to benefit from the generic systems of audit and governance that apply to the safety and quality of clinical practice in other areas of complex medical interventions and more importantly their supporting infrastructure and the accountability framework that underpins them. This would deliver considerable benefits to patients.

2. **Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?**

Transfer of functions to CQC

- On the assumption that the transfer of HFEA's functions to the CQC will lead to combined inspections, there will be a reduction in burdens on clinics currently inspected by both. Current estimate is a 60-70% overlap for some clinics inspected by both HFEA and CQC. We cannot provide an estimated cost saving but would be happy to work with DH to quantify this. [see paragraphs 17-21 above]
- For clinics that are part of larger NHS organisations, or large private organisations delivering a range of services, removal of separate regulation of assisted conception and a move to regulation by CQC will facilitate greater executive level ownership of the quality and safety standards that pertain to this area of clinical practice. Greater integration will ultimately lead to continued improvements in patient care. [see paragraphs 22-25 above]

Transfer of functions to HRA

- If, as hoped, this creates a 'one-stop shop' for approval for embryo researchers, the process for researchers will be simplified, removing a bureaucratic barrier to embryo research in the UK. [see paragraphs 47-56 above]

The Register of Assisted Conception Information

- The BFS has identified savings that could be achieved through an improved data collection process and is seeking a major review, with the resulting savings passed back to clinics as a fee reduction. [see paragraphs 57-64 above]

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

Yes. The current system which requires researchers to go through different routes to obtain ethical approval and a research license is unnecessarily complex and inhibits embryo research in the UK. Most BFS members wish to see a 'one stop shop' for all research applications to put an end to the damaging bureaucratic complexities of the current system. There is evidence to suggest that the current system has inhibited rather than enabled the UK to be at the forefront of medical research involving human embryos.

The BFS believes that the IRAS application system is sufficiently generic to allow the integration of key questions about any embryo research that will then initiate 'behind the scenes' action by the HRA to assess these applications, perhaps by one or two ethics committees which have received specific training and have the specific support to do so. [see paragraphs 47-52 above]

The BFS understands that the HRA would not wish to undertake the inspection of embryo research laboratories as they do not have this expertise. BFS members would support the transfer of this function to the CQC or to another appropriate body. [see paragraphs 53-56 above]

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

Yes

There are two HFEA functions which many BFS members believe would sit better with other bodies:

The Provision of Information to Donors and Donor Conceived People

Many BFS members support the view in the consultation document that the provision information to donors and donor conceived people is not a regulatory activity and therefore does not belong with either the HFEA or the CQC. This should instead be a fully professional service, providing mediation and origin counselling similar to that established in post adoption services. [see paragraphs 65-69 above]

The Development of Policy and Ethical Opinion (other than Regulatory Policy)

Many BFS members argue that the HFEA is not an expert body and is not constituted as such. Nor is it appropriate for a regulator to make policy other than on regulatory issues, in the same way that we would not consider asking the police to make the law. There is a conflict in a situation where the body that has to implement the rules also makes them. BFS members consider that the public interest in many of the policy and ethical issues currently considered by the HFEA, would be better and more democratically addressed through a properly constituted DH advisory group. [see paragraphs 70-74 above]

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

No. We would have no confidence that the level of change called for would be delivered by HFEA if it retains its current functions. For some of the issues outlined above the BFS has a long history of dialogue and lobbying for change [see paragraphs 37-38 and paragraph 50 above] and this has largely fallen on deaf ears.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

Most BFS members remain sceptical that this would happen. In any case, as this response demonstrates, the case for change (especially the case for delivering benefits to patients by mainstreaming the regulation [see paragraphs 22-25 above] of assisted conception) goes beyond savings to the public purse. Many BFS members believe that this cannot be achieved while the HFEA is in existence.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Were the HFEA to be retained, many BFS members would still wish to see the transfer elsewhere of the HFEA's ethical and policy role and the function to provide information to donors and donor conceived people (see response to question 4 above). The majority of BFS members would also still wish to see a major review of data held on the Register and the transfer of the HFEA's embryo research functions, other than inspection, to the HRA.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

Paragraph 157 of the Impact Assessment states "The proposal to transfer HFEA and HTA licensing functions to CQC would, therefore, present CQC with the opportunity to make efficiency savings in terms of removing duplication of effort for both the regulator and providers in the assurance process. It would be for CQC to decide how it discharged any inherited functions."

BFS members would expect cost savings to be delivered to clinics through combined inspections. These need to be quantified.

We would also look to the HRA to deliver savings to researchers through the development of a 'one-stop shop' for submission of applications.

Additional efficiencies could also be achieved through the major review of the collection of data proposed by BFS and other stakeholders.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

There is a strong expectation on the part of BFS members that there must be complete openness by regulators around planning for implementation and that stakeholders must be fully engaged in this process in line with Coalition objectives on government transparency. BFS members also expect to see full stakeholder involvement in key areas such as the development of the Code of Practice required by the HFE Act.

In a situation where regulators will be taking on functions that are new to them, it is vital that expertise follows function. This is particularly essential in relation to the transfer of HFEA's expertise in inspection of laboratories.

However implementation is managed, BFS members expect to see properly integrated inspections and arrangements that bring together CQC registration and licensing of assisted conception.

BFS members also expect to see a single fee levied by the CQC to cover registration and licensing, although we recognise that this may not happen immediately.

A key priority in all of this should be to avoid fragmentation, for example by CQC undertaking inspections of both research and treatment centres, by managing the siting of the Register of Information and by managing the outsourcing of a Post Donation Care Service for donors and donor conceived people

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Assuming a decision is taken to implement Option 1 or 2, BFS members would expect to see a further consultation with stakeholders on how a future model might work in practice. The BFS would be willing to work with DH along with other stakeholders to advise on the best way forward.

11. Can you provide examples of costs and benefits of these proposals?

This is not possible given the absence of detail about how these proposals might be implemented in practice. However, the BFS would be happy to contribute to further work on the impact assessment as plans develop.

12. Do you have any comments on the consultation Equality Analysis?

In line with the conclusions of the Equality Analysis, we are not aware of any impact that these proposals would have on the equality groups.

About the BFS

Background

1. With the encouragement of IVF pioneer Patrick Steptoe, the British Fertility Society was founded in 1972, by a small group with a common interest in infertility. Since then the burgeoning knowledge in this exciting area of medicine has resulted in the development and introduction of many new reproductive technologies and into clinical practice. The interests of the BFS have broadened to a range unimaginable 40 years ago. The British Fertility Society has grown alongside the development of our speciality and now actively promotes the sharing of knowledge, further education and raising standards of practice.
2. Today, the Society is the only professional body with multi-disciplinary membership across the medical and scientific practice of reproductive medicine. It welcomes andrologists, counsellors, embryologists, endocrinologists, nurses, and other professional groups working in this field, into its membership. At the end of 2011, the BFS had 899 members, comprising 404 clinicians, 129 Nurses, 100 scientists and a mixture of Counsellors, Students and Associates.

BFS Executive Committee

3. The activities of the BFS are directed by the Executive Committee, elected by the membership. A number of sub-committees have remit for specific areas, namely Training, Policy & Practice, Meetings, and Website. The Committees are held quarterly and report to the Annual General Meeting at the Annual BFS Meeting.

4. The current members of the Executive Committee are:

President	Mr Richard Kennedy
Chairperson	Dr Allan Pacey
Secretary	Mrs Alison McTavish
Treasurer	Dr Susan Avery

5. The current elected members of the Executive Committee are:

Andrologist Member	Mr Kevin McEleny
Clinician Member	Dr Jane Stewart
Clinician Member	Professor Adam Balen
Clinician Member	Mr Charles Kingsland
Counsellor Representative	Ms Ruth Wilde
DGH Member	Dr Valentine Akande
Embryologist Member	Dr Virginia Bolton
Junior Clinician Member	Mr Richard Russell

Nurse Member
Scientist Member
Scientist Member
Nurse Member

Ms Trudi Campbell
Dr Joyce Harper
Professor Sheena Lewis
Mrs Karen Woodcock

Initial BFS Response to the DH Consultation

6. Following the launch of the DH consultation on 28th June 2012, Dr. Allan Pacey, Chair of the BFS, said:

“The British Fertility Society is absolutely committed to upholding the principles enshrined in the Human Fertilisation and Embryology Act. However, in today’s difficult economic climate, it is clear that we must take a long hard look at how the fertility sector in the UK is regulated and see whether there are alternative models that can do this more efficiently. Whilst it is under consideration, we currently have no firm view of how this might work, however we will be studying the Government’s proposals carefully and will be consulting with our membership over the summer to formulate a response to the consultation. Improvement in the current process of regulation would be supported by the Society, although change for change sake without clear evidence of benefit would not.”

Process for Developing this Response

7. The response from BFS members set out in this document has been developed through a process of detailed consultation and discussion with members and stakeholders. Key stages in this process have been:

12 th July 2012	Meeting of the BFS Executive Committee
25 th July 2012	BFS members invited to submit written comments
30 th August 2012	Deadline for responses from BFS members
4 th September 2012	Workshop for BFS members held in Newcastle
25 th September 2012	Draft response circulated to BFS Executive
27 th September 2012	Session at BFS Senior Staff Conference
28 th September 2012	Response submitted to DH

Response 102 – Association of Medical Research Charities

Key points:

Any changes to the current system should be made with a view to streamlining the experience of conducting research, ensuring regulation is proportionate and effective and with public safety central to benefit patients. The eventual aim should be for researchers to experience a one-stop-shop when engaging with regulators.

Central to any successful improvements is public confidence. Key characteristics of the regulators which underpin this confidence and must be retained, sufficiently financed and resourced are:

- Expertise in monitoring scientific progress, advising and making regulatory decisions
- Conducting deliberative dialogue supporting policy development
- Transparency of process and a recognised public face

Function first, form second. The required functionality can be delivered by several of the structural options proposed.

- No functions should be moved to organisations that are not fit-for purpose
- Reorganisation should be focused on improving the operation of these regulators.
- A review of functions would be valuable to improve delivery of regulation in areas involving human tissue, gene therapies or human stem cells

The key issues we have raised are shared across the community and should be taken into account, whichever model is adopted.

1. We welcome the opportunity to respond to this consultation. Several of our members have also responded individually.

2. The Association of Medical Research Charities (AMRC) is a membership organisation of the leading medical and health research charities in the UK. AMRC has 125 member charities that together invested over £1 billion into UK research in 2011/12, equating to approximately one third of all public expenditure on medical and health research. Our members are focused on benefiting patients and many have strong patient groups allied to them, they are the voice of these patients and of the 11 million members of the public who expressly choose to support medical research through donations every month.¹

¹ Charities Aid Foundation/NCVO report (2011) *UK Giving 2011* http://www.ncvo-vol.org.uk/sites/default/files/clickable_UK_Giving_2011.pdf

3. Medical research charities invest in research to speed improvements in healthcare for patients. Among our members this includes funding research into new fertility techniques, embryo research and research using human tissue samples. Several of our members fund tissue banks including the Breast Cancer Campaign Tissue bank², Ovarian Cancer Action's BriTROC (British Translational Research Ovarian cancer Collaborative), UK Biobank³ and Parkinson UK's Brain Bank⁴.

4. As a result, our members are concerned to ensure that any transfer of functions of the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) does not adversely impact on the conduct of this research and public confidence in its regulation and conduct.

5. Rather than advocate a specific model, we would like to highlight the key considerations that should be taken into account as a decision is made on whether and how to reorganise the functions of these regulators. These key considerations apply whichever model is chosen.

Streamline the experience of funding research

6. Medical research charities are focused on ensuring their investments bring the maximum benefits to patients. Medical research charities have a responsibility to ensure their investments effectively speed improvements in healthcare for patients and so support streamlining of the regulatory system.

7. The Health Research Authority should become the focal point for advice and guidance on research regulation to provide clarity in the system, connecting researchers with genuine expertise either within or outside the HRA. A single portal or entry point for researchers should be developed to provide an approachable point of contact to facilitate research applications and support researchers in navigating the regulatory process. As the home of the Integrated Research Application System portal, the HRA could build on this to provide further integration of the licensing and approvals process, leading towards a unified approvals system for research projects. Crucial to the success of this is clear and targeted communication to all stakeholders. Any new regulatory model for the functions of the HFEA and HTA should be developed with this ambition at its heart.

8. The HRA could deliver this single portal through several possible structural models.

9. The Academy of Medical Sciences recent review of the regulation and governance of health research in the UK⁵ recommended the establishment of a single Health Research Authority whose responsibilities would include providing specialist approvals and licenses for studies involving human tissue, gene therapies or human stem cells – i.e. the research regulatory functions currently conducted by the HFEA and HTA.

10. However the Academy's recommendations were made on the understanding that the HFEA and HTA were to be abolished. As option 3 proposes a model in which they continue to operate, it would be valuable to review this work to identify whether a transfer of functions or alternative models involving increased joint working and cooperation between regulators under an HRA umbrella might be more valuable. It is important to recognise that the HFEA and HTA have very different regulatory approaches and the consideration of transferring their functions should be separate.

11. The eventual aim should be to develop a system in which researchers experience a one-stop-shop when engaging with regulators. However in the journey to achieving this, maintaining the HFEA and HTA and developing a model of enhanced cooperation with the HRA may deliver more effective and immediate streamlining of the regulatory process, allowing the HRA to develop the required capacity to deliver a single portal and best retaining professional and public confidence throughout this period of

² <http://breastcancertissuebank.org/about-tissue-bank.php>

³ <http://www.ukbiobank.ac.uk/>

⁴ http://www.parkinsons.org.uk/research/parkinsons_brain_bank.aspx

⁵ 2011, *A new pathway for the regulation and governance of health research*, Academy of Medical Sciences <http://www.acmedsci.ac.uk/p99puid209.html>

transition. The priority is the delivery of an ongoing safe, effective and efficient regulatory framework.

12. Whatever structural model is chosen, the opportunity must be taken to streamline the researcher's experience of regulation for studies involving human tissue, gene therapies or human stem cells. It is important to ensure the UK has effective and proportionate regulation in these areas to make this an attractive place to conduct research, bringing economic benefits and speeding medical advances.

Central to any reorganisation is maintaining public confidence

13. The HFEA and the HTA both regulate in ethically sensitive and contentious areas. These regulators are key to public confidence in the handling of human tissue and embryos for research and treatments. To uphold this confidence, the key attributes of these regulators must be retained and supported while delivering a clear, effective and proportionate regulatory pathway.

14. Expertise in monitoring scientific progress, advising and making regulatory decisions

The HFEA and HTA have considerable expertise in the areas they regulate and are supported by independent expert panels to ensure robust, informed decision-making. This open process, gathering external evidence and expertise and ensuring consideration of different perspectives, underpins public confidence in the decisions made.

15. In the areas regulated by the HFEA, new treatments, such as pre-implantation genetic diagnosis, can move from research into treatment very quickly. Treatment decisions over these novel therapies require detailed ethical consideration with outcomes which may be controversial. It is important that any regulator in this area of research and treatment has the expertise and processes to address these issues effectively and authoritatively to ensure public confidence in the decisions made. Should the regulator of research and treatment be separate, steps will need to be taken to ensure coordination between the two regulators.

16. It is important not just for regulators to have access to this expertise but also to clearly communicate this to professionals and the public. An AMRC-INVOLVE workshop held in 2010 to contribute patient perspectives into the Academy's review of the regulation and governance of health research in the UK found that people were cautious about proposals for a single research regulator.

While able to see the rationale for such a move, people expressed concern about the risks of losing the expertise and experience that had been built-up by existing regulatory agencies.⁶

17. As the home of IRAS and NRES and taking on further regulatory functions, the concentration of expertise and access to external expertise within the HRA umbrella provides fertile ground to increase cooperation and sharing of expertise. It is important that any future regulator retains access to existing respected expertise and process and communicates this.

18. Conducting deliberative dialogue supporting policy development

The HFEA plays a key role in policy development – horizon-scanning to identify new ethical questions raised by scientific progress and conducting independent deliberative dialogue and consultations to address these. This process is valuable to ensure public opinion is taken into account as policy is developed, providing an overview of public and expert opinion to inform government and parliament in making decisions over the acceptable balance of new technologies.

19. For medical research charities and the patient groups allied to them, this consultation process provides a valuable route to ensure their voice is heard as policy is developed by government and parliament. This is an important constituency which needs to be heard to inform policy development. For the public

⁶ AMRC INVOLVE, *Patient perspectives on the regulation and governance of medical research*, 2010
http://www.amrc.org.uk/news-policy--debate_consultation-responses_external-consultations-by-topic#healthres

to have confidence in any regulator, it is important that this opportunity to engage in the debate and policy development is maintained.

20. Case study: ***Consultation on whether to license new techniques that could allow women to avoid passing on genetically inherited mitochondrial disease to their children***

Research into mitochondrial replacement techniques during IVF to allow women carrying mitochondrial disease to avoid passing this on their children is currently underway. This is an ethically contentious area as it involves the change of germ line DNA. The Secretary of State for Health asked the HFEA to advise on whether this technique should be made available as a treatment for carriers of mitochondrial disease if the research proves successful. The HFEA has constituted independent expert panels to explore the scientific evidence and is now holding a public consultation, including deliberative dialogue, to explore public opinion and advise the Secretary of State. Should the Secretary of State choose to introduce regulations to allow this technique to be available therapeutically, this evidence will also prove valuable to Parliamentarians as they make a decision over the new regulations.

21. Wherever these regulatory functions are housed, they must be accompanied by the capacity and financial support to conduct these consultative functions. Were there to be greater cohesion between the regulators, this consultative expertise could potentially be available to underpin public confidence in other regulatory areas such as the use of data for research.

22. **Transparency of process and a recognised public face** The HFEA and HTA have a relatively recognisable and well-established public face and 'brand'. They publish detail of the process and content of their regulatory decisions. This external face and international authority underpins public confidence in the handling of human embryos and tissues.

23. Particularly important to this respected public face is the ability of the regulators to offer informed spokespeople to speak to the media⁷. This is supported by dedicated communications teams who are fluent with the sensitive issues that they regulate. This enables them to develop specialist resources designed for the public and media to communicate the complex issues they deal with in an accessible way. This ensures that these issues are accessible, facilitating public discourse and opportunities for the public to have a say as policy is developed and decisions made. This reinforces public confidence in the regulator.

24. Enjoying high recognition and the confidence of researchers is also important for a regulator to be successful. Any regulator must have a research-face, providing clear communication about process, decision-making and opportunities for feedback and review for the researchers applying.

25. It is key to ensure continuity of brand to maintain public confidence. To successfully act as a single-portal for researchers, the HRA must develop its own distinctive brand. Thought must be given to how the HFEA and HTA brands should interact with this. For any of the options proposed these brands should be retained. Regulators must be sufficiently resourced to support and develop communications expertise and supply informed spokespeople capable of speaking authoritatively on the issues they regulate.

Function first, form second. The required functionality can be delivered by several of the structural options proposed.

- **No functions should be moved to organisations that are not fit-for purpose**
- **Reorganisation should be focused on improving the operation of these regulators.**

⁷ For example - Lisa Jardine, Radio 4 Any Questions, Friday 21 September 2012 ⁸ 11 September 2012, Commons Health Select Committee, *Annual Accountability Hearing with the Care Quality Commission*, Dame Jo

26. Effective regulation is vital to ensure the UK remains an attractive place to locate research and retains public confidence. Any reduction in capability and expertise will introduce increased delays to research and risk impacting negatively on public confidence in the regulation of these ethically sensitive areas – something which once lost, is difficult to regain. Improving operation should be the priority in any transference of functions; this should take into account whether the proposed destination bodies are fit for purpose to carry out additional functions.

27. The Care Quality Commission (CQC) There is merit in taking the opportunity to streamline the inspection process for sites already inspected by the CQC. However we are not convinced that the CQC will be in a position to take on the inspection functions of the HFEA and HTA and the necessary public face that must accompany this to maintain public confidence to a sufficient standard by the proposed date of 2015. The CQC itself has expressed concerns over its ability to do so.⁸ If functions are to be transferred in 2015, we would need reassurance that the CQC were ready and able and confident in its own abilities to take on the process of inspection and to develop the necessary public trust and authority to inspire confidence in its regulation.

28. Enabling the HRA to deliver The Health Research Authority is a very new organisation, rapidly expanding to take on functions including the research functions of the NIGB around data. It has been created to remove real, practical barriers to research in the UK through streamlining the regulatory and approvals process and working in partnership with other bodies including the MHRA, NIHR and HTA. We welcome the plan to establish the HRA as a non-departmental public body and develop its capacity as a regulator. These steps will contribute to making the UK a more attractive place to locate research.

29. The HRA would need considerable time and resources to develop the necessary expertise and structures to be able to take on further regulatory functions. Were it to do so, work would be required to ensure it is financially supported and resourced to develop the required expertise and public face to maintain public confidence in regulation. Any migration of functions would need to be clearly communicated to both researchers and the public and delivered alongside a strategy to earn trust and authority in the new organisation.

30. When structural change is made in 2015, consideration should be given to ensure any change does not draw the HRA away from delivering its key functions including supporting NIHR in its efforts to improve research governance in the NHS and to successfully take on the research functions of the NIGB around data which will make a considerable difference to the funding of health research in the UK.

31. Don't break what isn't broken The benefits of streamlining the regulatory process through the HRA are valuable, and functional cohesion in the existing HTA and HFEA must not be lost.

32. There is a high level of functional cohesion in the HTA. The Authority is well-liked by researchers and respected for its clear, proportionate approach. It has developed codes of practice, guidance and advice tailored to the area it regulates and its expert inspectorate plays a valuable advisory role. This valuable expertise, which supports effective, proportionate regulation, must be maintained.

33. Consideration should also be given as to whether separating the regulation of research and non-research functions of the HTA would increase the regulatory burden on establishments. A HTA license is currently required for the storage of tissue for research, not the use itself. Many sectors store tissue for research and non-research functions. A splitting of these functions across regulators must be considered carefully to ensure it does not lead to dual regulation of a single activity.

34. Case study: **Researcher engagement with the Human Tissue Authority** Professor Louise Jones, Barts Cancer Institute at Barts and the London School of Medicine and Dentistry, Breast Pathologist and a co-PI for the Breast Cancer Campaign Tissue Bank:

“Over the years since its creation we have developed a good relationship with the HTA. We have seen seven rounds of inspections, all of which have been very constructive. The inspectors are extremely experienced and their visits allow them to impart their advice and expertise, thereby improving our existing practices. My main concern about any potential change to the HTA, whether it is moved in full to another body like the CQC or its existing functions are divided up between a number of different organisations, is the possible loss of experience and knowledge as a result of this and the negative impact this could have on the research community.

“I am also wary of any separation of the licensing of tissue storage for research from the licensing of tissue storage for other purposes as it is highly likely that this could result in an increased workload and additional cost for those wishing to undertake research using tissue.”

35. The HFEA, although there is room for improvement, has a valuable level of functional cohesion which should be preserved.

36. As streamlining is undertaken, thought should be given to how best to retain and build on current functional cohesion while taking the opportunity to improve on areas where this is not currently delivered.

Whichever option is chosen, efficiencies of cost will be relatively small and should not be the guiding factor

37. Any decision over transfer of functions must be guided by the operational benefits that will be gained, facilitating research and practice for patient benefit, rather than seeking potential efficiencies of cost in the function of the regulators.

38. Creating an effective and proportionate regulator and streamlining the application process for researchers will improve the UK research environment, bringing greater long-term economic and patient benefits than can be garnered through one-off organisational efficiencies.

39. The migration process

Any changes to the regulatory system must be well-communicated to researchers and the public to reduce the impact on research applications and ensure public confidence is maintained. This process should involve all stakeholders and must be given suitable resourcing and time to be effective.

A review of functions would be valuable to improve delivery of regulation in areas involving human tissue, gene therapies or human stem cells

40. A far greater priority than a reorganisation of functions is a review of functions. Change cannot be forced through structural reform. It would be valuable to look at where functions could be rationalised and regulations implemented more effectively, maintaining public confidence but reducing the impact on researchers. This may include considering specific amendments to the existing legislation.

41. A review of the Human Tissue Act would be valuable to ensure a more proportionate approach can be taken to the regulation and governance of the use of human tissue in research; specifically, reviewing the broad scope and application of the Human Tissue Act to materials such as urine, faeces and saliva and its application to tissue from living subjects.

42. The HFEA holds valuable data on the clinical technologies that it regulates. Evidence in this area, particularly in terms of long term safety, is relatively weak when compared to other similar well

established clinical techniques⁹. Steps to improve safe and secure access to this data for researchers would facilitate the development of a stronger evidence-base in this area and should be considered in any review of the HFEA.

The key issues we have raised are shared across the community and should be taken into account, whichever model is adopted.

43. The regulatory system is designed to protect patients and central to its success and ongoing public support for UK research is public confidence that it is delivering this effectively. Effective delivery includes not just protecting public interests and involving the public in the development of regulation but also facilitating research by streamlining regulation.

44. There is consensus across the sector that central to achieving this is the development of a single portal for researchers, reducing duplication and providing researchers with a clear entry point to the regulatory system. Alongside this, work can be done to improve operation so that regulation is delivered proportionately and effectively.

45. However there are a range of structural options which could deliver this single portal and streamline the system. The success of any relies on an evidence-based approach, developing effective cooperation between regulators and, should there be any transfer of functions, ensuring the existing expertise and functional cohesion are properly managed in transition.

46. Any reorganisation should be focused on delivering the key functions outlined in this response and be subject to ongoing review to ensure it is delivering a regulatory environment that facilitates research and practice for public benefit and is responsive to changing patient needs. Getting this right will support UK research, speeding work to improve healthcare and making the UK a more attractive location for research funders.

⁹ Medical Research Council, *Assisted reproduction: a safe, sound future*, 2004
<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002393>

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Response 103 - Infertility Network UK

CONSULTATION QUESTIONS

1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

Infertility Network UK does not agree to this option. The HFEA “brand” is well known across the world and is held up as an example of how to regulate fertility treatment. Patients find the existence of a specific body purely focussing on infertility treatment reassuring to say the least. The HFEA staff has built up a vast amount of experience in the field and of how clinics practice and we are concerned that all that experience would be lost which could cause problems in the future including adverse incidents which could damage the public opinion on fertility treatment which could be catastrophic.

Trying to retain that expertise within the CQC would be more than difficult and lead to additional costs within the CQC. The data held about patients and donors by the HFEA is highly sensitive and confidential and we have concerns that these sensitivities would/could not be addressed. The lack of public confidence in the CQC and the problems it has had also leads us to our response on this question.

As stated in the Impact Assessment, the HFEA have an impact on patients, service users and the public by the services they provide to the clinics, the information they provide, publications they produce and the reassurance they provide. All of this is “under one roof” and one website with incredibly important information for patients – in particular about choosing a clinic and providing their inspection reports etc. and of course important information for those requiring donor treatment and information for those donors. All under the HFEA brand which, as already mentioned, is hugely respected and known.

Overall, we believe that, whilst not perfect, the HFEA has provided a specialist service in what is a complicated field of medicine which provokes widely ranging views – more than in any other field of medicine. It requires specialist attention for that reason.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

As described in response to Q1 above - Patients will not have the same confidence in any body other than the HFEA. If the CQC had problems with carrying on the work of the HFEA, either due to lack of knowledge and experience or of time and inefficiencies, adverse incidents could occur which could be devastating to patients and to clinics as well as being costly.

Currently most people know where to go for information – the HFEA. If its responsibilities disappear in to the CQC this may be lost.

3. Do you agree that HFEA functions relating to research should be transferred to

the HRA? Please explain why you think this. If anything could be moved from the remit of the HFEA elsewhere, it would be this. The workload in this area for the HFEA is minimal compared to their other responsibilities allowing the transfer to be done in a controlled and coordinated manner. The reasons given in the consultation are all good ones which make sense.

3. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

No – we stand by our response to Q1 above.

4. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Infertility Network UK do believe that both the HFEA and the HTA should retain their existing functions apart from their responsibilities in relation to research on which we have replied above which would of course result in less expenditure for the HFEA thus savings.

Furthermore, with the current financial crisis everyone has recognised that mistakes have been made by banks, politicians, governments which have resulted in the current financial crisis leading everyone to look frantically at cost cutting. It would be a false economy to lose the HFEA for the reasons of confidence, expertise etc. already mentioned.

We do not believe that this would result in a risk that the motivation to achieve further savings could be reduced. We believe that, if anything, this exercise as well as the current financial crisis has focussed everyone's minds on making savings – particularly if the organisation is at risk if they don't.

The risk could also be mitigated by the DoH setting targets for savings to be made, how and by when. The Department of Health would need to insist on a complete and thorough review of the services the HFEA provide, what they cost, and where savings will be made – something we are sure they can do. (See also our response to Q5 below)

However, it needs to be recognised that if too many savings were asked to be made it could undermine confidence and safety therefore the need for a total review on the expenditure of the HFEA. It would be foolish to make cuts in order to make savings which may put patients and donors at risk – this should also be borne in mind.

5. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify Savings could be made by separating out the research to the HRA as described in our response to Q3 above. We believe that further efficiencies can be made around the number of inspections; the number of authority members is far too high and can be reduced significantly and we are sure that there are other areas where savings could be made. The review suggested in our response to Q4 would identify where savings could be made and how and then quantify them.

<p>6. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p> <p>As already stated above, we would support moving the research element of the HFEA's functions to the HRA.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>10. Do you have any other comments on the consultation proposals that you would like to share with us? A few workshops with patients and patient bodies would be useful.</p>
<p>11. Can you provide examples of costs and benefits of these proposals?</p>
<p>12. Do you have any comments on the consultation Equality Analysis?</p>

Response 104 - GlaxoSmithKline

1. Summary

- Research using human tissue or human biological samples must be conducted in a manner that respects the rights of research participants and donors and meets legal and ethical obligations. High standards of data and sample management are crucial to making good scientific decisions and delivering high-quality research for public benefit.
- The current division of roles between the Human Tissue Authority (HTA) and the National Research Ethics Service (NRES)¹ creates a complex situation where one authority grants a license to store tissue for research (the HTA), but approval to use that tissue is provided by a separate organisation (NRES).
- In December 2011, NRES became a central component of the new Health Research Authority (HRA). **Our preferred position is for the approval of tissue storage for research to be transferred from the HTA into the HRA.** A situation where the research storage and use of human tissue are overseen by the HRA would support the delivery of clear guidance, promote consistent standards, and simplify the research approval process.
- If the Government opts to retain the HTA (option 3) or transfer all functions into the Care Quality Commission (CQC) (option 1) we hope that steps are taken to deliver an approach that functions as a single pathway. As a minimum this should include publication of joint codes of practice and guidance with the HRA.

2. Introduction

2.1 GlaxoSmithKline is a science-led global healthcare company that researches and develops a broad range of innovative products. We make innovative medicines, vaccine and consumer healthcare products that are used by millions of people around the world, allowing them to do more, feel better and live longer. Headquartered in the UK, we employ over 97,000 people in over 100 countries.

2.2 This response will focus only on the functions of the Human Tissue Authority and will not comment on the future of the Human Fertilisation & Embryology Authority (HFEA). GSK does not conduct any research directly involving human embryos or the derivation of stem cells from embryos and does not have a UK HFEA license. We are involved in external collaborations involving the use of embryonic stem cell lines (and non-embryonic stem cells) for human applications, but none of this work is carried out within the UK.

2.3 Research using human tissue and human biological samples is fundamental to the discovery, development and safety monitoring of GSK medicines and vaccines. We are committed to conducting research in a manner that respects the rights of research participants and meets legal and ethical

¹ As of December 2011, the National Research Ethics Service (NRES) became a central component of the new Health Research Authority (HRA) <http://www.hra.nhs.uk/> .

obligations. The regulation of research using human tissue or human biological samples needs to be underpinned by high standards of sample and data management. Samples need to be collected with respect for the interests of sample donors and managed to high standards to unlock the raw data and deliver high-quality research for public benefit.

2.4 We welcome the stated objectives of the consultation to reform the current regulatory arrangements and deliver functions in a more streamlined manner. While recognising the Government's efforts to ensure cost-effectiveness, we hope that future changes are underpinned not only by cost-savings, but by the stated objectives to:

- Reduce the complexity of the regulatory landscape
- Strengthen the effectiveness of regulation in this area
- Clarify the regulatory landscape for service providers

3. The regulation of human tissue storage and use

3.1 The regulation of human tissue **storage** for research and the research **use** of that tissue are divided between two bodies: the HTA (for collection and storage of tissue) and the National Research Ethics Service (NRES) (use of tissue). This split creates a division where an organisation undertaking research receives a licence to store tissue from one authority, but seeks approval to use that tissue from (and reports research activity to) a separate organisation. Therefore, while the HTA sets standards and inspects the quality of internal systems for tissue storage at a given site², it is NRES that reviews specific research projects.

3.2 The current situation creates a complicated interplay between the roles and functions of the HTA and NRES. The complexity is illustrated by statements from the HTA's own 'Code of practice: research' and statements on the NRES website. For example:

- *"Tissue stored for a specific research project approved by a recognised research ethics committee does not need to be stored under an HTA licence. However, when the approval expires, or no further approval is pending, legally the tissue must be stored under a HTA licence."*
- *"REC-approved banks can provide human tissue to researchers; the recipients of the tissue do not need to store it under an HTA licence during the period of the research project, subject to certain requirements. If the research is not carried out in accordance with these requirements, specific project approval by a recognised research ethics committee will be required or, alternatively, the samples will need to be stored under an HTA licence".*
- *"Under the Human Tissue Act 2004, research in England, Wales and Northern Ireland requires ethical review in certain circumstances: Where the research involves material consisting of or including human cells taken from the living or the deceased (unless it is held on premises with a licence from the Human Tissue Authority to store relevant material for research)."*

² These include for example, standards on governance and quality focus on the establishment's internal systems and processes to support staff in the delivery of high quality output; and the need for documented policies and procedures covering all aspects of activity relating to the storage of human tissue for research, for example, how to obtain consent.

While researchers at GSK are experienced in navigating this arrangement to ensure that all ethical and legal requirements are fully met, the status quo is not in the best interests of efficiency, or the provision of clear and consistent guidance.

3.3 The consultation paper states that the research related activity of the HTA is limited to: “licensing the storage of tissue for the Scheduled Purpose of research”. However, in practice the HTA’s involvement extends further. Research falls with the HTA’s statutory remit and the legal framework it oversees includes consent requirements that apply to the storage and use of tissue. As such, the HTA provides guidance on issues such as what is considered ‘appropriate consent’. While such guidance is of value and well-intended, it overlaps with advice from other organisations, including NRES. The multiplicity of guidance and advice is illustrated by the recommendation from the HTA that their code of practice is read in conjunction with guidance from the General Medical Council³, the Medical Research Council⁴, the National Research Ethics Service, the UK Clinical Research Collaboration, and the National Information Governance Board for Health & Social Care.⁵

Research Tissue Banks

3.4 One area of increasing importance where the work of the HTA and NRES overlaps relates to research tissue banks and the provision of generic ethical approval. Research tissue banks (RTB) are collections of human tissue or other human biological material, for potential research use beyond the life of a specific project. The benefits of these ‘Biobanks’ include maximising the use of samples, in alignment with the original consent by which they were collected.

3.5 The HTA and NRES have agreed a position whereby certain ethics committees can give generic ethical approval for an RTB’s arrangements for collection, storage and release of tissue, provided the tissue in the bank is stored on HTA-licensed premises. ⁶This evidence of joint-working is welcome. However, it also demonstrates the duplicity of the current situation: the RTB being open to inspection by the HTA as well as providing annual reports of activity to the NRES. **There is a clear need to ensure that the ethical review of Research Tissue Banks should be complementary to, rather than duplicate, Human Tissue Authority licensing.**

4 Proposals to transfer the functions of the Human Tissue Authority

4.1 The three options presented in the consultation paper are:

Option 1: transfer all HTA functions to the Care Quality Commission and abolish the HTA.

Option 2: transfer HTA functions to the CQC, with a number of alternatives to move specific HTA functions into other bodies. One stated option is to transfer the licensing of storage of tissue for the specific purpose of research to the Health Research Authority.

Option 3: HTA retain all functions but ‘deliver further efficiencies’.

³ General Medical Council (GMC) [www.gmc-uk.org/guidance/ethical_guidance/index.asp] on the ethical considerations relating to seeking patients’ consent.

⁴ [www.mrc.ac.uk/Newspublications/News/MRC004137]

⁵ <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code9research.cfm>

⁶ <http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/research/faqs.cfm>

4.2 Option 1: It is unclear how transferring the HTA functions into the Care Quality Commission (CQC) will increase efficiency and benefit the HTA or its stakeholders. While we recognise that the CQC would have until 2015 to prepare for the transfer of new functions, there would be concern the CQC could provide the necessary expertise at a time when it is also accommodating other significant functions. In 2010/11, 158 (~25%) of the storage licences granted by the HTA were for research. By comparison, CQC registered 22,000 sites during this period. Were the CQC to inherit the licensing of tissue storage for research there would be concern around the reduced emphasis that research would receive and the CQC's ability to operate as a focal point for the HTA Act and emerging issues in tissue storage and research.

4.3 Option 2: Includes the alternative to “*separate licensing storage of tissue for the specific purpose of research and transfer it to the HRA, and transfer licensing the storage of tissue for other Scheduled Purposes to the CQC*”. As stated in the consultation paper, the HRA was established in 2011 in recognition of an “urgent need to reform research regulation” and “promote simplification and co-operation”.⁷ The HRA's focus on streamlining approvals should not be diluted through added functions that do not pertain to these objectives. However their stated aim to promote consistent standards and streamline research approvals is fully aligned with the prospect of the HRA licensing the storage of tissue for the specific purpose of research. The HRA subsumed the functions of NRES on its conception and **our preferred position is for the licensing for the storage of tissue for research to be transferred from the HTA into the HRA.**

4.4 Option 3: Proposes that “HTA retain their current functions but deliver further efficiencies”. Little indication is provided on how these efficiencies would be achieved and we would be concerned that a reduction in capacity would negatively impact on the ability of the regulator to provide timely and high quality review. Prioritising financial efficiencies may foster an inward focus and reduce the ability of the organisation to identify opportunities to work in collaboration with other regulators and streamline processes. **If the option to retain the HTA is chosen we would encourage a focus on ensuring efficiencies in the approvals process, rather than prioritising financial savings. If the HTA retains the approval of tissue storage for research we would recommend the HTA works with the HRA to deliver an approach that functions as a single pathway. This could be supported by the publication of joint codes of practice and the possibility of discharging the approval of tissue storage for research purposes to the HRA.**

5. Discussion:

5.1 The transfer of licensing of tissue storage for research into the HRA is consistent with the Government's preferred option in 2010: “*We propose that the Human Tissue Authority's regulatory function relating to research could be transferred to a new research regulator... we consider that there could be significant advantage in consolidating the Human Tissue Authority's research regulation with similar functions from*

the Human Fertilisation and Embryology Authority and the National Patient Safety Agency (i.e. the National Research Ethics Service)”.⁸ (Department of Health, 2010).

⁷ <http://www.hra.nhs.uk/>

⁸ http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118053.pdf

5.2 The Academy of Medical Sciences review of research regulation in 2011 also recommended that: the HRA be established as a 'one-stop shop' for specialist approvals and accompanying guidance; and that the HTA research functions should be transferred into the HRA. The adoption by the HRA of the HTA's research roles would not only address the inefficiencies and complexities previously described, it would also align the regulation of tissue research with other related research approvals being undertaken by the HRA. These include the functions of the Ethics & Confidentiality Committee (ECC) which advises on the ethical issues relating to the processing of health information.

5.3 We recognise that transferring the approval of tissue storage for research into the HRA would separate this from the approval of storage for other specified purposes such as public display. One option would be to manage this by ensuring only one licensing event needs to take place per establishment. If the HTA were to take over the approvals for research, it could work with the CQC to provide 'multi-use' storage licenses for those institutions that collect samples for research and other purposes.

5.4 The emphasis should be on streamlining the approval of medical research and finding a solution that supports the provision of clear guidance, delivers public reassurance and ensures clarity across the collection, storage and use of tissue for research. The recent formation of the HRA creates a unique opportunity to deliver efficiency and clarity and we have indicated our preference that the HTA research functions are transferred into the HRA. **If the Government's preferred option is to retain the HTA (option 3) or to place all its functions within the CQC (option 1), we hope that as a minimum: a 'duty to operate' is put in place with the HRA; consideration is given to the possibility of the discharging research functions to the HRA; and joint guidance and codes of practice are developed with the HRA.**

If you have any questions relating to this consultation response please contact: Policy Director, GSK;

Response 105 – Natalie Gamble Associates

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	We are not intrinsically involved in the specific workings of the CQC or HTA to make an assessment if the functions of the HFEA is transferable. However, we have explained in Question 10 the key reasons why the functions of the HFEA ought to continue to be integrated in a single consistent body.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	We are not able quantify what impact this would have except that we understand that this would result in only one inspection for clinics as opposed to two which seems to be an insignificant reason for change in comparison to the other reasons (see question 10)
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	We are not involved enough with the HTA to understand the workings in sufficient depth to comment.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	We are not familiar enough with the specific workings of the HFEA or HTA to evaluate this
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
	Please see answer in question 10.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
	Our understanding is that there have already been savings made and that overall the cost saving anticipated by transferring the HFEA function to the CQC will be only £300,000 per year, which seems small. Whilst efficiency savings ought to be made where possible, we would not advocate seeing the functionality of the HFEA fragmented or reduced if this in any way affected public confidence, the integrity of the register of information or the overarching focus that the HFEA has in the evolving dynamics of families made possible by clinical advancement.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
	We are not familiar enough with the specific workings however, we do understand that there is a duplication of inspections. If there was an effective way of reducing this duplication, then this ought to be reviewed
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?
	We are not in a position to comment.
9.	This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any

views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

See question 10.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Natalie Gamble Associates has assisted hundreds of people building their families through alternative ways (donor conception, surrogacy, IVF, adoption) and as such we are keenly aware that the dynamics are still evolving and changing. The UK is still undergoing a culture change and with that the law is still evolving and indeed there are inconsistencies across society and specifically clinics. This is a global phenomenon as families are being created not just in the UK but also internationally.

There is disparity between the rights different children have to information about their donors. There is also disparity between different couples as to whether they share parenthood status or not. A lot can hinge on what happens at conception.

Known donation is another emerging area, with growing numbers of people conceiving with a known sperm donor, with an expectation of him playing a role in the child's life. The traditional demarcations between fathers and donors are being eroded. The family courts have been striving to develop new concepts and terminology to deal with resulting issues, with a number of key cases over the past year.

Surrogacy is another fast moving area. Now a much more common route to family building for infertile couples, as well as for gay and solo dads, we are in our infancy in handling this. Our law is already outdated, and as a result parents are flocking abroad to jurisdictions like India where there is virtually no regulation of safety or ethics.

We are only just starting to see the possible issues associated with all these new scenarios, and the way we regulate our fertility treatment practices will undoubtedly need to evolve in response. The HFEA does not just regulate clinical facilities, but the whole remit of patient care and safety (and most importantly the welfare of resulting children). To give just a few examples, the HFEA forms signed before conception dictate who the legal parents are; the kind of counselling and information provided by clinics affects people's choices about how they conceive and what they tell their children; the welfare of the child assessment plays a significant role in how patients are treated. Our regulation of these aspects of treatment will need to keep evolving, not just to regulate the treatment processes, but to adapt to growing social diversity.

If this function is to be carried out by someone other than the HFEA, it needs care and appropriate experience of the issues involved and certainly there cannot be a downgrading of the importance of this function which could easily happen if it was subsumed or fragmented.

For those at the coal face, it feels like we are just at the very start, and how clinics deal with increasingly complex families is far from settled – in fact, we've barely started.

Similarly, the HFEA currently has a significant input into development of policy on new and changing ethical issues. Examples include the recent review of payments for donation, and the current public consultation concerning new techniques for treating

mitochondrial disease. This role, which again goes far beyond regulation of mere clinical practice, has long required considerable understanding of both bioethics and cutting edge science. More issues like this are likely to be on the horizon, not least the issue of payments for surrogacy which is begging for a regulatory review.

Register of Information

The Register holds information about all donor conceived children conceived in the UK since 1991. The fact that this information is publicly held and protected is a massive credit to the way things work in the UK.

Whether it is the HFEA or another body which does this, this information must be looked after and protected, and distributed with appropriate sensitivity to those who need to access it.

11. Can you provide examples of costs and benefits of these proposals?

We are not in a position to comment on this.

12. Do you have any comments on the consultation Equality Analysis?

No,

Response 106 - The British Infertility Counselling Association

Who We Are

Founded in 1988, [BICA](#)

- is the only professional association for infertility counsellors and counselling in the UK
- seeks to promote the highest standards of counselling for those considering or undergoing fertility investigations and treatment
- is committed to the total wellbeing of people with fertility problems before, during and after treatment and of those who choose not to undergo any kind of medical intervention
- seeks to develop and influence best practice for the life-long needs of families formed through donation and surrogacy.
- has a membership of approx.170 specialist infertility counsellors and interested parties

Infertility counselling offers patients an opportunity to explore their thoughts, feelings, beliefs and their relationships in order to reach a better understanding of the meaning and implications of any choice of action they may make. Counselling can offer support to patients as they undergo treatment and can help them to accommodate feelings about the outcome of any treatment. It is a key way in which clinics can be assured that the consent, which patients are giving to their treatment choice, is truly informed. Prospective parents have an opportunity to consider the lifelong implications for themselves and the needs of any child conceived through donation or surrogacy.

Administered by an elected Executive Committee, [BICA](#) is financed almost entirely through annual membership subscriptions. The Association is a registered Charity with its own constitution and guidelines for practice.

[BICA](#) achieves and maintains the highest standards of counselling practice through the provision of support, training, setting standards for and monitoring practice. Support is provided through a network of contacts and regional support groups which meet throughout the four nations, provision of a Journal three times a year, annual national Study Days and website forum discussions. Introductory training for new counsellors is complemented by a series of more specialist training on relevant issues throughout each year.

[BICA](#) administers its own Accreditation Scheme – the only scheme to accredit the specialism of infertility counselling in the UK - and arranges for the on-going re-accreditation of its counsellors. [BICA](#) has published a series of Practice Guides for counsellors and monitors standards through auditing practice against a series of quality standards during accreditation, re-accreditation and at HFEA Inspection. Our members must adhere to the BACP Ethical Framework for Good Practice in Counselling and Psychotherapy or another professional Code of Ethics. These processes maintain [BICA](#)'s position as the national and international leader in developing guidance for professional practice in specialist counselling.

[BICA](#) has a presence on a range of infertility related organisations in order to keep updated with developments in the field and contribute to/influence any such developments. We work closely with the HFEA being represented on its Stakeholder's Group and Licensed Centres' Panel.

Drawing as we do on the expertise of experienced counsellors who work directly with patients affected by infertility and assisted conception treatments, we feel competent to contribute to this Consultation.

RESPONSE TO THE DEPARTMENT OF HEALTH CONSULTATION ON PROPOSALS TO TRANSFER FUNCTIONS FROM HFEA AND HTA

PROCESS OF CONSULTATION:

THE RESPONSES IN THIS DOCUMENT REFLECT THE VIEWS OF THE BICA MEMBERSHIP AND THE BICA EXECUTIVE. ALL MEMBERS WERE CONSULTED AND THE EXECUTIVE COLLATED THE MEMBERSHIP RESPONSES TO FORM THIS DOCUMENT. THE CHAIR OF BICA HAS ATTENDED AND CONTRIBUTED TO VARIOUS STAKEHOLDER MEETINGS AND EVENTS SINCE THE GOVERNMENT ANNOUNCED THE PUBLIC BODIES BILL IN ORDER TO GIVE ALL THE PROPOSED OPTIONS DUE CONSIDERATION.

BICA MEMBERS ARE NOT ROUTINELY INVOLVED WITH THE HUMAN TISSUE AUTHORITY OR WITH APPLICATIONS FOR RESEARCH LICENSES AND THEREFORE OUR RESPONSE IS LIMITED TO THE FUTURE OF THE FUNCTIONS OF THE HFEA, EXCLUDING THOSE IN RELATION TO THE LICENSING OF RESEARCH.

This response is submitted on behalf of the British Infertility Counselling Association by the Chair of the BICA Executive Committee:

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Consultation Questions

- 1. Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.**

BICA does not support Option 1.

We consider that the government's aims of reducing bureaucracy, increasing efficiencies and streamlining services can be achieved by retaining the HFEA as an independent body and that the costs associated with transferring the functions could be better spent on reviewing the functions of the HFEA rather than transferring it wholesale into the CQC.

The regulatory overlap between HFEA and CQC is already being addressed as both organisations are working together to reduce the burden of two regulators on licensed centres.

The public currently has no confidence in the CQC as a regulator and both the Public Accounts Committee and National Audit Office have warned of the risks of transferring the functions of the HFEA. Although the difficulties within CQC are not a reason per se to object to the transfer, the risks associated with transfer of complex functions to an organisation already under pressure cannot be under-estimated. The proposed timescale of transfer by 2015 is unrealistic and CQC resources are better used to 'get its own house in order' rather than taking on entirely new functions when the CQC is clearly already stretched.

BICA accepts that the government would intend to transfer expertise with function but the individual decisions of the experts about whether they would wish to transfer to CQC cannot be assumed. The risk of losing expertise is too great to justify the potential savings of approx. £500k per year. The government intends to make savings by not transferring the senior members of staff to CQC. We are concerned about the potential lack of expertise of the Board members and senior management within CQC and the consequent effect on managing the functions of the current HFEA, which the CQC has no experience of, or expertise in, such as the Register of Information. There is a risk of needing to increase the bureaucratic functions at senior level within CQC in order to maintain expertise.

BICA is a UK wide organisation and our membership in Wales, Northern Ireland and Scotland are concerned about the fact that the CQC has no remit in their countries. The consultation document is not clear about what will be the intended situation in these devolved administrations and how reduction of regulatory overlap would be achieved, if at all, outside England.

BICA does not accept the premise that infertility treatments are mainstream and should be regulated together with all other medical treatments. Needing to undergo infertility treatment is anything but 'normal' for patients and the decisions they need to make in the course of trying to resolve their infertility are complex and affect every aspect of their life. BICA accepts that the medical procedures associated with fertility treatment have become routine, but the clinical aspects of fertility treatment are only a part of the HFE Act. The Act takes into account the psychosocial aspects of infertility, together with what we consider to be the public's view of the 'special status of the embryo'. Transferring all the functions that are required under the Act – i.e. not just the functions related to clinical and laboratory practice - to a non-specialist regulator risks dilution of the principles of the Act and fails to take adequate account of the complex issues involved for patients.

The loss of the HFEA 'brand' has been much discussed but cannot be underestimated. For example, although as far as the sector is concerned the HFEA can do better, patients and resulting offspring have confidence that a trusted regulator holds their information securely and confidentially. With the public perception of the CQC at an all time low, it is difficult for professionals working within the sector to have confidence that patient's will not suffer detriment as a result of the transfer.

Regulation of health care is about patients – their safety and welfare. The proposed transfer to CQC is about reducing the number of Arms length bodies, and marginally cutting costs. We consider that the proposals and all the discussions about the proposals focus too much and almost entirely on reducing the burden of regulation for clinics with very little attention given to what if any benefit there would be to patients. BICA has been unable to identify any benefits to patients from the proposed transfer to CQC and can only envisage risks to the services currently provided to patients, risks that we consider to be both unnecessary and undesirable. Focusing on improving the processes within the HFEA is a more coherent and efficient approach to saving money and rationalising regulation with the benefit of not adversely affecting the progress made since it's inception for patients and clinics.

2. Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

There is a risk that the resources – (staff, time and money) needed to carry out the functions of the HFEA will not be ring fenced and could be diverted to meet some greater priority need within CQC reducing the service that the 'infertility directorate' within CQC is able to provide. This could impact on any of the current functions and would be detrimental to patients and service providers.

The benefits of a 'one stop shop' would be lost and there is a potential threat to the relationships that clinics have built up with the teams within the HFEA.

We are concerned about the maintenance and development of current HFEA functions for example in relation to donor conception: there is much work to be done in preparation for the many more donor offspring who will be able to apply for identifying information about their donor in the future from the Register and the services that they will need in order to support them in doing this. Work on this is on going within the HFEA and further development of policy and operational procedures is vital. Diverting attention away from this in order to manage the transfer and assimilation into CQC is a waste of resources and risks progress on many on-going projects slowing down or stopping altogether.

BICA has worked continuously with the HFEA to ensure that counselling provision for patients is fit for purpose and regulated within clinics. Counsellor External Advisers to the HFEA have been appointed to ensure that counselling is provided for patients as stated in the Act. We are concerned that the psychosocial needs of patients which we contend are different to any other area of medicine, will get lost in the drive for streamlined regulation.

The regulation of counselling is yet another new area for CQC. It is a small but important part of the HFEA's current regulatory regime. Transfer of this function to such a large generalist organisation risks losing any focus on the support needs of infertility patients. Some patients experience deep distress and serious life problems as a result of not being fully supported and counselled about the implications of treatment and embryo storage and use.

BICA is concerned that insufficient attention would be paid to unethical practice and non-evidenced based provision of services to ‘improve fertility’ to the vulnerable patient population. There is a risk that the merging of regulatory principles between CQC and HFEA could dilute the dedicated and robust regulation and inspection protocols currently in place and that if inspection of clinics is included in broader inspections of private or NHS establishments, the nuances of the fertility sector may be overlooked. We are further concerned that the welfare of the child considerations enshrined in the Act may not be understood and maintained by a non-specialist regulator.

Although the medicine may be mainstream, the issues for some patients are becoming more complex and the need for a specialist regulator and specialist support services more acute. E.g. with the availability of egg, sperm and ovarian tissue freezing for fertility preservation, the subsequent decisions facing patients considering the use of their gametes and embryos post gamete/embryo freezing are very involved and have potential for life long consequences. Many need support in making these difficult decisions. Further advances in fertility preservation and treatment cannot be currently envisaged and the need for a specialist organisation advising on and implementing policy, setting standards and effectively regulating is essential to ensure that the long-term welfare of patients and offspring is fully taken into account.

Patients, colleagues across many organisations who are affected by these proposals and within DH will already be experiencing the negative consequences of senior staff diverting their time and attention from service delivery and improvement to consideration of these proposals for such a small financial gain. It is BICA’s view that the money and time invested in consideration of these proposals should stop now so that resources can be directed at where they are needed most – reviewing and improving the effectiveness and efficiency of the HFEA for the benefit of patients and the public generally through reducing costs.

3. Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

BICA is unable to comment on this proposal as it is not within our area of expertise.

4. Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?

BICA has been working with other stakeholders to produce recommendations for how the functions relating to donor conception could be carried out in the future. This paper has not yet been endorsed by all the stakeholders, but consultation processes are underway. The draft recommendations are attached in the Appendix to our response.

The function that we consider would sit better elsewhere is that of responding to so called ‘Opening the Register’ requests. In our view, the HFEA has not taken on any duty of care towards individuals who seek genetic origin information from the Register: donors, donor off spring and parents of donor offspring. Although some

front line staff at the HFEA have been trained in counselling skills, we consider that this is not sufficient for dealing with the complex needs of those applying for information. There is already an established post-adoption network with the skills and expertise in intermediary work. We would like to see as a matter of urgency, the 'Opening the Register' function delegated to specialist staff trained in the issues of donor conception sitting within the post-adoption network. Our view is that the HFEA would retain responsibility for the Register and the gathering of the relevant information, but would delegate the dissemination of that information to specialist staff within post-adoption services. As is currently the case with adoption, we would strongly oppose any fee being charged to applicants for this service.

We further consider that overall policy making should stay within the remit of the HFEA, as we would not want to see policy divorced from regulation. However, policy should be developed by specialist advisors and experts convened by the HFEA for their particular area of expertise. BICA has lost confidence in the ability of the Authority members to properly consider important policy issues following the recent decisions made as a result of the Donation Review and how those decisions were made.

5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

Yes. All our members were in favour of retaining the HFEA and could not see any benefit in transferring the functions wholesale or splitting the functions up (apart from the 'Opening the Register' function mentioned in Q4)

We consider that the risks of the fragmentation, proposed in Option 2, are too great in terms of the inter-related nature of the functions. Regulation informs policy and vice versa. The data held on the Register informs Regulation and Regulation ensures that licensed centres comply with data collection requirements.

We consider that the envisaged cost savings of transferring the functions to the CQC are unrealistic given the difference in the remit and operation of the two organisations and that whatever can be achieved by streamlining regulation and inspection within CQC can also be achieved by co-operation between the CQC and the HFEA. We further consider that the necessity of transferring expertise at senior level has not been properly accounted for in considering the cost savings, as without this senior level expertise, the governance of the HFEA functions cannot be robust enough or fit for purpose.

We note the collaboration that is taking place between the HFEA and other agencies in order to reduce the burden of regulation on licensed centres, simplify the process for research applications and introduce further efficiencies in the way the data on the Register is managed.

However, we consider that it is essential to review how the HFEA carries out its functions in order to deliver efficiencies not only in terms of cost, but also in terms of the effectiveness of its delivery of its functions. We would like to see an Authority that is more accountable in

terms of the decisions it makes and the areas of policy it chooses to pursue. We would not support the continuation of the HFEA as it is and consider that maintaining the status quo is not a viable option. BICA, together with the majority of stakeholders that we engage with, firmly believe that there is an opportunity to make significant changes and deliver further efficiencies for example in the areas of data collection and regulatory overlap that would make a real difference to both clinics and patients. We believe that this can take place within the HFEA.

6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.

We note that the HFEA has made significant savings over the past two years and has put in place plans to reduce expenditure further.

The HFEA has already accumulated a surplus of £3.4 million, which as far as we are aware was not reinvested into the HFEA or used for the benefit of infertility patients.

We envisage that the consultation process, the proposed transfer of the functions to the CQC, the decisions and arrangements to be agreed with the devolved authorities and the cost of transitional arrangements will remove more from the public purse than the anticipated savings. That coupled with the cost efficiencies that the HFEA is implementing lead to in our view an overall net benefit to the public purse of retaining the HFEA.

7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

Please see our response to Q4 above. We consider that the only function that should transfer elsewhere is the service provided to applicants for information from the Register.

8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

We consider that the costs of transferring the functions of the HFEA are understated. The entirely unnecessary, in our view, rebranding of the fertility regulator has some hidden cost implications, which are difficult to quantify at this stage and therefore inevitably have not been included in the impact assessment. These include expenditure on changing the 'small stuff' such as the HFEA logo on just about everything, the website, forms, public information etc. This together with the civil service, management and staff time spent on discussions, reaching agreement and transferring of expertise will we believe amount to significantly smaller savings than are envisaged.

There is considerable ambiguity in any savings envisaged for the fertility sector itself and thus no discernable cost benefit that could be passed onto patients. We note that there is no intention to reduce license fees for example. We agree that during the transition, there will be additional costs for the affected regulated organisations in familiarising themselves with the new regulatory regime.

As stated above, we also believe that the savings envisaged by not transferring senior staff may be realised in the short term i.e. by redundancies of the current post holders, but we consider that loss of all this expertise at the top of the organisation is ill-advised and that expertise will need to be brought in to continue to oversee the HFEA functions within the CQC. It is clear that the CQC after taking action to remedy its current shortcomings has the expertise to govern the regulatory functions, but not we would argue, the whole remit of the HFEA as specified in the HFE Act.

Concern has also been expressed by our members that the full financial and resource implications of dealing with the devolved administrations in the other nations of the UK has been fully accounted for in the proposals to transfer the HFEA's functions. The CPC, HRA and HSCIC have remits for England only – links with the administrations within Northern Ireland, Scotland and Wales will need to be made. These Nations have their own data collection/regulation agencies, which may need to re-align, change or develop to accommodate the proposed changes. The number of clinics in each of these nations should be considered in relation to the expenditure involved.

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

We have stated that the functions related to donor conception treatments must be reviewed and that some of this function could be carried out elsewhere – see draft recommendations in the Appendix to this response.

We are very concerned that the support given to patients considering and undergoing fertility treatments in the future will be compromised if regulation of the sector is diluted in any way. There is a statutory obligation to offer counselling to patients in a variety of circumstances and in order to protect patient's interests and also safeguard the welfare of resulting children, we would seek to have this requirement strengthened and would continue to engage with the regulator to ensure that patient's emotional needs are taken account of. Fertility patients can be very vulnerable and susceptible to any suggestions made about how they can increase their likelihood of having a family. Infertility counsellors in clinics not only provide counselling to patients, but also as part of the multi-disciplinary team, can help steer clinic policies and procedures in more ethical directions. BICA has collaborated with the HFEA to ensure that patients' support needs are fully integrated into

regulatory regimes and we are committed to continue this with whichever organisation regulates the fertility sector in the future.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

Transferring the policy function of HFEA to DoH has been proposed. We consider that there are good reasons why policy in this still controversial, complex and continually evolving area is made at 'Arms length' from government – i.e. without the politics of the day influencing ethical and highly charged issues. The HFEA has made some use of experts and the professional bodies and we would like to see this extended so that neither the HFEA on its own nor the DoH can make far-reaching policy decisions without involving specialist advisers. We particularly believe that this should be the case in matters related to donor conception where there are specialists in family and social policy who have expertise in the psychosocial issues pertinent to family formation. We argue that the HFEA should however retain ownership of policy in order to inform the way it regulates and vice versa.

11. Can you provide examples of costs and benefits of these proposals?

No. We do not have sufficient details of costs.

12. Do you have any comments on the consultation Equality Analysis?

We agree with the Equality Analysis that the consultation proposals would not adversely affect minority groups.

We conclude our response with our view that the potential cost savings of abolishing the HFEA do not justify the risks.

APPENDIX

DONOR CONCEPTION

Draft Recommendations for Family Building using Donated Gametes and Embryos in the UK

Recommendation 1: The collection of the data on donors, treatment with donor gametes and live birth outcomes should continue to be a statutory obligation. We suggest that this data should be held on a **dedicated Donor Conception Register** for the whole of the UK, run by a body competent in handling large data sets. For the purposes of this paper this organisation will be referred to as the **Central Register Service. (CRS)** Such a body should also maintain Donor Sibling Link. National quality standards and regulatory regimes for clinics and the Registers should be in place to ensure the quality, safety and sufficiency of the information collected, to include:

- **A Donor Information Form** to be completed by the donor at the clinic in which the donation is taking place, prior to the donated gametes being used in treatment. The Donor Information Form should include a requirement for biographical information. The categories for information collected should be kept under review in the light of emerging research and practice evidence.
- The creation of a **'Child's File'** by clinics comprising the Donor Information Form(s), details of treatment cycle, legal parentage and any other information that the donor(s) wishes to supply. This file should be passed to the CRS following the notification of the child's birth. Clinics should retain a copy for their own records but all requests for information from those affected should be dealt with centrally. Donors who contact clinics post donation to supply updated information should be directed to the CRS. The Clinic's involvement and responsibility ceases once the Child's file has been passed to the CRS.
- The CRS must have robust **systems for collecting and updating information** from donors, offspring, recipients and family members (the latter in the event of mental incapacity or death of the party directly affected) and supplying updated information to existing enquirers. Updated information could include change of address; new medical information; notification of the birth of the donor's own children or further biographical information.
- **The Central Register Service** to be responsible for updating Child files to include non-identifying information about any other children conceived using the same donor(s) and any other new information as it becomes available.
- **The Central Register Service to be responsible for releasing information as appropriate, on application, to a national information release and intermediary service** (see below)

DONOR CONCEPTION

Draft Recommendations for Family Building using Donated Gametes and Embryos in the UK

Recommendation 2: There should be a centrally funded dedicated **UK wide information release and intermediary service**²⁷ through which all enquiries to the Register and Donor Sibling Link are routed. National quality standards and regulation arrangements should be in place to ensure its quality, safety and sufficiency including:

- A ‘triage’ system that assesses the support needs of those seeking information.
- Service provision for all parties affected by donor conception to include: donor-conceived adults; parents of donor-conceived off-spring; donors and families of donors
- Service Provision for parents of donor-conceived offspring to support them in their on-going task of talking to their children about their genetic origin
- Staffing requirements that reflect the need for professional qualifications and experiences in sensitive areas of information release and intermediary work

Recommendation 3: Donor conception treatment services should **continue to be regulated and inspected** but with more emphasis placed on it as a family building approach in clinic’s policies and procedures including:

- Provision of information on the implications of donation and treatment using donated gametes
- Obtaining accurate, appropriate and sufficient donor information
- Mandatory implications counselling (minimum two sessions available) for both donors and recipients before consent is obtained and allowing a suitable time for reflection
- Encouragement of partners to attend pre-treatment/donation implications counselling sessions with the donor/recipient
- Recipients’ involvement in the selection of the donor(s)
- Provision of non-identifying donor information to the recipients of donor gametes before treatment and following successful treatment
- Creation of the ‘Child’s file’

Recommendation 4: The setting of **national quality standards and the development of policy in** relation to donor conception should be undertaken in collaboration with other government departments concerned with family policy across all four nations. Collaboration with the organisation responsible for the regulation and inspection of clinics, the Central Register Service and the information release and intermediary service should also inform policy, with specialist external advisers being brought in when needed. I.e. Standard setting and policy development should not be divorced from the organisations carrying out the other functions in relation to donor conception.

²⁷ Such a service could also incorporate responsibility for the voluntary register for those affected pre 1991

The Department of Health’s Review of the HFEA and HTA

The DH consultation options for transferring the functions of the HFEA and the HTA are:

1. All functions should transfer to the CQC except the HFEA functions relating to research that would pass to the Health Research Authority; and the HFEA and HTA be abolished. (This is the Department of Health’s preferred option)

[SEP]

2. All functions should transfer, as set out above, but a limited number of functions would transfer to organisations other than the CQC.

3. The HFEA and HTA should retain their functions but deliver further savings. The proposals within the consultation document about where the functions of the HFEA could be carried out in the future do not, in our view adequately address what is urgently required to be in place for people affected by donor conception as recommended in this paper.

Two models outlining how the HFEA functions in relation to donor conception could be managed in the future are set out below:

Function	Model 1	Model 2
Central Donor Conception Register Service	HFEA	The Health and Social Care Information Centre
Regulation and Inspection	HFEA	Care Quality Commission or HFEA
Policy and Standard Setting	Specialist external advisers working with the HFEA in collaboration with Family Policy Units within government departments	Specialist external advisers working with the Department of Health in collaboration with Family Policy Units within government departments
National Information Release and Intermediary Service for adults affected by donor-conception	Specialist staff within Post-Adoption Services, nationally co-ordinated	Specialist staff within Post-Adoption Services, nationally co-ordinated

Even if the status quo is maintained – i.e. the HFEA retaining all its functions, there is a need for Government (through delegation to appropriate authorities and advisers) to take on the responsibility for both reviewing the current service provision and providing the appropriate services

for people affected by the donor conception route to family building. The Government takes on this responsibility and the associated financial implications as far as adoption is concerned and it is argued that it now needs to also ensure and finance the appropriate provision of services to adults affected by donor conception.

DONOR CONCEPTION

Draft Recommendations for Family Building using Donated Gametes and Embryos in the UK

In terms of cost implications, it is argued that the costs associated with transferring the functions relating to donor conception from the HFEA could be better used to set up the services identified by this paper. There is also little discernable advantage in splitting up the functions – apart from hiving off the specialist expertise required by those who seek information from the Register – as in the area of donor conception, all the functions are inter-related and will need to collaborate with each other in order to set and maintain standards and policy in the future.

Response 107 – Scottish Council on Human Bioethics



Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the *United Nations Universal Declaration of Human Rights* which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

Not all questions will be answered.

SCOTTISH COUNCIL ON HUMAN BIOETHICS RESPONSE

The SCHB agrees with the following objectives of the proposed reforms

- **Reducing complexity of the regulatory landscape.** Over the years, the number of arm's-length bodies has grown and their roles adapted to meet changing needs. With the creation of Care Quality Commission and the advent of the Health Research Authority, there is scope to simplify and streamline the institutional landscape and improve efficiencies
- **Strengthening the effectiveness of regulation in this area.** Effective enforcement of the law in these areas is paramount to ensure public confidence and protect health and safety
- **Clarifying the regulatory landscape for service providers.** A reduction in the total number of regulatory bodies provides an opportunity for the regulators that remain to clarify their roles with providers and where possible reduce the regulatory burden on providers.

Concerns relating to HFEA functions

The SCHB notes that Biomedical Research is a devolved matter for the Scottish Parliament and thus, is very uncertain how the proposed future responsibility of the **Health Research Authority** will affect Scotland especially if it takes some of the responsibilities from the **Human Fertilisation and Embryology Authority (HFEA)**.

The Scottish Council on Human Bioethics considers that the HFEA regulatory decisions should become more accountable to Parliament. An appropriate parliamentary committee, such as the Science and Technology Committee of the House of Commons, should be able to closely monitor any regulatory decisions of the HFEA and intervene if it feels that a particular issue requires wider discussion and consideration.

The SCHB is of the opinion that the current HFEA does not adequately regulate (and seems to slavishly support, without serious ethical consideration) new scientific research involving embryos with no adequate weight being given to other views and considerations.

In this respect, the SCHB notes that the absence of any minority reports often gives the impression of a unanimous decision. This suggests that the composition of the HFEA does not adequately reflect the wide spectrum of views within society. Indeed, it would appear that the 18 members of the HFEA are selectively appointed to only represent certain views and that they have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

The SCHB notes that many in the UK have lost all confidence in the HFEA and that it has not made any effort, in its past 20 years of existence, to include in its membership persons who disagree with the use of embryos for destructive research. As a result, the HFEA has decided to ignore the views of up to a quarter of the UK population. In any future committee, the composition of representatives reflecting different sections of society and worldviews should be decided beforehand as is done with the French National Consultative Ethics Committee.

New solutions should be considered to enable the general public to become better informed and more engaged in decision-making relating to what should be acceptable. In other words, a body, such as the HFEA, should undertake sufficient and appropriate consultations with the general public. Moreover, the Houses of Lords and Commons, as the bodies representing the UK members of society, should be more involved in the decisions of the HFEA. Any future body replacing the HFEA should have powers to deal with the question of parliamentary involvement.

Concerning the dual role of the HFEA relating to its licensing and regulatory powers, the SCHB is of the opinion that the licensing and inspection responsibilities should remain the remit of the HFEA but that the regulation of any new biological or reproductive possibilities should take place under whatever new regulatory body is established in collaboration between the experts in the different fields, the general public and the democratic representatives of Parliament.

Consultation on Proposals to Transfer Functions from the Human Fertilisation & Embryology Authority and the Human Tissue Authority

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
5.	Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.
6.	Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify.
7.	Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?
8.	Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?

9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

10. Do you have any other comments on the consultation proposals that you would like to share with us?

RESPONSE –

The SCHB notes that many of the changes proposed do not take appropriate consideration of the different aspects of regulation in Scotland nor the possible outcome of the 2014 referendum on Scottish independence.

The SCHB is unclear which bodies will continue to organise public consultations on any new developments in applications such as new proposed fertility treatments.

Concerns relating to tissue collections

At present, in Scotland, it is practically impossible to know (1) how many human tissue collections actually exist, (2) where they are situated and (3) who is responsible for them. Thus, it may be extremely difficult for members of the general public, who have donated some of their material, to contact all the human material collections which have stored their tissue over the years if they are concerned about its use.

Because of this challenging situation, the Chief Scientist Office in Scotland is seeking to set up four research based tissue banks through the Scottish Academic Health Sciences Collaboration. These will be open to researchers so that they can access the tissue they need for their studies. In the future, and since these banks will be monitored to HTA standards (but without the suggested expensive regulation at force in the rest of the UK) and have research ethics approval, it would not make sense, according to the Chief Scientist Office, for researchers to obtain tissue from elsewhere²⁸.

However, all the old collections banked outwith these four centres will only be encouraged to transfer their tissue. This will not be compulsory since there is no statutory basis for such a requirement. These banks will also have the option to become accredited, but they will have to bear the costs themselves so it is unlikely they will do so²⁹. Moreover, because the collection of human material does not have any statutory setting in Scotland, any legal action would have to occur through the civil courts, since the issue would be a matter of 'breach of best practice', rather than a 'breach of the law' that would allow action in a criminal court.

With respect to the possibility for members of the general public being able to write to the four new tissue banks to (1) ask if they have tissue of theirs being stored (whether or not it is linked anonymised), (2) withdraw their consent or (3) ask for their tissue to be destroyed, it is not yet clear how this will be possible in Scotland. Indeed, the exact roles of each tissue bank are still to be agreed in these four centres.

Theoretically, the human tissue banks should be able to address these enquiries from the tissue donors though they may not yet have a mechanism in place to do so.

In Scotland, there is no equivalent to the **Human Tissue Authority** for research purposes and there is, therefore, no regulation through the licensing system that exists in the rest of the UK. Thus, it is very difficult to ascertain the exact number of tissue banks in the country.

More Parliamentary regulation in Scotland regarding human tissue collection is necessary.

²⁸ Information received by the Scottish Council on Human Bioethics from the Chief Scientist Office on the 16th of September 2009.

²⁹ Information received by the Scottish Council on Human Bioethics from the Chief Scientist Office on the 16th of September 2009.

11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?

Response 108 – British Neuroscience Association

Below is a statement from the British Neuroscience Association in response to the Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority. We are not in a position to answer most of the questions in your questionnaire, but we hope this statement will be useful to you.

CONSULTATION BY THE DEPARTMENT OF HEALTH ON THE FUTURE OF THE HUMAN TISSUE AUTHORITY

The British Neuroscience Association has considered the Department of Health's consultation on the future of the Human Tissue Authority (HTA) and is of the opinion that it needs to remain an independent organisation. The HTA manages, monitors and regulates the use of tissue for research, medical treatment, post-mortem examination, teaching and display in public. Of particular interest to the BNA is the donation, storage and subsequent use of brains and central nervous system tissue for research and therapy. It could be argued that of all organs that are donated, the brain is the organ that requires handling of the utmost sensitivity.

The changes being proposed in the consultation document seem to create costly and cumbersome processes, and inevitably bring with them the risk of misinterpretation by transferring all or some of the HTA's responsibilities to other bodies.

The HTA should continue to collaborate closely with similar organisations, and those with a related remit, taking a leading role in best practice for the benefit of the public, the medical professions and the scientific community whose respect and support the HTA deserves.

The HTA has strongly expressed the preference for Option 3 that maintains the HTA's function, whilst endeavouring to deliver greater efficiency. The BNA endorses the HTA's view due to its unique expertise in this highly specialised field.

Response 109 – University Research Ethics Committee – University of the West of England - Individual

CONSULTATION QUESTIONS	
1.	Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.
	The assumption underlying this option is that most organisations regulated by HFEA and HTA are also already regulated by CQC. This is not the case for universities who conduct research using human tissues. So the requirement to obtain a licence for research from CQC will create a new regulatory relationship for those researchers in this sector.
2.	Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?
	See above – the assumed model here is that the proposals affect only service providers and patients – other groups need to be considered. For example, human tissue research may involve the tissues of other non patient groups – eg ‘healthy volunteers’. HEI researchers are not service providers or patients.
3.	Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.
	If no new research functions are transferred to the HRA it is difficult to see the purpose of its establishment. Having decided already to create the HRA retaining the HFEA and HTA research functions separately (as in Option 3) appears somewhat incoherent and inconsistent with the earlier policy decision. In HE institutions which hold human tissue licences but also carry out embryo research, they will continue to need to relate to two separate regulatory bodies – CQC and HRA under these arrangements. The potential benefits of option 1 and 2 are therefore harder to assess.
4.	Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?
	The interface between HTA and MHRA has caused considerable confusion and frustration for researchers in the stem cell field. However this relates in part to the regulatory regime and legislative framework. The dual role of HFEA and HTA as competent authorities for implementation of the EU Directive on Human Tissues and Cells for therapeutic application is a peculiarly national characteristic which doesn’t mirror arrangements elsewhere in Europe. What is striking in the consultation document is the lack of any attempt to make international comparisons. The international legislative framework for regulation in the area of human tissues and

<p>embryos is distinctive from the existing work of CQC and HRA and fits more with the work of MHRA with respect to therapeutic products. The need for continuing engagement with international regulatory agencies in this field may be worth considering further.</p>
<p>5. Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.</p>
<p>The longer established relationships between these regulatory agencies and HE institutions may be the basis of further efficiencies. It isn't clear what kind of support or guidance CQC might offer HE institutions.</p>
<p>6. Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify</p>
<p>No comment</p>
<p>7. Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?</p>
<p>If they were retained it makes little sense to fragment and dismember them unless there are clear benefits for so doing. No such benefits are evident from the consultation paper.</p>
<p>8. Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?</p>
<p>No</p>
<p>9. This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.</p>
<p>The HTA has worked closely with others on developing education and training for staff working in the different sectors and the HFEA also has a long history of educational and public engagement activities. If their responsibilities and functions were to be transferred, the need for continuing support, education, training and public engagement activities should be given a high priority alongside the inspection and enforcement aspects of regulation. CQC and HRA will need to find effective ways to engage with those working within HEI's rather than being entirely focused on NHS and social care organisations.</p>

10. Do you have any other comments on the consultation proposals that you would like to share with us?
11. Can you provide examples of costs and benefits of these proposals?
12. Do you have any comments on the consultation Equality Analysis?