Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

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Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

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Contents

Executive Summary

1. The Coalition Government made a commitment in its programme for Government to cut the number of health arm's-length bodies and reduce bureaucracy significantly. In line with this, in *Liberating the NHS: Report of the arm's-length bodies review* (July 2010), the Department of Health (DH) set out its intention to reduce radically the number of NHS bodies and DH arm's-length bodies.

2. In *Liberating the NHS* the Department also set out proposals to retain the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) in the short term and transfer their functions to other bodies by 2015.

3. The consultation on the proposals to transfer functions from the HFEA and the HTA took place between 28th June 1012 and 28th September 2012 and set out 3 options as follows:

    - Option 1 proposed that all functions of the HFEA and the HTA transfer to the Care Quality Commission (CQC) with the exception of HFEA research-related functions that would transfer to the Health Research Authority (HRA); and the HFEA and the HTA be abolished. This was the Government's preferred option;
    - Option 2 proposed a transfer of functions and abolition as for Option 1 but also proposed that a limited number of functions might transfer elsewhere;
    - Option 3 proposed that the HFEA and the HTA retain their functions but deliver further efficiencies.

4. The consultation was launched with a Written Ministerial Statement. It was published on the DH website accompanied by a Press Release and advertised in *The Week* which goes to NHS organisations. It was sent to around 350 organisations, representative bodies and individuals across the UK. A DH workshop was held for almost 40 stakeholder organisations and views were sought from stakeholders and experts in the field throughout the consultation. Respondents returned a response form either electronically or by post.

5. A total of 109 responses were received, the vast majority being from organisations rather than individuals. They were split evenly between those stakeholders whose primary interest was in respect of either the HFEA or the HTA (over one third of responses for each organisation) with the remainder of respondents expressing an interest in both organisations.

6. In analysing the responses, we have also been mindful of the fact that the consultation has its origins in the need to take stock of existing regulation across the wider ALB sector to see how a reduction in bureaucracy and in the regulatory burden might be achieved. We have, therefore, been careful to balance the views of those who may have been commenting on only one organisation with the need to look across the wider landscape. Thus for the purposes of this consultation reference is often made to both bodies together to help ensure this wider perspective is achieved.

7. The Department heard from all four main bodies directly affected by the proposals (HFEA, HTA, CQC and the HRA). It also heard from key organisations such as the British Medical Association (BMA), the British Fertility Society (BFS), the Academy of Medical Sciences (AMS), the Wellcome Trust and a number of Royal Colleges as well as private sector organisations.

8. This response provides a summary of the key messages and themes arising from the consultation responses and a detailed analysis of what respondents said in respect of each individual question.

9. Overall, the majority of respondents (75%) disagreed with the proposal to transfer the functions of the HFEA and the HTA to the CQC and the HRA. This included a number of key organisations and the main regulators (HFEA and HTA). Some 8% agreed with this option, one of which was the BFS. An additional 8.5% thought this option might be possible and a similar number either didn't know whether they agreed or didn't comment on the proposal.

10. Respondents cited a number of reasons for not transferring functions, primary of which was that the HFEA and the HTA have developed considerable expertise in highly specialised fields. They were said to be trusted and respected by the regulated sectors and respondents believed this would be lost should a transfer of functions take place. In respect of research-related functions in particular, respondents recognised that the HRA was an important development in achieving streamlining of regulation and governance in health research and that building and maintaining close working links with the regulators would be a crucial element in helping to realise that.

11. Almost half of respondents also said that the HFEA and the HTA should be retained as they believe that the CQC is not well placed currently to take on the functions, and HTA and HFEA functions would be subsumed by CQC's other responsibilities. It was felt that the consequence of this would be a loss of public confidence, a decrease in the quality of regulation and disruption to business.

12. Whilst there was significant support for retaining the bodies and achieving further efficiencies, around a quarter of respondents also gave a clear message of the need for a review of the way the bodies undertake their functions.

13. Half of respondents commented on the consultation impact assessment. The overall message was that the anticipated savings did not merit the risks associated with the proposed transfers and that too little regard had been given to transition costs. Very few respondents commented on the consultation Equality Analysis but the importance of reducing the impact on staff was stressed by those who did.

14. The range of respondents contributing to this consultation, from a variety of backgrounds, has given us confidence that our response takes account of the views of those who have a deep understanding of the issues involved whether that is at a personal level, a practical level, a business level or a strategic level.

15. In drawing conclusions, we have taken careful account of the qualitative evidence from the responses and have not relied solely on numbers expressing a preference for one option over another. We also recognise the considerable body of opinion (the majority) opposed to a transfer of functions from the HFEA and the HTA to the CQC and the HRA. We carefully balanced this with the views of those in favour of a transfer, such as the BFS.

16. We paid careful attention to how those who said that the two bodies should be retained (but also deliver further efficiencies) expressed their views. Many respondents do not regard a decision to retain the bodies as an argument for maintaining the 'status quo' but see the need for review of how the bodies undertake their functions.

17. Regardless of the option favoured, there was a range of strongly expressed views about the need for a review, and this has been a significant element in forming our conclusion.

18. We have decided, on balance, that we will not pursue a transfer of functions at this time. The HFEA and HTA will therefore remain as separate statutory bodies but with the introduction of further efficiencies. To this end, the Department will arrange an immediate review of how the two bodies carry out their regulatory functions, with a view to reducing regulatory burden. The review will give serious consideration to the merger of the HFEA and HTA. The Department will also include the two bodies in its Shared Services programme with a view to streamlining their non-specialist functions.

19. The Department wishes to thank all those who commented on the consultation.

Introduction

20. The Coalition Government made a commitment in its programme for Government[1] (May 2010) to cut the number of health arm's-length bodies and to reduce bureaucracy significantly.

21. In *Liberating the NHS: Report of the arm's-length bodies review*[2] (July 2010), DH set out its intention to simplify and reduce radically the number of NHS bodies including DH's arm's-length bodies. The Department also set out its proposals to retain the HFEA and the HTA as separate arm's-length bodies in the short term, with a view to transferring their functions to other bodies by 2015. Since that review, and before we consulted, we received significant representations asking us to consider retaining the two bodies, or, if we do transfer functions, to keep those bodies' functions together as much as possible.

22. It was in this context that the Government launched a 13-week *Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority*[3] on 28 June 2012. We consulted on proposed reforms, covering the UK, with the objectives of:

    - reducing the complexity of the regulatory landscape – acknowledging that with the creation of the CQC and the advent of the HRA there is scope to simplify and streamline the institutional landscape and improve efficiencies

    - strengthening the effectiveness of regulation in this area – recognising that effective regulation enforcement is paramount to ensure public confidence and protect health and safety

    - clarifying the regulatory landscape for service providers – considering 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.

23. The proposals in the consultation document were:

[1] The Coalition : our programme for Government
http://www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_187876.pdf

[2] Department of Health, *Liberating the NHS: Report of the arm's length bodies review*.. July 2010
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_118053.pdf

[3] Department of Health, *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/Consultation-on-proposals-to-transfer-functions-from-the-Human-Fertilisation-and-Embryology-Authority-and-the-Human-Tissue-A.pdf

Option 1 (preferred option):

Transfer all HFEA and HTA functions to the CQC with the exception of HFEA functions relating to research that will transfer to the HRA; and abolish the HFEA and HTA

Option 2

Transfer all HFEA and HTA functions to the 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 the HTA

Option 3

The HFEA and HTA retain their functions but deliver further efficiencies

24. The consultation exercise was run in accordance with the Government's Code of Practice on Consultation in place at that time (Annex A).

How we consulted and raised awareness

25. The consultation was launched with a Written Ministerial Statement, a press release and an announcement on the DH website[4]. We also included details in *The Week* that goes to NHS organisations. We sent the consultation document to around 350 organisations, representative bodies and individuals across the UK, with interests across the board and also attended meetings with stakeholder groups to talk about the proposals. We asked respondents to fill in a questionnaire response form and return it either electronically or by post to the Department. A detailed analysis of responses is at Annex B. A list of respondents is at Annex C.

26. We sought the views of stakeholders and experts in the field throughout the consultation period, in order to ensure that a wide range of views was captured. This included the Department taking part as an invited speaker in a public debate held by Progress Educational Trust on 11th September 2012. It also included the Department holding a workshop for around 40 key stakeholder organisations on 19 September 2012. The aim of the workshop was to enable participants to explore in depth, and in discussion with other stakeholders, the potential of each of the three options set out in the consultation document with a view to this helping them to develop their own written responses to the consultation.

27. A summary of some of the key points that emerged from that day is at Annex D.

Number and range of responses

[4] http://www.dh.gov.uk/health/2012/06/consultation-regulators/

28. We received 109 responses to the consultation. The Department wishes to thank all who responded to the consultation and attended the workshop.

29. Table 1 summarises respondents by type of body and shows those who commented specifically on either the HFEA or the HTA and those who have responded on both.

30. Our consultation and this response takes a broad view across the regulatory landscape encompassing a number of regulators. A key aim was to look at how that landscape might be simplified, how bureaucracy might be reduced and how we could eliminate parallel running of regulators to reduce the burden of regulation overall. We acknowledge in this analysis where respondents express views from their experience in one sector only. However, to provide an overall picture across this area of regulation we have, in this response, largely dealt with the HFEA and the HTA together.

31. We re-iterate that the safeguards in the Human Fertilisation and Embryology Act 1990 (as amended), the Human Fertilisation and Embryology Act 2008, the Human Tissue Act 2004, and associated legislation, for instance around quality and ethical provisions, would remain in place regardless of any transfer of functions.

Respondents by type and by which organisation they are commenting on

TABLE 1

Type of Body	***Responding on***				
	HFEA only	*HTA only*	*Both HFEA and HTA*	*Total*	*%*
Advisory body	0	1	0	1	1
Healthcare provider - NHS	6	4	6	16	15
Healthcare provider - independent	1	3	2	6	6
Individual	6	4	1	11	10
Membership organisation	18	14	11	43	39
Other	1	4	1	6	6
Regulatory body	1	2	2	5	4
Research body	2	2	3	7	6
University	4	6	4	14	13
Total	**39**	**40**	**30**	**109**	**100**

32. Responses were evenly split between those stakeholders whose primary interest was with the HFEA or the HTA (over one third of responses for each organisation) with the remainder of respondents expressing an interest in both organisations. Membership organisations, regulatory bodies and research bodies account for half of all responses made.

33. The respondents included all four main bodies directly affected by the proposals (the HFEA, HTA, CQC and HRA), other key organisations such as a number of the Royal Colleges (Obstetricians & Gynaecologists, Surgeons, Pathologists, Physicians and Nursing) the BMA, the Wellcome Trust, the Medical Research Council (MRC), the BFS, the AMS and the Association of Medical Research Charities (AMRC).

Key Messages and Themes Arising

34. A summary of the key findings from the analysis of responses is set out in this section. Further detailed analysis of the individual questions is at Annex B.

35. The majority of respondents (three quarters) disagreed with the option of transferring the HFEA and HTA functions to the CQC and HRA. These include the BMA, the Royal College of Surgeons (RCS), the Royal College of Nursing (RCN), Infertility Network UK, the Wellcome Trust, the BioIndustry Association, the British Transplantation Society (which represents over 800 people across the range of disciplines involved in transplantation) and the Church of England.

36. One common – and strongly expressed – reason for not transferring functions was that the HFEA and HTA have developed considerable expertise in highly specialised fields and are trusted and respected by the regulated sectors (over half of all respondents covered this theme). Respondents believe there is a high risk of this being lost should a transfer of functions take place.

37. Almost half of respondents also said that the HFEA and the HTA should be retained as they believe that the CQC is not currently well placed to take on the functions; and that HTA and HFEA functions would be subsumed by CQC's other responsibilities. It was felt that the consequence of this would be a loss of public confidence, a decrease in the quality of regulation and disruption to business.

'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.'
(Consultant Embryologist and Andrologist)

'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 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.' (a Human Tissue Working Group)

38. Over three fifths of respondents expressed the view that the current regulators were working well and they saw no reason to abolish either or both organisations.

'…….. 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. (Royal College of Surgeons)

Our view is that both regulators ……..are best placed to continue as statutory regulators for each sector. (PHG Foundation)

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.' (GE Healthcare)

39. Very few respondents (8%) agreed with the transfer to CQC and the HRA and these tended to be individuals rather than organisations. However, one organisation that did agree with transfer to the CQC was a key HFEA stakeholder, the BFS, which represents a large number of fertility clinicians, nurses, scientists and others who work in the field. The main reason for their support for transfer was that in their view IVF no longer requires specialist regulation – the BFS considers it a mainstream medical procedure; they also believe that regulatory overlap could be reduced.

'There are no compelling reasons to continue to regulate IVF as a distinct category of treatment, and some serious downsides to doing so……there are clear synergies between the CQC and the HFEA on regulatory and licensing functions.' (British Fertility Society)

40. Furthermore, the BFS believes that there are disadvantages to the separate regulation of IVF. BFS members recognise that the focus of the CQC and the HFEA is different but thinks there is considerable crossover.

'…… 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.' (British Fertility Society)

41. Focussing on HFEA functions relating to research, around a quarter of respondents thought that these should, or possibly should, be transferred to the HRA and around the same number did not agree with such a transfer. Almost half of respondents did not make any comment in relation to the possible transfer of HFEA research related functions.

42. Where there was support for transfer to the HRA, one of the reasons given was that the establishment of the HRA was seen as beneficial to the 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.'(The Institute of Biomedical Science).

43. Even where respondents did not support a transfer, they nevertheless saw the HRA as an important development in achieving streamlining of regulation and governance in health research. However, some felt that the HRA had not, as yet, developed the necessary expertise:

'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.' (Academy of Medical Sciences)

whilst others did not see the benefit in splitting regulation and research.

44. Around one fifth of respondents said that they did not accept that the transfer would generate savings. Rather, many believed the costs of transfer would outweigh any savings; and others believed that the inevitable disruption to service delivery was not worth the likely small savings (if any).

'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 numerous organisations that operate within the regulated sectors…….. there is 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……..' (A Human Tissue Act Committee, Foundation Trust)

45. In line with messages we had received prior to consultation, many respondents were concerned about the detrimental effect of fragmentation if the HFEA and HTA's functions were transferred to a range of bodies. The HTA itself stated:

'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.' (Human Tissue Authority)

46. The AMS and the AMRC (amongst others) highlighted the value of the expert, rapid response advice provided to researchers and indicated that the facilitation of a better research environment would produce longer term economic and patient benefits which were considered more important and more cost effective than short term, one-off operational efficiencies.

General overview from HTA respondents

47. Amongst those stakeholders responding only in respect of the HTA, almost all favoured retaining it as a separate regulator. Overall, respondents believed that the HTA had developed considerable expertise in which there was public and professional confidence. Responses also indicated that the HTA was viewed as an efficient and effective regulator providing a timely and efficient service to the sectors it serves. Most respondents commented on the fact that the HTA had already delivered efficiencies and whilst it was recognised that further efficiencies could be achieved this should not be at the expense of safety or ethical considerations.

General overview from HFEA respondents

48. Amongst those stakeholders responding only in respect of the HFEA, the majority favoured retaining it as a separate regulator although preferences expressed were more varied that for the HTA. Respondents felt, overwhelmingly, that the HFEA provided a valuable source of expertise in a specialised and sensitive area which would be lost if functions were to transfer. Whilst recognising the substantial efficiencies already achieved by the HFEA, many nevertheless called for review of how it carries out its functions to ensure a tighter focus and deliver further savings. Whilst regulatory overlap was acknowledged, the importance of retaining the HFEA 'brand' was cited by many. However, as discussed previously, a major HFEA stakeholder – the BFS – saw integration with the CQC as desirable with considerable benefits for patients.

Efficiencies

49. Both the HFEA and the HTA highlight in their responses, the efficiencies that they have already achieved since the ALB Review was announced.

50. The HFEA has achieved cost efficiencies of 25% and the HTA has achieved cost efficiencies of 27%. Both have reduced the level of staffing and reduced fees to the regulated sector and continue to review their ways of working to achieve further efficiencies.

51. Many respondents, while not wishing to see functions transferred, do want to see further efficiencies introduced. Efficiencies cited covered a range of functions and activities which, in summary, are that the regulatory bodies should:

- continue to develop joint working with other regulators and facilitate greater collaboration between regulatory bodies on accreditation procedures;

- maintain a focus on core legislative duties and ensure avoidance of regulatory/mission creep (this was primarily commented on in relation to the HFEA);

- make greater use of other forms of accreditation, specifically Clinical Pathology Accreditation (CPA) which could possibly replace HFEA and/or HTA inspection in many instances;

- streamline the inspection process (including eliminating duplication of inspection requirements);

- co-operate with one another in order to develop unified approval processes for research to streamline their own research functions;

- introduce a number of management efficiencies including reduction in Chairs and Chief Executives, greater integration of back office/management functions, relocation out of London;

- review of a number of legislative requirements eg the requirement for licensing storage of tissue from living people in the Human Tissue Act 2004.

52. There were some respondents who made a case against seeking further efficiencies. Responses made clear that the sectors recognised the programmes of efficiencies already undertaken by the regulators and the savings those had brought alongside reduction in fee costs to the sectors. Many respondents felt that there was little or no scope for achieving further efficiencies and that a push to achieve cost savings could risk delivery of efficient regulation.

'While delivering savings to the public purse is important, I feel that by far the most important consideration is the effectiveness of these 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.' (Individual, University of Bristol)

53. In its comments on why it disagreed with a transfer of functions, the HFEA itself stated:

'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'. (Human Fertilisation and Embryology Authority).

Independent Review of HFEA/HTA

54. Over a quarter of respondents called for some degree of review. This ranged from calls for DH to commission an independent review of the way in which the HFEA and HTA carry out their functions to reviewing aspects of legislation. Amongst those calling for some form of the above were the AMS, the Association of Clinical Embryologists, the AMRC, the UK Bioindustry Association, the BMA, the MRC,

Royal Colleges (Nursing, Obstetricians & Gynaecologists, Pathologists, Physicians) and the Wellcome Trust.

'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……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?'
(British Medical Association)

'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……. this may include considering specific amendments to the existing regulation.'
(Association of Medical Research Charities)

'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.' (Royal College of Physicians)

55. Nearly two thirds of the calls for change or review came from stakeholders whose primary interest was in the HFEA with the remainder of stakeholders having an interest in both regulators.

56. The need for review of the HFEA itself was articulated by a number of bodies such as the Association of Biomedical Andrologists who said:

'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.'

57. Other HFEA stakeholders were more focussed about the type of change they would wish to see. UK DonorLink said:

'If the HFEA is retained, we would like to see some changes to the Authority's membership.'

whilst an individual response from an NHS consultant with experience in fertility services stated :

'Undoubtedly the inspection process could be simplified and the bureaucracy of the HFEA could be less cumbersome. Data collection needs to be reviewed and there are potential savings.'

58. One individual respondent working in reproductive medicine, whilst supporting the retention of the HFEA, stated that:

'The process of review should involve the professional bodies and stakeholders.'

59. Of the two respondents highlighting the benefit of some sort of review, whose primary interest was in the HTA, the Royal College of Pathologists said:

'……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.'

Geographical Issues

60. Around a fifth (21%) of respondents commented on the fact that the CQC currently exercises functions in relation to England only and extending its reach to the whole of the UK could raise governance issues. Respondents commented that this would place extra demands on the CQC such as building new relationships and liaison with other UK regulatory authorities. For example, the Royal College of Nursing (RCN) noted that the CQC, HRA and the Health and Social Care Information Centre (HSCIC) all cover England only. It said that extending those bodies' remit and establishing processes to work with Devolved Administrations will incur a financial cost and lead to an extra administrative burden.

61. Some respondents felt that there was a lack of clarity in the consultation on the implications of transfer for the devolved nations. The Belfast Health and Social Care Trust said:

'……. further clarity regarding the proposed approach between the CQC and the RQIA[5] within Northern Ireland would be helpful to allow a more robust evaluation of the transfer of regulatory functions.'

and the Human Tissue Authority said:

'It is not clear how a cross-UK solution would be delivered after the transition of functions.'

62. Some felt that a transfer of functions affecting the whole of the UK would be complex. The AMS said that:

[5] Regulation and Quality Improvement Authority; http://www.rqia.org.uk/home/index.cfm

'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 CQC to work closely with existing regulators in the devolved administrations ……..'

and that :

'*…. 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.'*

Conclusions and Next Steps

63. The Department is very grateful to all those who took the time to submit such detailed, considered responses to this consultation. As shown in the key messages above, respondents came from a range of backgrounds; from parents of donor conceived children to clinicians and other healthcare professionals working in the relevant regulated sectors, from small and large charitable organisations, from private businesses, from professional bodies such as the medical Royal Colleges and others. This has given us confidence that we have heard from those who have a deep understanding of the issues involved whether that is at a personal level, a practical level, a business level or a strategic level.

64. This consultation is rooted in the need to take stock of existing regulation across the wider ALB sector to see how a reduction in bureaucracy and in the regulatory burden might be achieved to offer better value to the public, professionals and patients themselves. Thus, in analysing the responses, we have been careful to consider views in the context of the wider landscape and to weigh up the views of those who have perhaps been commenting on only one of the bodies and setting this against the bigger picture.

65. Our conclusions reflect not just the numbers favouring or opposing any one of the options but also the very detailed qualitative points made. We have carefully considered the strength of feelings expressed across a range of critical issues including the ethical aspects of the areas regulated, the importance of retaining public and professional confidence, the impact on staff and the regulated sectors and the practicality and cost of transfer weighed against possible savings.

66. In considering whether or not to proceed with a transfer of functions from the HTA and the HFEA, we recognise that there is a considerable body of opinion opposed to the transfer of functions from the HFEA and HTA to the CQC and the HRA. We recognise that the majority of respondents felt this way. On the other hand, we gave careful thought to the views in favour of a transfer of functions which although fewer in number included organisations such as the British Fertility Society. As a leading multi-disciplinary organisation representing a large number and range of professionals working in the fertility field, the views of the BFS clearly made a significant contribution to the consultation and had to be balanced carefully with those against a transfer.

67. We have also looked carefully at how those who agreed that the two bodies should be retained (but also deliver further efficiencies) expressed their views. The evidence from the consultation responses gives a clear message that, even where respondents favoured retaining the bodies, they did not see this as a reason to maintain the ‘status quo’. Many thought there was a need to review the way both bodies undertake their functions to enable efficiencies to be delivered.

68. The BFS and Parkinson’s UK, leading organisations favouring a transfer of functions, also favour change in how HFEA functions are carried out.

69. In the light of the above, we have decided, on balance, that we will not pursue a transfer of functions at the present time. However, retaining the HFEA and the HTA with further efficiencies must take account of the support for a review of the way in which the two bodies undertake their functions, with a view to reducing the regulatory burden. It must also include a programme of work on achieving efficiencies to deliver streamlining of their non-specialist functions.

Independent Review

70. In line with our conclusion above, the Department will arrange an immediate independent review of the way in which the HFEA and the HTA undertake their regulatory functions.

71. The review will address a range of issues including :

- the scope to streamline the way in which the two bodies undertake their regulatory and statutory functions, including through joint working, sharing resources and information and working more closely with other health sector regulators
- the scope to reduce and rationalise the burden of inspection, information collection and process of research approvals that falls on the regulated sector, without compromising the safeguards in the respective Acts;
- the scope for shared Authority membership and leadership, and of a merger of the two bodies.

72. The review will start immediately and report its findings to Ministers by April 2013. The findings of the review will be published.

Shared Services

73. We intend to undertake an assessment under the DH Shared Services programme of the scope to achieve further efficiencies through functions such as Finance, Human Resources, Audit and Legal Advice being provided elsewhere either through the Department of Health or in the ALB sector. We will also assess the scope for the regulators to move to shared premises.

74. As well as streamlining resources, this approach would enable the HFEA and the HTA to concentrate more on their specialised 'policy' and 'ethical' functions rather than corporate functions.

Streamlining the Department's ALB Sector

75. In our ALB Review, we made a commitment to considerable changes in our established ALB sector, both in terms of Executive non-Departmental Bodies and Special Health Authorities.

76. The Department will deliver this programme, with 8-10 bodies either removed from the sector or significantly reformed and substantial changes to our 31 Advisory non-Departmental Bodies by April 2013. We remain committed to delivering the changes and savings we proposed in July 2010.

Annex A

Code of Practice on Consultation[6]
(July 2008, Department of Business, Innovation and Skills)

Criterion 1: When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2: Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3: Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4: Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5: The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6: Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7: Capacity to consult

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

[6] Now superseded by Cabinet Office guidance on Consultation Principles at:
http://www.cabinetoffice.gov.uk/resource-library/consultation-principles-guidance

Annex B

DETAILED ANALYSIS OF CONSULTATION RESPONSES

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.

TABLE 2

Responding on	*HFEA*	*HTA*	*Both HFEA and HTA*	*Total*	*Percentage*
Agree	5	1	3	9	8
Disagree	27	36	19	82	75
Possibly	6	1	2	9	8.5
Don't know	1	1	0	2	2
No comment	1		6	7	6.5
Total	40	39	30	109	100

77. The majority of respondents (75%) did not agree with this option noting the highly specialised nature of both the HFEA and the HTA functions. Respondents were concerned that the proposal would lead to a loss of expertise, damage to public confidence, and a decrease in the quality of governance and service provision. A number were concerned that CQC was not in position to take on new functions. Some questioned why there was a need to change something that was working well and put forward the view that the risks associated with change appeared to outweigh the benefits.

'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.' (Baroness Ruth Deech, House of Lords)

'HFEA have established what good and best practice is, it ensures compliance and monitors outcomes. They have a specialist role and perform it to a high standard.' (BMI Healthcare Ltd)

' (In relation to CQC) 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.' (All Party Parliamentary Group on Stem Cell Transplantation)

'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.' (Belfast Health and Social Care Trust)

78. 9 respondents supported the transfer of functions from both bodies to the CQC and HRA and a further 9 respondents thought that it was possibly the right thing to do. Of those who supported a transfer of functions, most were responding on behalf of the HFEA or both organisations.

79. One of these was the BFS, a multi-professional group with members across the fertility sector involved in the science and practice of reproductive medicine. The BFS noted that 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.'

80. They made the case for IVF being a routine medical procedure and that CQC would enable it to raise its profile and status alongside other services.

81. Health Ethics and Law at the University of Southampton responded:

'In broad terms, we support the proposed Option 1. We are aware of criticisms that the HFEA is perceived to be unwieldly, expensive and slow.'

82. Parkinson's UK also supported transferring functions from the HFEA expressing a specific interest in the research agenda. It said:

'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 members 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.'

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

83. The majority of HFEA-focused respondents commented on this question. Responses carried on the themes raised in Question 1. Concern was raised about the potential loss of expertise and the risk that CQC inspectors might not understand the issues. Respondents also pointed to the chance that the sector and public may lose confidence in this area. There were some who thought there might be a reduction in burdens locally, but this was not the majority view.

84. The Progress Educational Trust noted:

'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. 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.'

85. The HFEA in its own response recognised the need for clarity in regulatory arrangements for licensed clinics and other registered establishments, but believed that the amount of regulatory overlap had been overstated in the consultation document. They noted that in some instances the regulatory overlap is caused by a failure to apply current exemptions in the CQC legislation.

86. Parents of children conceived using donors voiced concerns about transferring HFEA functions:

'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.'

and

'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.'

87. The majority of HTA-focused respondents also commented on this question. The key messages were as above but specific concerns were raised in relation to the need to maintain public confidence to ensure that levels of donation of tissue and organs for teaching and /or research – as well as transplantation - did not drop. Comments included :

'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.' (The Professional Guidelines and Practices (Anatomy) Committee)

*'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 has been invaluable in ensuring such confidence.' (*Confederation of Cancer Biobanks, National Cancer Research Institute)

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

TABLE 3

Responding on	*HFEA*	*HTA*	*Both HFEA and HTA*	*Total*	*Percentage*
Agree	10	2	4	16	15
Disagree	18	3	10	31	28
No comment	8	30	10	48	44
Possibly	2	3	4	9	8
No response	1	1	0	2	2
Would be feasible	0	0	1	1	1
Not applicable	0	1	1	2	2
Total	39	40	30	109	100

88. Only just over half of all respondents replied to this question. Unsurprisingly, as the question focussed on HFEA functions, the majority of respondents were those whose principal interest is the HFEA. Those who agreed with transferring functions recognised the potential to streamline activities, while stressing the need to ensure that expertise followed function.

89. The Royal College of Obstetricians and Gynaecologists noted:

'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. '

90. A consultant working in Sheffield Teaching Hospitals NHS Trust commented:

'The impact to research is greater in terms of potentially enabling research that may have a net contribution to 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.'

91. With the creation of the HRA respondents saw merit in bringing all aspects of research under one organisation. Cwm Taf Health Board said:

'There are advantages to bringing all research matters under one organisation in particular ensuring a consistent approach to research regulation.'

92. Twice as many respondents disagreed with the proposal. The reasons for not agreeing with the move of HFEA research related functions from the HFEA to the HRA were that it was beneficial to keep HFEA research and treatment functions together in the same organisation, that the HRA is not resourced to carry out inspections, and that a move would run the risk of damaging reputation and public confidence. That said, the BMA and the Royal College of Physicians noted that *if*

HFEA functions were to transfer, it would be better for research functions to transfer to the HRA rather than the CQC.

93. The following comments reflect concerns raised:

*'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 passing of legislation in a timely way.' (*Royal College of Nursing)

'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 are separated, it could be detrimental to future translation efforts'. (Royal College of Physicians).

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?

TABLE 4

Responding on	*HFEA*	*HTA*	*Both HFEA and HTA*	*Total*	*Percentage*
Agree	3	4	0	7	6
Disagree	20	24	18	62	57
No comment	8	8	7	23	21
Possibly	8	4	5	17	16
Total	39	40	30	109	100

94. The consultation presented a range of functions which might be better transferred to a place other than the CQC or the HRA. Almost 80% of respondents expressed a view on this but only 6% supported this proposal.

95. A range of views were expressed which included suggestions to:

- transfer policy making to the Department – this could be through a DH advisory group
- establish the Department of Health as a hub for information on techniques, advances and clinics
- moving the Treatment Register (including details of treatment involving donated sperm, eggs and embryos) to the Health and Social Care Information Centre
- setting up an independent Bioethics committee.

96. The BFS asked for simplification of the data collection process and an end to the collection of information that is not needed for regulatory purposes or to meet the requirements of the HFE Act. UK DonorLink suggested the development of National Minimum Standards to ensure the quality of information collected. PROGAR asked for more work to be done to ensure that the core functions in relation to information are delivered safely and ethically.

97. The Association of Clinical Embryologists, the BFS, the British Infertility Counselling Association, Health, Ethics and Law, University of Southampton and UK DonorLink asked for action to be taken in relation to the Register. The BFS noted that counselling and support (in mind of donor treatment and the function of telling people if they were donor-conceived) is not a regulatory activity and could be carried out by a specialist body (potentially contracted to CQC). Some respondents suggested that this function might best be undertaken by specialist staff within post-adoption/social services.

98. The Association of Biomedical Andrologists suggested the MHRA or UKAS might play a part in HFEA-related research regulation – and that it would be beneficial if UKAS were involved in a single inspection process for clinics.

99. The majority of respondents did not believe that transferring selected functions would be beneficial and risked causing further fragmentation. The HFEA raised concern about moving Register information collection away from other functions. The split of information gathering from compliance could result in centres not complying with the statutory reporting requirements.

100. The HFEA also raised concern about transferring the information provision functions to the DH. External agencies are not permitted to see Register entries, and so the Department of Health would have to seek information from HFEA or whichever body was holding the Register (although it is possible this could be addressed and avoided through the modification of functions in order to effect a transfer of them). Finally, the transfer of remuneration policy making would be at odds with other policy making which would be retained by the HFEA.

'We are particularly concerned about the proposals regarding the HFEA Register and data collection. ….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.' (Multiple Births Foundation)

'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 donation, 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 cancer….It is essential that such decisions are made independent of Government and free from political interference'. (British Medical Association)

101. There was limited support for moving some HTA functions to:

- NHS Blood and Transplant (NHSBT) to regulate the majority of transplant-related functions of the HTA, and
- the MHRA (in respect of tissue obtained and subsequently prepared as a therapeutic product and the work on human tissues and embryos that is currently regulated by both the HFEA and HTA.

102. We also received a suggestion to establish a separate Inspector of Anatomy (as in Scotland and Ireland).

103. The HTA has, both before and during this consultation, always maintained the position that HTA functions should remain together if any transfer took place. It believes that:

'…. the risks associated with fragmenting them are too great. …..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.'

104. In its response, the HTA acknowledges that it might seem that the HRA should be the '*natural home*' for all regulatory responsibilities relating to research. The HTA's function in respect of research is to ensure that premises are licensed to meet the required standards under the Human Tissue Act 2004, for the removal (and subsequent storage) of human material for research from deceased people. It makes the case that this is more closely linked to other activities for which premises are licensed (undertaking post mortem examinations and transplantations) than to the remit of the HRA. The HTA also questioned the timescale (2015) for such transfers and the regulatory fit between the organisations being regulated (often not in the health sector) and the proposed regulator.

105. The Royal College of Surgeons questioned the benefit in the proposals:

'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.' (Royal College of Surgeons)

and NHSBT remarked on the real or perceived conflict of interest were it to take on the proposed function:

'NHSBT considers the proposals in Option 2 to be largely undesirable for the following reasons:

- *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 CQC, MHRA and HRA'.* (NHSBT).

Question 5: Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies?

TABLE 5

Responding on	*HFEA*	*HTA*	*Both HFEA and HTA*	*Total*	*Percentage*
Agree	21	26	18	65	60
Disagree	3	4	2	9	8
No comment	6	1	5	12	11
Possibly	6	6	4	16	14.5
HFEA only	3	0	1	4	3.5
HTA only	0	3	0	3	3
Total	39	40	30	109	100

106. Although only 8% of respondents disagreed outright with the regulators retaining their functions but delivering further efficiencies, one of these was the BFS representing almost 900 members across the fertility sector. The BFS commented:

'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…….and this has largely fallen on deaf ears.'

The main reasons for supporting this option are outlined below.

- Unclear advantages/practical benefits in transferring functions

107. Many respondents considered the regulators to be lean, efficient and cost effective regulators and thought that there was little practical benefit to be achieved by transfer.

*'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.' (*The Church of England)

'I am unconvinced that transferring their (HTA) functions to other organisations will save money.' (Individual)

- Loss of knowledge and expertise

108. As highlighted in the key themes above, the loss of knowledge and expertise was an almost universal concern amongst respondents. We were told that both regulators had built up specialist knowledge and provided excellent, rapid response advice to those working in the relevant fields. The risks of losing this were considered high.

'In GE Healthcare's experience as a major commercial organisation that operates in areas regulated by both the HFEA and the HTA, we have found both these regulators to be efficient, knowledgeable, transparent and above all, extremely helpful to us in our maintaining compliant operation,'s (GE Healthcare)

109. Linked to this was concern about the loss of recognised 'brands'. The BMA expressed concern about the loss of the HFEA brand which is recognised nationally and internationally, noting that there is merit in retaining a single, specialist regulator for this area and that the various functions the HFEA undertakes are very closely inter-related.

- Loss of public confidence

110. Respondents emphasised the value they attached to public confidence in these sensitive and complex areas. They saw the existing regulators as instrumental in having built up that public confidence.

'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.' (Loughborough University)

'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.' (Royal College of Surgeons)

'The HFEA provides a sound regulatory framework which is recognised internationally. The organisation has high public confidence in a sensitive area of practice' (Association of Clinical Embryologists)

111. We did, however, receive an individual response from the University of Reading that offered a word of caution in relation to public confidence and the HFEA:

'*…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*[7]*on its role revealed a very low awareness of it by the public.'*

[7] Results of the Public Attitude Survey were minuted in the Authority meeting on 8 September 2010. Available at : http://www.hfea.gov.uk/docs/2010-10-13_APPROVED_and_SIGNED_Authority_Meeting.pdf

112. This was echoed by the Scottish Council on Human Bioethics who noted:

'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.'

- CQC's state of readiness to take on new functions

113. A common theme raised by respondents was about the ability of CQC to take on functions - this has been discussed earlier in this response.

'*….concerned that the CQC may not have the skills or resources to take on board the highly specialized functions from the HFEA and HTA .'(*Parkinson's UK)

*'… 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.' (*Association of Medical Research Charities)

- Cost Benefits not Proven

114. In supporting Option 3, respondents emphasised the low costs of running the current regulators and their cost efficiency. Many indicated that the consultation under-estimated transition costs (see Question 8).

'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.' (Future Health Biobank)

- Calls for Review

115. However, a number of respondents underlined that their preference and/or support for Option 3 did not mean they did not want to see change or that this meant they supported the status quo.

116. Over a quarter of respondents called for some sort of review either of the HFEA on its own or both organisations. Although only 2 respondents specifically proposed a review of the HTA and its functions, the scope for HTA efficiencies was mentioned in a number of responses. Some respondents suggested a review of the law governing the HTA, which we cover in Question 10.

117. Comments on this included:

'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'. (UK BioIndustry Association)

*'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.' (*Association of Biomedical Andrologists*)*

118. Views were mixed on the status of the review (ie whether it should be independent, led by the Department of Health or by the HFEA or HTA) and what it would address. Some of the main areas that were suggested for review were:

- efficiency of operation
- legislation framework (primarily HT Act)
- regulation creep (primarily HFE Act)
- Authority membership
- organisational culture
- inspection procedures
- functions carried out
- duplication of roles/tasks
- burden of regulation and proportionate inspection
- administrative duplication

119. The Royal College of Obstetricians and Gynaecologists commenting on efficiencies said:

'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.'

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

TABLE 6

Responding on	*HFEA*	*HTA*	*Both HFEA and HTA*	*Total*	*Percentage*
Agree	8	13	10	31	28
Disagree	5	4	6	15	14
No comment	12	8	11	31	28
Possibly	10	12	2	24	22
Don't know	4	2	0	6	6
No response	0	1	1	2	2
Total	39	40	30	109	100

120. Half of all respondents agreed that the HFEA could or possibly could deliver further savings. Some common themes emerged for both organisations in relation to efficiencies. There was general acknowledgment of the savings that had already been achieved, but respondents believed there was scope for more by:

- reducing regulatory overlap
- managing streamlining, including shared Chairs and Chief Executives
- sharing services
- increasing collaboration with the HRA
- using common forms such as the Integrated Research Application System (IRAS)
- reducing the remuneration of the Chair and members.

121. The Academy of Medical Sciences noted:

'We believe that more effective cooperation 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. '

122. The Medical Research Council suggested efficiencies in a number of domains including:

'… a review as to whether the licensing function of the HTA in relation to research purposes is necessary. Removal of the need for licensing 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.'

123. In relation to the HFEA, some respondents suggested that the HFEA could deliver further efficiencies by concentrating on its core legislative duties such as inspection and the data register and looking at any activity it is not required by legislation to perform. Progress Educational Trust suggested:

'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.'

124. Progress Educational Trust also cited in particular the HFEA's establishment of a National Donation Strategy Group which it believes covers the same work as the National Gamete Donation Trust. It also noted that the HFEA could deliver savings by developing a more rigorous and disciplined organisational culture at events it runs.

125. In relation to the HTA, respondents tended to focus on streamlining inspections and recognising other bodies' accreditation processes. One respondent suggested more joint working with Clinical Pathology Accreditation. The Northern Institute for Cancer Research commented:

'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 could be limited to a few sites undertaking particularly high risk activity. Exemption could be granted to sites with other forms of accreditation.'

126. A number of respondents, including the HFEA and the HTA themselves, cautioned against over-focusing on efficiencies at the cost of safety and quality. An individual respondent from the University of Bristol noted:

'While delivering savings to the public purse is important, by far the more important consideration is the effectiveness of these organisations' regulatory activities. Public and professional trust and confidence come not so much from how cheaply regulators operate, but by how effectively they operate.'

127. Some respondents did not agree that retaining functions with the HFEA and the HTA could deliver savings to the public purse. The main reasons were because the organisations had already delivered efficiencies or because multiple regulators cannot deliver efficiencies.

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?

TABLE 7

Responding on	*HFEA*	*HTA*	*Both HFEA and HTA*	*Total*	*Percentage*
Agree	13	3	0	16	14.5
Disagree	17	22	12	51	46.5
No comment	7	10	11	28	26
Possibly	1	4	6	11	10
None	1	0	0	1	1
No response	0	1	1	2	2
Total	39	40	30	109	100

128. Nearly half of respondents did not think that within the option of retaining the HFEA and the HTA as independent regulators, there are any of their functions that could be transferred elsewhere. One of the main reason given was that things are working well currently:

'The HFEA and the 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 with another regulator such as the CQC. …..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.' (GE Healthcare)

129. That said around a quarter felt that there was potential to move some functions – the two functions which received the most comments were the HFEA's research function and HFEA's policy role:

*'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.' (*Association of Biomedical Andrologists)

'*…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.' (*Christian Medical Fellowship)

'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…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.' (British Fertility Society)

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?

130. Whilst half of respondents commented on the impact assessment, they made broadly similar points around the estimated levels of cost savings and the risks associated with transfer of functions and abolition. Many comments re-iterated points made in earlier questions. The main points raised were that the estimated savings were small, did not merit the risks associated with the proposed transfers and that too little regard had been given to transition costs.

131. Respondents noted that the HFEA and the HTA are small and highly specialised with very low expenditure. Some questioned whether the estimated costs could be realised and even if savings were possible, others felt that the disruption and risk simply did not justify such a level of savings.

132. The Multiple Births Foundation expressed concern that the costs of transferring functions to other organisations may be underestimated as there was no detail about the practical aspects of how a transfer would work. They also 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.'

133. Respondents noted that as staff are highly specialised it would not simply be a case of transferring functions (expertise would have to follow) and therefore savings would not materialise. There was a risk to continuity of business.

134. The Donor Conception Network noted:

'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 as cost to a small charity such as ourselves.'

135. Respondents did accept that savings could be achieved by more collaboration with the CQC (without abolishing the bodies) but many believed that the transition costs presented had been under-estimated. Indeed the HFEA itself stated:

'We believe there is overestimation of benefits and underestimation of costs of transfer.'

136. Many felt that reducing inspection was the means to achieving further efficiencies but many also emphasised that this should not be at the expense of safeguarding effective regulation. The British Medical Association stated that improving and streamlining the regulatory processes of the regulators could occur without abolishing the HFEA and HTA and that :

'Both bodies are currently moving towards joint inspections and far greater collaboration with other relevant bodies.'

137. The BFS expected there to be cost savings delivered to clinics through combined inspections, savings to researchers from the HRA developing a one-stop shop for submission of applications, and further savings derived through a major review of data proposed by it and other respondents.

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 the 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

138. Around 40% of respondents commented on this covering a number of areas.

139. The Scottish National Blood Transfusion Service (SNBTS) and NHS National Services Scotland both commented on streamlining functions as follows:

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

140. As in responses to Question 5, a number of respondents called for a review. The AMS called for:

'A review of the definition of 'relevant materials' in the Human Tissue Act 2004 – to bring it into alignment with the Human Tissue (Scotland) Act 2006 ……A regular review of the functions and form of the HFEA and the HTA, considering whether integration into the HRA as opposed to closer alignment is appropriate.'

141. The Medical Research Council responded:

'…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 the 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. '

142. The United Kingdom Accreditation Service took a slightly different approach in its response commenting that :

'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.'

and noted that trial joint assessments are already taking place with the HTA on Clinical Pathology Accreditation Ltd (CPA).

143. This approach to streamlining was supported by Belfast Health and Social Care Trust who commented on the efficiency and effectiveness of the HFEA but wrote:

'..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.'

144. In relation to the HFEA, other areas covered in this section included:

- a call for the needs and rights of children to be the primary concern
- the need for more counselling and professional support for donors and surrogates, recipient parents, donor-conceived people and those born through surrogacy arrangements
- a review of birth registration
- more representation of different view points and a suggestion to set up a National Bioethics Committee

145. Finally, echoing the views expressed by the Progress Educational Trust in relation to the organisational culture (in response to Question 6 above), the British Fertility Society noted:

'*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.'*

146. Respondents' comments focusing on the HTA numbered less than those focusing on the HFEA, and included the following :

- the introduction of funding mechanisms to support the Independent Assessor role
- Independent Assessor standards are maintained in any transfer
- review of current legislative framework for the licensing and removal of material from deceased organ donors for the primary purpose of research
- MHRA should consider setting up a Cellular Biologies section handling the use of all therapeutic human cellular material, including blood (as it currently does), hospital transplant centres and the Advanced Therapy Medicinal Products (ATMP) licences it issues to cell manufacturers.

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

147. Calls for review were again expressed in responses to this question. Where the response related only to the HTA the main area for review cited was human tissue legislation. Comments included the following:

'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 of the Human Tissue Act to materials such as urine,faeces and saliva and its application to tissue from living subjects.' (Association of Medical Research Charities)

'We are aware of 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.' (Royal College of Physicians)

148. Others used this question to raise more fundamental points:

'The consultation starts from a premise – that current functions are misallocated and that savings can be made without detriment to service to users – for which no evidence is produced.' (Donor Conception Network)

and the British Medical Association who responded:

'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……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?'

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

149. Only a small number of respondents addressed this question but where comments were made they related to:

- the need to reflect transition costs of these proposals;
- the need to be more precise about how the proposals might be implemented in order to answer the question;
- that the proposed options are still not addressing the functions of the regulators and will not improve the current position; and
- the scope to reduce costs in relation to the HFEA by restricting its functions.

150. Biovault cautioned:

'*The true costs of these proposals will be borne by the licensed sector in terms of a less focused service from the regulator. It would be better directly identified and covered by proportionate license fee increase rather than hidden in 'efficiencies' but ultimately the cost of the outcome of this consultation will be paid for by the licensed establishments.'*

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

151. Only a small number of comments were received in response to this question. One respondent questioned its usefulness and another stressed the importance of reducing the impact on staff as much as possible.

Annex C

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

Respondents (alphabetical order)

Aberdeen Maternity Hospital (individual)
Academy of Medical Sciences
Addenbrookes Hospital (individual)
All Party Parliamentary Group on Stem Cell Transplantation
Anthony Nolan
Association of Biomedical Andrologists
Association of Clinical Embryologists
Association of Medical Research Charities
Belfast Health and Social Care Trust
Belfast Health and Social Care Trust Regional Fertility Centre
Bereavement Advice Centre
Bereavement Services Association
BioIndustry Association
Biovault Ltd
BMI Healthcare Ltd
BOC Healthcare
Breast Cancer Campaign
Bristol Tissue Bank (individual)
British Association for Tissue Banking
British Fertility Society
British Heart Foundation
British Infertility Counselling Association
British Medical Association
British Neuroscience Association
British Transplantation Society
Brunel University Research Ethics Committee
Burton Hospitals NHS Foundation Trust (individual)
Cancer Research UK
Cardiff University, Governance & Compliance Division
Care Quality Commission
Christian Action Research Education (CARE)
Christian Medical Fellowship
Church of England, Mission & Public Affairs Council
Comment on Reproductive Ethics
Confederation of Cancer Biobanks
Cwm Taf Local Health Board
Dewsbury District Hospital
Donor Conception Network
ESRC Genomics Policy and Research Forum
Future Health Biobank

GE Healthcare
Genetic Alliance UK
GlaxoSmithKline
Health Research Authority
Hull York Medical School, University of Hull (individual)
Human Fertilisation and Embryology Authority
Human Tissue Authority
Human Tissues Group
Independent Cancer Patients Voice
Individual responses (11)
Infertility Network UK
Institute of Biomedical Science
Kings College Hospital NHS Foundation Trust
King's College London (individual)
Leeds Teaching Hospitals NHS Trust/University of Leeds
London School of Hygiene and Tropical Medicine (individual)
Loughborough University
Medical Research Council
Multiple Births Foundation
Natalie Gamble Associates
National Childbirth Trust
National Gamete Donation Trust
NHS Blood and Transplant
NHS National Services Scotland
Natural History Museum
Northern Institute for Cancer Research
Nottingham University Hospitals NHS Trust (individual)
Parkinsons UK
PHG Foundation
Professional Guidelines and Practices (Anatomy) Committee (PGaPAC)
Progress Educational Trust
Project Group on Assisted Reproduction (PROGAR)
Right to Life
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Pathologists
Royal College of Physicians
Royal College of Surgeons
Royal Liverpool & Broadgreen University Hospital Trust (individual)
Scottish Council on Human Bioethics
Scottish National Blood Transfusion Service
Scottish Transplant Group
Sheffield Teaching Hospitals NHS Foundation Trust – Centre for Reproductive Medicine & Fertility
Sheffield Teaching Hospitals NHS Foundation Trust (individual)
Shrewsbury and Telford Hospitals NHS Trust (individual)
Society and College of Radiographers
South Eastern Health and Social Care Trust
STRATUM
UK Accreditation Service

UK Donor Link
University of Bristol, Centre for Comparative & Clinical Anatomy (individual)
University of Bristol, Human Tissue Working Group
University of Cambridge (individual)
University of Reading (individual)
University Research Ethics Committee, University of the West of England (individual)
University of Sheffield (individual)
University of Southampton, Health Ethics and Law
Wellcome Trust
Wellcome Trust Sanger Institute

Annex D

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

Department of Health Workshop held on 19 September 2012
Synopsis of main comments from participants
(Organisations attending listed alphabetically at end)

Loss of expertise

- Loss of expertise/accountability – body with responsibility does not have expertise
- In option 1, need to ensure retain expertise and the right staff
- Loss of expertise from HFEA and HTA and key personnel

CQC not ready to take on the functions

- CQC not ready or able to take on the functions
- CQC would need to learn new skills eg standard settings – currently issues guidance on how to meet regulations
- Ensure CQC is suitable to take on functions before transfer to maintain confidence – eg delay transfer
- Public confidence in CQC is low

Loss of public confidence

- Loss of public confidence in brand/loss of brand
- Maintaining public confidence and safety
- Good reputation and brand – nationally and internationally

Further efficiencies required but risks highlighted

- Need clear definition of efficiencies – savings and service improvement and accountability for delivery
- Joint working with other regulators eg if CPA or ISO accredited, not looking at same issues – more sharing of information and good practice with other regulators, possible joint inspections
- Risk too many efficiencies required may undermine regulation and risks to confidence and safety
- Option 3 is not a do nothing option – need to ensure HFEA and HTA are accountable for further efficiencies
- Question as to whether it is possible to deliver further cost savings nationally and locally
- Efficiencies can be made in quality and inspections – streamlining
- It is feasible for efficiencies and improvements to be made – within organisations and between – and without risks and costs associated with transfer

Review required

- Review of functions before wholesale transfer to ensure appropriate functions/approach adopted in new system
- Should be about service improvement with teeth to make it happen eg Independent review/inquiry
- Under Option 3 need external review of efficiencies/independent review and boards made accountable for delivering savings
- Option 3 is not a do nothing option and needs accountability – external to HFEA and HTA
- Need review of what happens and why – identify what can be done without changes to legislation
- Review of decision making within HFEA
- Review of leadership in HFEA
- Review of HFEA role and duty of care re Register
- Review fees to ensure that they are appropriate to the organisation's needs

Organisations Attending

Academy of Medical Sciences
Association of Anatomical Pathology Technologists (AAPT)
Association of Clinical Embryologists
Association of Medical Research Charities
BioIndustry Association
Bourne Hall Ltd
British Fertility Society
British Infertility Counselling Association
British Medical Association
British Transplantation Society
Care Quality Commission
Comment on Reproductive Ethics
DHSSPS, Northern Ireland
Donor Conception Network
Healthcare Inspectorate Wales
Health Research Authority
Human Fertilisation & Embryology Authority
Human Tissue Authority
Infertility Network UK
Institute of Anatomical Sciences
Medical Research Council
National Gamete Donation Trust
NHS Blood and Transplant
PROGAR (British Assoc Social Workers)
Progress
Regulation and Quality Improvement Authority, Northern Ireland
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians & Gynaecologists
Scottish Government
UK DonorLink
Wellcome Trust