Title:	Impact Assessment (IA)
Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority IA No: 6044 Lead department or agency:	Date: 14/06/2012 Stage: Consultation Source of intervention: Domestic Type of measure: Other

Summary: Intervention and Options

RPC: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£3.8m	£0m	£0m	No	NA

What is the problem under consideration? Why is government intervention necessary?

The Government is committed to reducing NHS administrative costs by more than one-third over the course of this Parliament. This will partly be achieved by radically reducing and simplifying the number of NHS bodies, including the Department of Health's arm's-length bodies (ALBs). 'Liberating the NHS: Report of the arm's-length bodies review' (July 2010) set out this intention and its justification. The report proposed the Human Fertilisation & Embryology Authority (HFEA) and Human Tissue Authority (HTA) continue as separate ALBs in the short term with a view to transferring their functions to other bodies by 2015. Legislation is needed to transfer these functions, in order to achieve such reductions in administrative costs.

What are the policy objectives and the intended effects?

The objective is to improve the efficiency of the Arm's Length Body sector, through reducing the number and costs of public bodies. These costs include (i) the running costs of the HFEA and HTA, which represent an administrative burden, and (ii) the burden on providers of demonstrating compliance with HFEA- and HTA-related regulations. The transfer of functions is intended to be done in such a way that protects and ensures quality and safety. The Government is consulting on proposals to transfer the functions of the HFEA and the HTA.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

(1) Transfer all HFEA and HTA functions to Care Quality Commission with the exception of HFEA functions relating to research that will transfer to the Health Research Authority and abolish the HFEA and the HTA.

(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 the HTA.

(3) HFEA and HTA retain their functions but deliver further efficiencies that will accrue from closer working and the further use of shared services by the HFEA, HTA and CQC. The HRA would continue as research regulator, but without the research functions of the HFEA transferred to it.

Option 1 is the preferred option because it has the potential to release greater efficiency savings than option 3, while minimising the risk of fragmentation that may be greatest in option 2.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: Date: 18th June 2012

URN 11/1109 Ver. 3.0

Summary: Analysis & Evidence

Policy Option 1

Description: Transfer all HFEA and HTA functions to CQC and the HRA; and abolish the HFEA and HTA

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	High: 7.8	Best Estimate: 3.8

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0	1	0	**0**
High	0.34		0	**0.34**
Best Estimate	0.16		0	0.16

Description and scale of key monetised costs by 'main affected groups'

Reorganisation costs (including redundancy payments) will fall on the HFEA and HTA and their future home organisations, the CQC and HRA. Costs over and above those in option 3 may arise from reductions in senior personnel. These will be purely transitional and would not occur until 2014/15, when any transfer of functions would take place. The scope of additional monetised transition costs are detailed in the Annex.

Other key non-monetised costs by 'main affected groups'

There will be costs to organisations licensed by the HFEA and HTA to familiarise themselves with the new regulatory landscape. These will be purely transitional. There will also be likely costs incurred by the Department of Health and to the Devolved Administrations (to a lesser extent) as they work with the organisations to support the transfers and the eventual closure of those being abolished.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0	N/A	0	**0**
High	0		0.94	**8.1**
Best Estimate	0		0.46	3.9

Description and scale of key monetised benefits by 'main affected groups'

There will be savings from reduced staff salaries and remuneration. Savings over and above those in option 3 may arise from reductions in senior personnel. Any savings will accrue either to licensed organisations (through lower fees, although the receiving regulators will decide the final level of fees) or the Department of Health (depending on decisions over grant-in-aid which are beyond the scope of this Impact Assessment).

Other key non-monetised benefits by 'main affected groups'

There may also be savings from streamlining registrations and inspections. These may be in the form of reduced costs for licensed organisations in demonstrating compliance with regulations, or reduced running costs to the CQC and HRA (which may be passed on in lower fees to licensed organisations). There may also be savings to the Department of Health in reduced sponsorship costs.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is a risk that expertise may be lost in the transfer of functions from the HFEA and HTA to the CQC and HRA. This may be in the form of staff members, or in the form of expert advisors.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Summary: Analysis & Evidence

Policy Option 2

Description: Transfer most HFEA and HTA functions to CQC and the HRA with limited exceptions; and abolish the HFEA and HTA

FULL ECONOMIC ASSESSMENT

Price Base Year **2014**	PV Base Year **2014**	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: 0	**High:** 7.8	**Best Estimate:** 3.8

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	0	1	0	**0**
High	0.34		0	**0.34**
Best Estimate	0.16		0	0.16

Description and scale of key monetised costs by 'main affected groups'

Reorganisation costs (including redundancy payments) will fall on the HFEA and HTA and their future home organisations, the CQC, the HRA and other ALBs. Costs over and above those in option 3 may arise from reductions in senior personnel. These will be purely transitional and would not occur until 2014/15, when any transfer of functions would take place. The scope of additional monetised transition costs are detailed in the Annex.

Other key non-monetised costs by 'main affected groups'

There will be costs to organisations licensed by the HFEA and HTA to familiarise themselves with the new regulatory landscape. These will be purely transitional, and are likely to be greater than under option 1, as health-related organisations have to deal with multiple regulators. There are also likely costs incurred by the Department of Health the Devolved Administrations (to a lesser extent) as they work to support the transfers and the eventual closure of those being abolished.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	0	N/A	0	**0**
High	0		0.94	**8.1**
Best Estimate	0		0.46	3.9

Description and scale of key monetised benefits by 'main affected groups'

There will be savings from reduced staff salaries and remuneration. Savings over and above those in option 3 may arise from reductions in senior personnel. Any savings may accrue either to licensed organisations (through lower fees, although the receiving regulators will decide the final level of fees) or the Department of Health (depending on decisions over grant-in-aid which are beyond the scope of this Impact Assessment).

Other key non-monetised benefits by 'main affected groups'

There may be savings from streamlining registrations and inspections. These may (or may not) be greater than option 1 if the synergies between some HFEA and HTA functions and other ALBs are greater than with CQC. Savings may be through reduced costs for licensed organisations in demonstrating compliance, or reduced running costs to the CQC and HRA (which may be passed on in fee cuts to licensed organisations). There may be savings to the Department of Health in reduced sponsorship costs.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There is a risk that expertise may be lost in the transfer of functions from the HFEA and HTA to the CQC and HRA. This may be in the form of staff members, or in the form of expert advisors. This risk will be greater than under option 1, as functions are transferred to a greater number of bodies. There is also the possibility that transition costs will be higher under option 2 than under option 1.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: 0	**Benefits: 0**	**Net: 0**	No	NA

Summary: Analysis & Evidence

Policy Option 3

Description: HFEA and HTA retain their functions and deliver further efficiencies

FULL ECONOMIC ASSESSMENT

Price Base Year **2014**	PV Base Year **2014**	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional	N/A	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	0

Description and scale of key monetised costs by 'main affected groups'

As there will be no additional intervention by the Department of Health, these are defined to be zero (existing and planned efficiencies and associated costs are described in more detail in the main text).

Other key non-monetised costs by 'main affected groups'

As there will be no additional intervention by the Department of Health, these are defined to be zero (existing and planned efficiencies and associated costs are described in more detail in the main text).

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional	N/A	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	0

Description and scale of key monetised benefits by 'main affected groups'

As there will be no additional intervention by the Department of Health, these are defined to be zero (existing and planned efficiencies and associated costs are described in more detail in the main text).

Other key non-monetised benefits by 'main affected groups'

As there will be no additional intervention by the Department of Health, these are defined to be zero (existing and planned efficiencies and associated costs are described in more detail in the main text).

Key assumptions/sensitivities/risks **Discount rate (%)** N/A

Without formally transferring the functions, there is a risk the HFEA and HTA will not achieve the savings they have predicted. It is difficult to assess the likelihood of this, as the likely outcome under this option is inextricably tied up with the announcement that HFEA and HTA functions may be transferred to the CQC and HRA. Therefore, if this prospect (of transferring functions to the CQC and HRA) were to disappear, it is uncertain whether further planned efficiency savings would be made.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: 0	**Benefits: 0**	**Net: 0**	No	NA

Evidence Base (for summary sheets)

Introduction

1. This consultation impact assessment considers the costs and benefits of taking forward action in relation to the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) as proposed in the Coalition Government's Programme for Government and the Department of Health's Liberating the NHS: Report of the arm's-length bodies review (July 2010).

2. Liberating the NHS: Report of the arm's-length bodies review (July 2010), noted the Government's intention to simplify and reduce radically the number of NHS bodies including the Department of Health's arm's-length bodies. It also set out our 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 then, we have received representations asking for us to keep functions together as much as possible. The attached consultation document, this consultation impact assessment and the attached consultation equalities analysis are the first steps in the process to establish where functions might sit in the future.

3. The efficiency savings put forward in this document are part of the wider intention to reduce administrative spending across the system by one-third in real terms by 2014/15. Any efficiency savings set out in this document are therefore included within the £1.5bn reduction in administrative spending across the system that is identified within the coordinating document for the impact assessments for the Health and Social Care Act 2012 (available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_123583). Similarly, any redundancy costs identified are a subset of the £810m total redundancy cost identified within the coordinating document.

4. This document gives more information about the particular impacts, through reducing running costs across the system and through redundancy payments that directly result from the proposed changes to HFEA and HTA.

5. The following paragraphs set out in more detail the existing roles of the main regulators involved – the HFEA, the HTA and the Care Quality Commission (CQC). They also briefly set out the developing role of the new Health Research Authority (HRA). The consultation impact assessment describes the impact of the options on regulators in the devolved administrations.

Human Fertilisation and Embryology Authority

6. The HFEA was established by the Human Fertilisation and Embryology Act 1990 and came into operation on 1 August 1991. The HFEA is the UK's independent regulator responsible for overseeing the use of gametes and embryos in infertility treatment and embryos in research. It licenses fertility clinics carrying out in vitro fertilisation (IVF) and other assisted conception procedures involving the use of donated gametes and embryos, and centres carrying out human embryo research. As part of its regulatory role, the HFEA maintains a register of all treatment cycles regulated by the Human Fertilisation and Embryology Act 1990 which includes information about every patient, their partner if they have one, all gamete and embryo donors and all children born as a result of such treatment.

7. The HFEA is one of the competent authorities (an authority, body or organisation and/or institution responsible for implementing the requirements of a European Directive) for the quality and safety aspects of the EU Tissue and Cells Directives as they apply to reproductive cells (gametes and embryos).

8. The Human Fertilisation and Embryology Act 1990 requires the HFEA to carry out an on-site inspection of all licensed establishments and research projects a minimum of once every two years. The HFEA inspection team evaluates and monitors the establishment's:

   - Premises, equipment and facilities
   - Laboratory processes
   - Documentation, including standard patient information
   - Ability of the establishment to provide the services it offers; and
   - The suitability of the Person Responsible and staff providing the services

   The HFEA also carries out a range of statutory non-licensing functions identified in the accompanying consultation document.

Human Tissue Authority

9. The HTA was established by the Human Tissue Act 2004. It regulates organisations that remove, store, use and dispose of tissue for purposes including research, medical treatment, post-mortem examination, teaching and display in public. The HTA also gives approval for organ and bone marrow donations from living people. The HTA is one of the competent authorities (an authority, body or organisation and/or institution responsible for implementing the requirements of a Directive) for the EU Tissues and Cells Directive. It is also the competent authority designate for the whole of the UK for the purposes of the EU Organ Donation Directive.

10. Under the Human Tissue Act 2004, the HTA has a statutory responsibility to satisfy itself that:

    - the Designated Individual for each licence is a suitable person to supervise the activity authorised by the licence;
    - the applicant for the licence is a suitable person to be a holder of the licence; and
    - the premises are suitable for the licensed activity

11. It fulfils this responsibility through a process of inspection encompassing desk-based assessment, on-site assessment and analysis of information to evaluate compliance with the conditions of a licence and HTA licensing standards which have been developed under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

Care Quality Commission

12. The Care Quality Commission (CQC) was established under the Health and Social Care Act 2008 as the independent regulator of health and adult social care in England. CQC was formed from the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission on 1 April 2009.

13. CQC regulates any provider of regulated health and social care activities, no matter whether that provider is NHS, local authority, independent, or voluntary sector. CQC aims to make sure better care is provided for everyone – in hospitals, care homes and people's own homes. CQC also seeks to protect the interests of people whose rights are restricted under the Mental Health Act 1983.

14. Under the Health and Social Care Act 2008 all providers of regulated health or adult social care activities (eg treatment of disease disorder or injury, surgery, personal care) including NHS and independent healthcare providers are required to register with CQC. While CQC is required to monitor providers for compliance with the registration requirements, the legislation does not set out how (or how often) CQC must do this; CQC is able to set its own methodology and approach. CQC carries out scheduled inspections which assess the provider's compliance with registration

requirements, at frequencies that depend on the type of provider (the actual period between inspections is determined by the level of risk identified). CQC also carries out responsive inspections when evidence suggests that is necessary.

Health Research Authority

15. The Health Research Authority (HRA) has been established as a Special Health Authority (SpHA) with the National Research Ethics Service (NRES) at its core. The purpose of the HRA as a SpHA is to protect and promote the interests of patients and the public in health research. It will protect patients from unethical research while enabling patients to benefit from participating in research by simplifying processes for approval to undertake research. The SpHA will hold responsibility for ethical review of health research, unify health research approval processes wherever it can and collaborate with existing regulators to promote simplification and co-operation.

16. The Government plans to establish the HRA as a non-Departmental public body (NDPB) in primary legislation to put the HRA on a stable and independent footing. This will also enable the HRA to be formally given functions beyond Secretary of State's health related functions. This would enable the HRA to take responsibility both for licensing embryo research (currently done by the HFEA) and to continue to provide for research ethnic committees (through NRES) to review research in this field. This would not only consolidate safeguards, benefiting research participants, but would also allow bureaucratic processes to be rationalised, benefitting researchers. The new legislation will not change any of the existing safeguards, only who is responsible for them.

Problem under consideration

17. The Government has agreed that spending on health will increase in real terms in every year of this Parliament and is committed to increasing the proportion of resource available for front-line services to meet the current financial challenges and the future costs of demographic and technological changes. To do this the Government will need to achieve unprecedented efficiency gains, with savings reinvested in frontline services. Over the next four years, the Government is committed to reducing NHS administrative costs by one-third and to improve the efficiency of the system. This is partly to be achieved by radically reducing and simplifying the number of NHS bodies, including the Department of Health's arm's-length bodies.

18. Services in health and related sectors are currently regulated by a range of organisations and must comply with a range of regulatory requirements. The HFEA, HTA and CQC all regulate services to provide independent assurance of the safety and quality of these services. The HRA is part of this landscape, ensuring patients are protected from the risks of unethical research. Complying with the requirements and demonstrating that the requirements have been met places an administrative burden, and, therefore, a cost, on health care organisations. The running costs associated with these regulators also generate an administrative burden. The Government is committed to keeping the burden of regulation to a minimum while providing the public with assurance about the safety of services.

19. The Coalition: Our Programme for Government (May 2010) set out the Government's proposals to reduce the number of health arm's-length bodies, with a view to reducing these administrative burdens on providers. This was followed up by Equity and Excellence: Liberating the NHS: Report of the Arm's Length Body Review (July 2010). This report found that both the HFEA's and the HTA's functions satisfy the criteria for being undertaken by an arm's-length body. It also noted that there are clear synergies between some of the functions performed by the HFEA, the HTA, CQC, the Health and Social Care Information Centre (HSCIC) and the scope of the HRA.

Rationale for intervention

20. The Arm's Length Body Review identified the potential of improving efficiency across the sector. The review found that there is overlap of cover between HFEA, HTA and the CQC, resulting in both inefficiency and complexity of the activities undertaken. The accompanying consultation

document and this consultation impact assessment consider the options to reduce the administrative burden on organisations associated with the activities of the HFEA and HTA. The options (see below) look at transferring the functions of the HFEA and HTA elsewhere. Government intervention is necessary, as the functions of the HFEA and HTA are set out in legislation and any transfer to another ALB would require legislation.

Policy Objective

21. Liberating the NHS: Report of the arm's-length bodies review (2010) set out proposals to ensure that the Department of Health's arm's-length body sector remains fit for purpose and affordable. We are proposing reform of the current regulatory arrangements that will result in services being delivered to the same high standards but in a more streamlined and cost-efficient way by :

    - Reducing complexity of the regulatory landscape
    - Strengthening the effectiveness of regulation in this area to ensure public confidence and protect health and safety
    - Clarifying the regulatory landscape for service providers.

    The proposed transfer of functions from the HFEA and the HTA and their abolition is part of the cross-Government agenda to reduce the number and costs of public bodies and to streamline regulation. These are costs incurred both by the regulators and by provider organisations through demonstrating compliance with the requirements. The proposed transfer will be achieved while ensuring treatment, services and research continue to be provided in a safe and ethical way, and retaining a core of skills and expertise in crucial areas, thereby maintaining public confidence.

Sectors and groups affected

22. The transfer of functions set out in the consultation document and this consultation impact assessment would change the landscape in this area of regulation. As the ALBs under consideration are responsible for supporting the existing health system, and providing guidance, these proposals would affect a number of bodies, organisations, sectors and groups. These are described below.

Arm's-length bodies

23. The HFEA, HTA, CQC and HRA would be affected by the proposed changes set out in this impact assessment and the consultation document it accompanies. Under option 1, the functions of the HFEA and HTA would be entirely transferred to CQC and HRA. Under option 2, while the majority of functions would transfer to CQC and HRA, other ALBs would have responsibility for some of these functions. These are Arts Council England (ACE), NHS Blood and Transplant (NHSBT), the Medicines and Healthcare Products Regulatory Authority (MHRA) and the Health and Social Care Information Centre (HSCIC). Incorporating the functions of the HFEA and HTA within existing ALBs could provide scope to reduce running costs through reductions in staff (including senior personnel) and possible streamlining functions.

Providers

24. The ALBs considered here work with a variety of health and social care providers and their work has an impact on providers' day-to-day activities. The options for change set out in this impact assessment would potentially reduce the number of regulatory bodies (moving most, if not all, functions to CQC and the HRA). This could affect health providers in two main ways: (i) altering administrative costs of demonstrating compliance with regulations by reducing the bureaucracy associated with registration and inspection, and (ii) potential changes in the operation of the functions, changing the costs to the regulator. This last mechanism could affect the fees paid for the regulation currently carried out by the HFEA and HTA. However, this is dependent on the level of Government grant-in-aid, which is outside the scope of this Impact Assessment.

25. Many ALBs also work with private and third sector providers. Private and third sector providers are regulated by the HFEA and HTA according to the same standards as NHS organisations. These proposals would therefore affect private and third sector organisations in the same way as NHS organisations.

Public sector providers

26. The HFEA regulates NHS fertility clinics, a small number of sperm banks and some NHS research centres. The HTA regulates NHS hospital pathology services; NHS bodies procuring, testing, processing, importing, exporting and distributing human tissue for treatment purposes; NHS bodies storing bodies, body parts and tissues for tissue for research, education and training; and public organisations (e.g. museums) involved in the public display of human tissue.

Private and third sector providers

27. The HFEA regulates private fertility clinics, sperm banks and independent sector research centres. The HTA regulates commercial bodies procuring, testing, processing, importing/exporting and distributing human tissue for treatment purposes; commercial bodies storing bodies, body parts and tissues for tissue for, research, education and training; and commercial bodies (e.g. art galleries) involved in the public display of human tissue.

28. While universities receive some public funding, they also receive private funding and may have charitable status. The HFEA regulates university research centres. The HTA regulates anatomy departments in university medical schools, universities storing bodies, body parts and tissues for tissue for, research, education and training.

Researchers and people involved in the research community

29. The HFEA regulates the use of embryos in research whilst the HTA regulates the storage of tissue for the scheduled purpose of research. Researchers, along with research sponsors and host organisations and those funding research would be affected by the proposed changes to the regulation of embryo research and regulation of storage of tissue. The proposals in this consultation would change the regulatory body that those involved in these areas of research deal with.

Department of Health

30. The proposed transfer of functions would directly affect the Department of Health (DH). Principally, changes to the financial basis of organisations may lead to changes in the level of grant-in-aid that DH provides to its ALBs. However, the overall scale of grant-in-aid is out of the scope of this Impact Assessment, as it is a separate policy decision that will be determined independently. Any savings in running costs would be taken into consideration in agreeing the final level of grant-in-aid.

31. In addition, there may be changes to the relationships and sponsorship arrangements between DH and its ALBs. Under option 2, the Department would also become responsible for providing information to donors and the donor-conceived and the consideration of remuneration issues for gamete and embryo donors (see the discussion of option 2 for more detail).

Devolved administrations

32. The Department has taken into account the picture of regulation across devolved administrations respecting that there are existing regulators. The remits of the HFEA, HTA and CQC vary considerably across the different countries in the UK.

    - The HFEA has functions in relation to the whole of the UK

- The HTA has functions under the Human Tissue Act 2004 in relation to England, Northern Ireland and Wales. It performs a limited number of functions by formal contract with Scottish Ministers. The HTA also acts as the competent authority for the whole of the UK in respect of the EU Tissue and Cells Directive, and currently assesses living organ donation in Northern Ireland, Scotland and Wales. A recent separate consultation on transposing the EU Organ Donation Directive 2010/53/EC into UK law proposed that the HTA act as the competent authority for all UK health departments. Implementing regulations were laid before Parliament on 14 June 2012 and are expected to come fully into force on 27 August 2012.
- CQC has functions in relation to England only
- The extent of the HRA's remit will depend on the type of research involved, for example functions relating to the health service will extend to England only. However, it is our intention that the HRA will work closely with the devolved administrations so that there is a co-ordinated approach to research regulation. If the HRA were to take on functions in relation to human embryo research these would relate to the whole of the UK.

33. The proposals set out in this consultation cover the UK and are aimed at ensuring consistency and effectiveness of services across the UK, while recognising the local differences that exist and taking into account the current arrangements that exist with the other UK health departments.

Patients, service users and the public

34. The regulators have an impact on patients, service users and the public through a number of mechanisms: (i) the services they provide to the regulated providers and DH, (ii) information for the public on these services, as well as guidance and publications that they issue, and (iii) the assurance they provide by regulating services and the individuals providing them.

35. The options set out in this Impact Assessment do not alter the safeguards under the Acts and relate only to the transfer of functions between ALBs; safeguards such as the requirement for consent would not be altered. Therefore, the baseline assumption is that standards in regulated establishments would not change. There is a risk that standards may change – this is set out in more detail in the Risks section.

36. Currently the public know where to turn for the public advice provided by the HFEA and HTA (for example around where to go for fertility treatments, or how to donate one's body to science). There is a risk that public knowledge of where to obtain this advice may be damaged in the transfer of regulatory functions to other bodies. Again, this is set out in the Risks section.

37. However, there are also potential benefits to patients, services users and the public. Improved interface between the functions currently carried out by CQC, HFEA and the HTA may reduce the administrative burden on providers and thus any associated burden on patients, service users and the public. This may improve patient experience, although such an outcome is highly uncertain.

Description of Options

Option 1: 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 the HTA (preferred option)

38. Research-related functions of the HFEA would be transferred to the HRA. All remaining functions of the HFEA and all the functions of the HTA would be transferred to CQC. This reduces the number of regulators in the sector taking these functions forward across the UK and keeps functions together.

39. Practically all licensed organisations currently dealing with the HFEA and HTA will see either a reduction in the number of regulators they have to deal with, or no change. In England, the majority of these organisations will see a fall (those that currently deal with at least two of the CQC, HFEA and HTA), while there will be fewer organisations in the Devolved Administrations (DAs) seeing such a fall. Organisations in the DAs will continue to deal with existing national regulators. This is set out in more detail below.

40. The overall reduction in the number of regulators in this area aims to drive up efficiency and value for money through removing duplication. It is not yet certain what the final organisational structures would be or how organisations would operate and carry out their functions, as this would be for CQC and HRA to determine. The eventual structure and arrangements would have an impact on benefits and costs.

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 the HTA

41. Research-related functions of the HFEA would be transferred to the HRA. Most remaining functions of the HFEA and most functions of the HTA would be transferred to CQC, with some exceptions. These include transferring functions to Arts Council England (ACE), NHS Blood and Transplant (NHSBT), the Medicines and Healthcare Products Regulatory Authority (MHRA), the Health and Social Care Information Centre (HSCIC), and the Department of Health (DH). In addition, some research-related functions of the HTA would transfer to the HRA.

42. This option would also reduce the number of ALB regulators overall, ensure alignment with wider system changes, and provide alternatives for some functions that might be more appropriately delivered by an organisation other than by CQC or the HRA. Again, it is not certain what would be the final organisational structure or how organisations would operate and carry out their functions as this would be for CQC, the HRA, and other ALBs to determine. The eventual structure and arrangements would have an impact on benefits and costs.

Option 3: HFEA and HTA retain their functions but deliver further efficiencies

43. Under this option, the HFEA and HTA would continue to fulfil their current functions. However, the organisations would continue to pursue efficiency savings plans, which include closer working with CQC and the HRA. The Shared Services programme would continue to generate savings in support functions (see below). These savings would include finance and human resources. However, this programme would not cover the total potential efficiency savings from reducing senior personnel and removing any duplication that arises in the delivery of core services. The HRA would still be established as a NDPB subject to parliamentary approval, but without the research functions of the HFEA transferred to it. These activities will deliver benefits and associated costs (which are described in more detail below). For the purposes of this impact

assessment, the benefits and costs of options 1 and 2 are incremental benefits and costs, over and above those in option 3.

Option 1: 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 the HTA (preferred option)

44. Further work to analyse the costs and benefits of the options will be undertaken using evidence gathered as the result of the consultation exercise on the proposals prior to a decision on the way forward being made. Responses to this consultation and further work will enable more robust predictions to be made around the final organisational structure and how functions are carried out. These will be incorporated into a subsequent Impact Assessment.

45. This consultation Impact Assessment takes the perspective of the whole health system. As discussed in more detail in the next subsections, transferring functions from the HFEA and HTA to CQC and the HRA would reduce the running costs of the HFEA and HTA (to zero), while increasing the running costs of the recipient bodies. The following discussion explains that the net effect of this would be neutral under a reasonable worst case, i.e. the reductions would match the increases. Under other more plausible scenarios, efficiency savings would lead to a positive net impact on the health system, i.e. the incremental reductions in running costs would outweigh the incremental increases, over and above those outlined in option 3 (no intervention). There may be residual costs such as premises lease, if, say, it could not be assigned.

46. This option is expected to result in a net reduction in costs across the system. However, it is not possible at this stage to say what the final impact would be on the budget and expenditure of individual ALBs. This will depend on a number of factors: (i) the size of any efficiency savings, (ii) the final organisational structures (which would be decided by CQC and the HRA), (iii) decisions about fees (which would be agreed by CQC and the HRA) and (iv) decisions about government grant-in-aid (which are beyond the scope of this Impact Assessment).

Benefits

47. Benefits achieved as part of this reorganisation fall into four categories

    a. Reduced running costs of the functions currently carried out by the HFEA and HTA (with benefits to the regulators, which may be passed on to licensed organisations and/or the Department of Health)

    b. Reduced administrative burden on organisations licensed by the HFEA and HTA in terms of demonstrating compliance (with benefits to licensed organisations)

    c. Reduced administrative burden of liaising between DH and the relevant regulators (with benefits to the Department of Health and the regulators, which may be passed on)

    d. Additional benefits to licensed organisations from increased cooperation at provider level.

48. All benefits are annual and ongoing; there are no transition benefits. As discussed in the preceding paragraphs, there is significant uncertainty over where the benefits (and costs in the next section) would lie: DH, the proposed regulators (CQC and HRA) or providers (public and private) of regulated services. Therefore, while indicative figures are presented, no robust estimation of the split can be made.

(a) Reduced running costs of the functions currently carried out by the HFEA and HTA

49. Total expenditure by the HFEA and HTA in 2010/11 was £12.3m (£7.0m and £5.3m respectively). Under the proposed efficiency gains described in option 3, total expenditure would be reduced by 2014/15 (when we envisage any transfers would take effect). These are set out in option 3. However, we cannot be certain about the actual extent of efficiency savings that will be delivered by the regulators, so these efficiency savings are subject to change. The total size of annual savings to running costs under option 1 would lie within this reduced figure.

50. Currently, over 90% of establishments in England licensed by the HFEA to provide fertility services are either registered by CQC or the services are provided in premises that CQC regulates. Over 60% of establishments in England licensed by the HTA are registered with CQC. Therefore, there is likely to be scope for savings both for regulators and providers through streamlining the regulators. This could be through three main mechanisms: (i) streamlining the registration process to remove any overlap, (ii) streamlining each individual inspection to remove any overlap, and (iii) greater coordination in the provision of data to demonstrate compliance (such as qualifications of staff and health & safety requirements). Final decisions on delivery would be made by CQC and the HRA. They may not see sufficient scope for streamlining in some of these areas, or find greater scope in others. As a result, it is currently not possible to quantify the effect of these mechanisms.

51. It is possible that the final organisational structure would lead to efficiency savings in running costs through two further mechanisms: (i) reduction in senior personnel numbers, and (ii) streamlining central support teams and sharing back office staff (over and above those made under the Shared Services programme). These would both reduce salary expenditure. Elements of these are already being pursued under option 3. However, it is possible to estimate the savings from reducing some of the senior posts under the final organisational structure. These would be additional to those savings under option 3.

52. There is some evidence that such an organisational change could result in salary savings. As discussed in the Introduction, CQC was formed from the Healthcare Commission (HCC), the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission (MHAC) on 1 April 2009. CQC has estimated that total expenditure on salaries for staff associated with MHAC functions fell by 5.9% in the year following the formation of CQC. While the type of change and organisations involved are different from those considered in this Impact Assessment, this evidence demonstrates the potential for efficiency savings to be made. In particular, it provides evidence in favour of CQC's ability to deliver such savings.

53. Most ALBs generally have a Chair, Chief Executive and Finance Director (and other Directors), regardless of their size. In organisations with a higher number of staff the total expenditure on senior personnel will be less in proportion to the total workforce than in organisations with fewer staff. While the final organisational structure of CQC and the HRA would be determined by the organisations themselves (having absorbed HFEA and HTA functions), we could expect the spend on senior personnel working on HFEA- and HTA-related functions would reduce in comparison to total staff costs working on these functions. For example, in 2010/11, 7.3% and 8.8% respectively of the total expenditure of the HFEA and HTA was on senior personnel (Chair, Chief Executive, and all Directors). In contrast, only 0.9% of CQC expenditure was on senior personnel. (See also Table 1 below.)

54. We recognise that the HFEA and HTA provide some different regulatory functions to CQC, which may mean that CQC in the future would require a different mix of senior personnel and other staff with necessary expertise in the delivery of transferred functions. However, such a significant difference in the current ratios suggests that there may be scope for a reduction in expenditure on senior positions (compared with total spend across all three organisations). As discussed in option 3, the HFEA and HTA already plan to further reduce staff numbers (with significant achievements to date). However, it is uncertain whether this would include senior personnel as well.

55. Table 1 below presents these potential benefits. The methods for calculating these figures are detailed in the annex. Four main scenarios are considered: (a) all staff or personnel continue to be employed, (b) the Chair and Chief Executive of the HFEA and HTA are no longer employed, (c) the Chair, Chief Executive, and half of all Directors and Members of the HFEA and HTA are no longer employed. A further figure (d) is presented, indicating the maximum scale of savings if all staff and personnel at the HFEA and HTA are no longer employed. It should be noted that (d) is not a plausible scenario, and provides only an indication of the scale of the benefits involved. All of these represent additional benefits over and above those currently being delivered.

56. The second column of table 1 states the total amount spent on the salaries and remuneration in 2010/11 on each of the four scenarios described above. The third column estimates what this figure would be by 2014/15. The fourth column shows the total savings that might be expected over ten years from when any transfer would take place (2014/15), taking into account salary and remuneration growth. The fifth takes the average annual saving. Finally, the sixth column shows the total savings over the same ten years, discounted at a rate of 3.5% per year.

Table 1. Savings from reduced salaries and remuneration

Staff made redundant	Salary and remuneration (£m)		Savings over 2014/15 to 2023/24 (£m)		
	2010/11	2014/15	Total	Average annual	Total discounted
(a) None	-	-	-	-	-
(b) Chair and Chief Executive	0.5	0.4	4.6	0.5	3.9
(c) Chair, Chief Executive, and half of all Directors & Members	1.0	0.9	9.4	0.9	8.1
(d) All Staff	7.7	6.2	67.8	6.8	58.0

57. The best estimate is for scenario (b), with scenario (a) forming the low estimate and scenario (c) forming the high estimate.

58. Co-location with CQC would also reduce annual accommodation expenditure. This has taken place with the HFEA, but not the HTA. Therefore, there could be additional savings for co-location of HTA-related functions. These have not been monetised.

Distribution of benefits from mechanism (a)

59. The HFEA and HTA receive income from two main sources, the Department of Health (through grant-in-aid) and organisations licensed and inspected by the HFEA and HTA (through fees), including private and charitable organisations. Any savings through increased efficiencies would be spread across these parties. However, there is nothing to determine that savings should be saved proportionately between the two sources of income. It is not within the scope of this Impact Assessment to determine grant-in-aid allocations or fees.

60. In 2010/11, fees accounted for 72% of HFEA and 81% of HTA income respectively, with the remainder of costs being supported through grant-in-aid. It is the Government's policy that regulators should aim to charge fees at a level that covers the full costs of regulation, but not the cost of other functions, which must be met by government grant-in-aid. In the case of the HFEA, the Human Fertilisation and Embryology Act 1990 allows it to charge a fee that has regard to exercising other functions ascribed to it by legislation. Nevertheless, it would be for CQC and the HRA to determine the final level of fees, based on the costs involved and would be part of wider discussions involving grant-in-aid.

61. Approximately 15% of providers licensed by the HFEA treat only private patients. However, a number of NHS organisations provide treatment to private patients. Therefore, the proportion of private HFEA-regulated activity will be significantly higher. This figure, and that for the HTA, is not known with any certainty, so it is not possible to estimate how any savings would split between private and NHS providers. In addition, the uncertainty over how savings are allocated between fees and government grant-in-aid means any such figure would be highly speculative.

(b) Reduced administrative burden on organisations licensed by the HFEA and HTA

62. As set out under benefit (a), there may be overlaps between the existing regulatory functions of CQC, HFEA and the HTA. If these can be streamlined, then there would be further benefits to organisations licensed by the HFEA and HTA. If the combined set of requirements on licensed organisations is reduced, then their costs in demonstrating compliance would also fall.

63. For the majority of licensed organisations in England currently regulated by the HFEA and HTA, the number of regulators they deal with would fall. Figures from the HTA website (in June 2011) showed that around 60% of the approximately 440 establishments licensed by the HTA were also registered by the CQC. These would see a drop in the number of regulators they need to register with or obtain a licence from, generally from two to one (some establishments hold multiple licenses from the HTA). Figures from the HFEA website (in July 2011) showed that around 90% of the approximately 100 organisations licensed by the HFEA in England were also registered by the CQC. Most of these would see a drop in the number of regulators they need to register with or obtain a licence from, from two to one. Those that have research and non-research activity (around 10%) might not see any change in the number of regulators (CQC and HFEA to CQC and HRA) or, if they already deal with the HRA over embryo research, they might see a fall (CQC, HFEA and HRA to CQC and HRA). Around a further 40 organisations are licensed by the HFEA and HTA and registered by CQC, so would see a drop from three to one (or possibly three to two if they only have research activity related to the HFEA that would pass to the HRA).

64. The HFEA and HTA also deal with a number of organisations in Wales, Scotland and Northern Ireland, where CQC has no current responsibilities, although the information available is less comprehensive than in England. For the HFEA, this represents around 20% of all UK organisations; for the HTA, it represents around 10% of all UK licenses. Those organisations in the devolved administrations that deal with both the HFEA and HTA would also see a fall in the number of regulators, although the majority (those that currently deal with only one) would see no change. Other national regulators in the devolved administrations would continue to work with some of these organisations.

65. A very small number of organisations across the UK (one has been identified) are currently regulated by the HFEA for research and non-research activity, but not regulated by the HTA or CQC. Such organisations would see an increase in the number of regulators they deal with (from the HFEA to the CQC and HRA). However, if the organisation has already begun to deal with the HRA around this research activity, it would see no change in the number of regulators. Therefore, practically all organisations in the UK would see either a decrease in the number of regulators they deal with, or no change. Through reducing the number of regulators, there is scope for such burdens on providers to fall.

66. Organisations that are required to have multiple licences are also currently inspected by different organisations. One organisation with responsibility for inspecting one organisation on multiple levels may combine teams. This could lead to a reduced demand on the organisation's time, to prepare for and host the inspection teams.

67. Although these savings to providers have been explored, it is not possible to determine at this stage what the actual impact would be. This would depend both on Orders setting out the functions and also on how the importing ALBs decide to carry out their functions. However, we are keen as part of this consultation to hear from providers about the potential for savings.

(c) Reduced administrative burden of liaising between DH and the relevant regulators

68. Currently, the Department of Health has different sponsorship teams that liaise with CQC, HFEA and the HTA. These teams are involved in the appointment of Chairs and Members, as well as with the clearance of business plans and annual reports, among other activities. They also act as a focal point for any queries from the regulators.

69. With fewer regulators (from the three of CQC, HFEA and HTA to the two of CQC and the HRA), it is possible that efficiencies can be made in performing these functions. However, this benefit is uncertain, as it would depend on the final organisational structure of CQC and the HRA (which would be for them to decide) and of the Department of Health.

(d) Additional benefits to licensed organisations from increased cooperation at provider level

70. Currently, CQC, HFEA and the HTA do not provide integrated registrations or inspections. This can lead healthcare professionals who work in licensed establishments to focus on their own area of regulation, neglecting potentially valuable information involved in other regulatory activities. By reducing the number of regulators, not only may there be more integration at the regulator level, but also at the provider level. This may result in a more robust internal processes, for example around incident management.

71. This may result in reduced running costs and administrative burden for the licensed organisation (captured in benefit (b)). However, it may also have an additional benefit in improving the overall running of the organisation (for example, in terms of delivering improved incident management). However, such a benefit cannot be quantified.

Costs

72. All costs are incurred in a transition period. There are no ongoing annual costs. These costs fall into two categories

    a. Costs of reorganisation, including redundancy payments (with costs to regulators, which may be passed on to licensed organisations or create a pressure on government grant-in-aid),

    b. Familiarisation costs (with costs to licensed organisations).

    c. Costs to Department of Health and the Devolved Administrations

(a) Costs of reorganisation to CQC and the HRA, including redundancy payments

73. The National Audit Office (NAO) surveyed central government organisations that had been reorganised, identifying areas of expenditure incurred with the reorganisation process. The main areas of expenditure identified included staff, IT, property, corporate functions, branding & communications and indirect costs. Staff redundancy costs made up 17% of all costs incurred by organisations in their reorganisation. Redundancy payments reflect a real cost to those made redundant and so they are not treated as a transfer payment. Due to uncertainty around the final organisational structure, the associated reorganisation costs are highly uncertain.

74. Table 2 below presents estimates for the total redundancy costs and the associated reorganisation costs. The methods for calculating these figures are detailed in the annex. Four main scenarios (mirroring those in the benefits section) are considered: (a) no redundancy payments are made, (b) redundancy payments are made to the Chief Executive of the HFEA and HTA, (c) redundancy payments are made to the Chief Executive and half of all Directors of the HFEA and HTA. Redundancy payments are not made to Chairs or Members. A further figure (d) is presented, indicating the maximum scale of redundancy payments if received by all staff at the HFEA and HTA. It should be noted that (d) is not a plausible scenario, and provides only an indication of the scale of the potential reorganisation costs involved.

75. The second column of table 2 estimates the size of the redundancy payments required under each of the scenarios. These are then multiplied by approximately 6 (i.e. 1/0.17) to provide a rough estimate of the total reorganisation costs, presented in the third column. This is the best estimate of the total transition costs that would be incurred under this option, and would be expected to last for one year only when the policy would start (i.e. 2014/15). However, as explained above, these provide only a rough estimate.

Table 2. Indicative costs of redundancy and reorganisation

Staff made redundant	Redundancy Costs (2014/15) (£m)	Transition Costs (2014/15) (£m)
(a) None	-	-
(b) Chair and Chief Executive	0.03	0.16
(c) Chair, Chief Executive, and half of all Directors & Members	0.06	0.34
(d) All Staff	0.86	5.08

76. The best estimate is for scenario (b), with scenario (a) forming the low estimate and scenario (c) forming the high estimate.

77. Due to the methodology adopted by the NAO, these figures include relocation costs. However, the HFEA has already co-located with CQC as part of their intended efficiency savings. As these cannot be excluded from the calculations, the above figures provide an overestimate of the likely transitional costs.

(b) Familiarisation costs

78. Local services that are currently used to dealing with a range of regulatory bodies would need to familiarise themselves with the new landscape, therefore imposing some cost on them. This may increase the time taken by those communicating compliance data, submitting licence information and coordinating inspections, as well as those managing the organisations processes.

79. In 2010/11, around 130 organisations in the UK held HFEA licenses, and around 600 main sites held HTA licenses. Therefore, small effects on individual organisations may combine to produce a large total effect, although these costs are not quantifiable. CQC is already a well-recognised regulator with relationships already established with many of the providers and so it would be a case of being clear about the additional functions it is taking on. There would be more costs associated with becoming aware of the HRA and its role, although these are related to the creation of the HRA, which is outside the scope of this Impact Assessment. These costs would be incurred only in the transition period.

(c) Costs to the Department of Health and Devolved Administrations

80. The Department of Health to a greater extent and the Devolved Administrations to a lesser extent are likely to incur costs during the transitional period as they work with the organisations to effect the transfers and to support the eventual closure of those organisations that are being abolished.

Net Present Value

81. The discounted benefits and costs that can be quantified are presented below in table 3. It should be stressed that this presents only those benefits and costs that have been quantified. Further benefits and costs that may arise (for example due to reduced burden on providers from streamlined inspections) are not included here.

82. While the estimates of costs and benefits are highly uncertain (as explained above), the table below demonstrates that potential benefits (assessed over a ten-year time period) could be around one order of magnitude (i.e. ten times) greater than the costs. It would be for CQC and the HRA to

decide how to implement operationally the relevant functions. Therefore, it is uncertain which (if any) of the scenarios considered would arise under this option.

Table 3. Net benefit of option 1 over ten years

Staff made redundant	Discounted benefits (£m)	Discounted costs (£m)	Net present value (£m)
(a) None	-	-	-
(b) Chair and Chief Executive	3.9	0.2	3.8
(c) Chair, Chief Executive, and half of all Directors & Members	8.1	0.3	7.8
(d) All Staff	57.2	5.6	51.6

83. The best estimate is for scenario (b), with scenario (a) forming the low estimate and scenario (c) forming the high estimate. In addition, the final row provides only an indicative figure for the scope of the net benefit if CQC and the HRA could entirely absorb the functions of the HFEA and HTA without loss of value. This is unlikely to be the case. It merely provides evidence that, were CQC and the HRA to choose to streamline services, the savings to salaries would outweigh the costs in redundancy payments and other reorganisation costs by roughly one order of magnitude.

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 the HTA

84. Under this option, most functions would follow option 1 (i.e. research-related functions of the HFEA would transfer to the HRA; all other HFEA functions and all HTA functions would transfer to CQC), but six main exceptions are currently considered:

    a. Transfer the HTA regulation of public display of human bodies or tissue to Arts Council England (ACE, which took over the functions of the Museums, Libraries and Archives Council (MLA)) from October 1st 2011

    b. Transfer the HFEA register of treatment cycles, patients, donors and offspring to the Health and Social Care Information Centre (HSCIC)

    c. Transfer the HFEA responsibility for setting remuneration for the supply of gametes and embryos for the treatment of others or for use in research to the Department of Health (DH)

    d. Transfer the HTA responsibility for licensing the storage of tissue for the specific scheduled purpose of research to the HRA

    e. Transfer HTA responsibility for the approval of donations from a living person to NHS Blood and Transplant (NHSBT)

    f. Transfer HTA responsibility for licensing of activities relating to use of human tissue for human application to the Medicines and Healthcare Products Regulatory Authority (MHRA)

    g. Transfer HTA responsibility for information to donors and the donor-conceived to the Department of Health

(a) Public display of human bodies or tissue – Arts Council England

85. Under the Human Tissue Act 2004, the storage and use of a deceased person's body and the removal, storage and use of body parts from a deceased person for the purpose of public display requires appropriate consent and the authority of a licence. These include in exhibitions or galleries as part of a show or display, or in museums.

86. The majority of establishments licensed for public display are well-established museums. Arts Council England (ACE), which is a registered charity and NDPB receiving grant-in-aid from the Department for Culture, Media and Sport, currently oversees, develops and promotes best practice in museums across England. It took on these functions from the Museums, Libraries and Archive Service (MLA) on 1 October 2011. Although primarily tasked with museum development in England, it did inherit from MLA some very specific UK-wide functions associated with cultural property. There is an Arts Council development framework for English museums and it also administers the Museum Accreditation Scheme (in which 1800 museums participate across the UK) that sets out nationally- agreed standards, including Governance and Museum Management and Collections Management. The majority of establishments holding an HTA licence for public display will also come within ACE oversight and the Museums Accreditation Scheme.

87. While we are committed to retaining the consent and licensing requirements that apply to this activity, there is clear potential for streamlining regulation and bringing it closer to the body that oversees all activities that museums engage in. It would also benefit the regulated sector which would have closer alignment to ACE than to a regulator whose primary focus is healthcare provision. Should it be decided to pursue this option, it would be necessary to ensure that the function was properly safeguarded.

(b) Register of treatment cycles, patients, donors and offspring – Health and Social Care Information Centre (HSCIC)

88. Section 31 of the Human Fertilisation and Embryology Act 1990 requires that a register be maintained containing data about:

    - Every treatment cycle involving the creation of embryos outside the body (e.g. in vitro fertilisation) and every treatment cycle involving the use of donated gametes and embryos
    - All patients undergoing treatment (and the patient's partner, if she has one)
    - The outcome of all treatment cycles and details of all live births
    - All gamete and embryo donors

89. The Register contains information about every cycle of treatment carried out in the UK since the Human Fertilisation and Embryology Act 1990 came into force on 1 August 1991. It now holds nearly 1 million records. It is a unique data collection and represents one of, if not the most, comprehensive record of these treatments in the world.

90. The information in the register is required to deliver the Authority's regulatory activities, including the calculation of clinic fees, to advise a person about his/her genetic origins or for a range of secondary purposes, such as research into the long-term health implications of certain treatments. The Government is committed to ensuring the Register continues in the future.

91. At present CQC is not typically a primary collector of data. CQC's regulatory functions are supported by data provided by a number of bodies, including the Health and Social Care Information Centre (HSCIC), the Department of Health, the NHS Litigation Authority, the National Patient Safety Agency, and Medical Royal Colleges.

92. The HSCIC has a role as the focal point for national data collections on health and social care, taking over data responsibilities from ALBs and other central collectors. It has extensive experience of managing large data collections and already has the hard/software necessary to hold and disseminate health data. While the HSCIC has considerable expertise in this area, its current remit would need to be extended to take on this function. Collecting data for regulatory purposes would represent primary use - the HSCIC's current remit extends only to collecting and holding data for secondary use.

93. Transferring the Register to the HSCIC would, however, create a one-stop-shop for researchers who wish to link Register data with other health registers and databases to determine if there are any health or social welfare implications arising from fertility treatments

(c) Setting remuneration for the supply of gametes and embryos for the treatment of others or for use in research – Department of Health

94. The HFEA currently makes Directions on the appropriate level of remuneration for the supply of gametes and embryos for the treatment of others or for use in research. It is a condition of every licence issued by HFEA that no money or other benefits shall be given or received in respect of the supply of gametes or embryos unless it is authorised by directions.

95. In addition, this activity would represent a significant new function for CQC.

96. For that reason, an alternative option might be to transfer this policy function to the Department of Health, which would have overall responsibility for setting remuneration limits, in consultation with stakeholders and the general public. Ministers would be accountable to Parliament and the public

for any payments or other benefits in kind that are given to people in return for donating their gametes or embryos.

97. Further work to analyse the costs and benefits of the options would be undertaken using evidence gathered as the result of the consultation exercise on the proposals prior to a decision on the way forward being made.

(d) Licensing the storage of tissue for the specific scheduled purpose of research – Health Research Authority

98. 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. This group will interface with the HRA on other research-related matters, and may therefore look more naturally in the direction of the HRA than the CQC for their licence. An option, therefore, is to separate licensing the 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.

99. There would be implications for those licensed establishments that store tissue for purposes which may be broader than research, or that are primarily engaged in other activities licensed by the HTA, for example anatomical examination, or the making of a post-mortem and which are also licensed for the storage of tissue for a scheduled purpose. Some of these establishments may not always know in advance the range of scheduled purposes for which their tissue may be used. Under current arrangements a single licence provides the necessary authority for storage. Under this option, a sizeable proportion of establishments would require a licence from both the HRA (for storage for research) and from the CQC (for storage for other purposes). Option 1 (transferring all HTA functions to CQC) would avoid the requirement for two licences.

100. HTA licenses storage of tissue on premises, not research involving stored tissue. This is similar to the regulation of exposure to ionising radiation and administration of radioactive medicines, where it is the activity (storage; exposure; administration) rather than the purpose (research; other purposes) that is subject to regulation. Redesigning the licensing of human tissue storage according to the purpose of the storage rather than the fact of the storage would set a precedent for these other areas of regulation too. This could mean more circumstances where a single activity, but for dual purposes, gets regulated by two bodies.

(e) Assessment of donations from a living person – NHS Blood and Transplant

101. Under the Human Tissue Act 2004 it is an offence to use material from a living person for a transplant unless the HTA is satisfied that no reward is to be given for the transplant and that the conditions set out in the regulations are fulfilled. The purpose of the approvals process is to ensure that donors are aware of the risks associated with transplants; and have not been offered any reward to donate and have not been put under any pressure to do so. Similar provisions are contained in the Human Tissue (Scotland) Act 2006 and Regulations made under that Act. The function of approving applications is one that the HTA discharges across the UK, and is the subject of a formal contract between the HTA and the Scottish Government. Potential donors are interviewed by an Independent Assessor, usually based in a hospital transplantation unit, who sends a report to the HTA. Some cases require a decision by a panel of at least three members of the HTA.

102. The HTA also approves donations of bone marrow and peripheral blood stem cells from children who are not competent to give consent, or from adults lacking capacity.

103. This function is discrete from the licensing functions of the HTA and would be a significant change to CQC's regulatory role. Although organ donation and transplantation activities are carried out in healthcare settings, there are currently separate systems for dealing with donations

from living donors and deceased donors. Donations from the deceased are overseen by NHSBT which is registered with the CQC as a provider and also holds licences from the HTA. There may be advantages in bringing all activities relating to organ donation and allocation within the remit of a single body.

104. However, under this option, a decision to transfer assessment of donations from a living person to NHSBT would mean that there would be two regulators looking at different aspects of the donation process (as opposed to one in option 1). In addition, there may be a conflict of interest between NHSBT's role in promoting living donation and a function of overseeing an independent process that may refuse a living donation.

(f) Licensing of activities relating to use of human tissue for human application – Medicines and Healthcare Products Regulatory Agency

105. The European Union Tissue and Cells Directive (EUTCD) seeks to establish a harmonised approach to the regulation of tissues and cells across Europe. The HTA is one of the competent authorities in the UK under the EUTCD and has responsibility for regulating tissues and cells (other than gametes and embryos) for human application (the use of human tissue to treat patients). Organisations across the UK that treat patients with human tissue and cells, including stem cells, skin and heart valves need to be licensed by the HTA. Thus, licences for human application can be issued to a wide variety of organisations, including eye banks, maternity units and organisations that store skin and bone.

106. For many healthcare establishments where these activities are carried out, for example, storing skin or other tissues for grafting, bringing regulation of this activity within the wider regulation by CQC of healthcare establishments should deliver benefits by reducing the number of regulators they have to deal with.

107. However, not all activity subject to licensing under the Quality and Safety Regulations is carried out in healthcare settings, and some practitioners may see synergies with other regulators rather than CQC. Those involved in stem-cell research with a view to the eventual development of therapeutic products, may see merit in aligning this regulatory activity with the Medicines and Healthcare products Regulatory Agency. From their perspective, there may be attractions in having a single regulator through to the licensing of a therapeutic product.

108. This transfer would see the regulation of the activities covered by the EU Directives (currently split between the HFEA and the HTA) continuing to be split between different regulators. This may be over complicated and could be a source of confusion for practitioners.

(g) Information to donors and the donor-conceived – Department of Health

109. One of the principal purposes of the Register (see function (b)) is to provide a source of reliable information for donor-conceived people wishing to know about their genetic origins. From the age of 16, donor-conceived people are able to seek information from the register as to whether they are genetically related to someone who they wish to marry, enter into a civil partnership with or to enter into an intimate physical relationship. Since 1 October 2009, at the age of 16 donor-conceived people can obtain non-identifying information about the donor of the gametes or embryos used in their mother's treatment. From age 18 they can obtain identifying information about their donor (but only when the donation itself took place after 1 April 2005).

110. For people who choose to seek this information the answers they receive have the potential to dramatically change their lives. There is no room for error in the information provided and the staff taking on these functions will need to be properly trained and equipped to assist applicants. The HFEA has addressed this by dedicating a small group of its staff to carrying out this function. To assist them in handling queries, the personnel involved have undergone counselling training.

111. This function is still developing. It was only in 2007 that the first donor-conceived people, born after the Human Fertilisation and Embryology Act 1990 came into force, started to reach age 16 and were able to apply for information. On average, there are 1,500 donor-related births occurring each year, so this is likely to become a significant activity in the future. This is not a regulatory activity, but one of the statutory duties in the Human Fertilisation and Embryology Act 1990 to provide information. It would represent a significantly new activity for CQC, unlike any other it carries out.

112. An alternative option might be to transfer this function to the Department of Health recognising the importance of this information to those who seek it. The Department of Health could contract out this service to an external provider but Ministers would retain direct, overall responsibly for the quality and efficacy of the service provided to stakeholders.

Benefits

113. Under option 2, the same benefits have been monetised as for option 1. However, there may be scope for greater synergies between limited specific functions than option 1, resulting in greater efficiency savings. By carefully allocating services to the organisations with the largest overlap in responsibility, the greatest scope for efficiencies could be exploited. This would reduce operating costs to carrying out functions and could potentially reduce compliance costs for regulated organisations, as well as simplify the regulatory landscape. However, this would depend on the final organisational structure of CQC, the HRA and the individual ALBs detailed above. Therefore, while there could be additional benefits relative to option 1, they cannot be quantified and have therefore remained as non-monetised benefits.

Costs

114. Under option 2, the same costs have been monetised as for option 1. However, costs may be higher than option 1. The administrative costs of the transfer may be greater, as staff and functions transfer to a greater number of organisations and locations. In addition, if greater efficiencies could be made (as explained above) in a way that reduces staff numbers, then redundancy costs would also rise. Again, the costs additional to option 1 are highly uncertain.

Net Present Value

115. The discounted benefits and costs that can be quantified are therefore the same as option 1. However, as described above, there are likely to be additional costs and benefits from option 2, over and above option 1, which are uncertain. This is discussed further in the Summary and Preferred Option section.

Option 3: HFEA and HTA retain their functions but deliver further efficiencies

Baseline for benefits and costs

116. Under option 3, the HFEA and HTA would continue to fulfil their current functions and to pursue their planned further efficiency savings, including through closer work with CQC. There would be no intervention by the Department of Health to transfer functions (although in this scenario, we would propose creating a duty to cooperate between the organisations). The Government's proposals for the HRA would still go ahead, but without the research functions of the HFEA transferred to it. To assess the marginal impact of options 1 and 2, the costs and benefits of option 3 are described below. The benefits and costs of options 1 and 2 are additional over and above those set out below.

117. Under the Shared Services programme, it is anticipated that the ALB sector will make savings in the cost of running or providing support services. This programme aims to achieve savings in DH and its ALBs' non core transactional services through: (i) shared services, (ii) standardised services, (iii) radical changes in what or how non core services are delivered, and (iv) proposing ceasing some non core work. These services include finance, accounting and human resources.

118. The Shared Services programme is looking at proposals that span the entire ALB sector, so it does not have specific estimates for the scale of its impact on individual ALBs, and at present does not include the HFEA and the HTA. However, the HTA and HFEA have declared intentions to make specific efficiency savings through closer working with CQC.

119. The HFEA has already moved towards shared services working with CQC. This includes co-location with CQC, which will reduce joint accommodation costs in the longer term. Shared services working also includes the sharing of back office functions, including HR and finance. The HFEA have proposed efficiency savings that would reduce their staff levels from 86 full time equivalents (FTEs) as of 2010/11, to 67 by 2014/15. This is associated with a reduction on their overall budget of around a quarter over the period. These moves are also associated with transition costs, which may include redundancy payments as well as accommodation moves. As a result of these efficiency savings, the HFEA has reduced licence fees from 1 October 2011. The HFEA has also consolidated its senior management team. Upon the departure of the incumbent Chief Executive, the posts of Chief Executive and Director of Strategy have been merged, generating further efficiency savings.

120. The HTA has advised that it has made efficiency gains in 2010/11 and expect to make further gains in 2011/12. It estimates that headcount will stabilise at 44 from 2014/15 onwards (down from 54 in 2010/11). The largest area in which HTA expect to make efficiencies is in relation to inspections. However, it currently has no plans to co-locate with CQC. The HTA estimates that 14% efficiency savings were made in 2010/11, and 31% in 2011/12.

121. While these plans under option 3 are likely to realise substantial efficiency savings, options 1 and 2 describe further actions to achieve additional efficiency savings. These may include (further) savings on senior personnel and reduced duplication of functions around core services, which are unlikely to be fully achieved under option 3 (see above). However, it should be noted that any change in organisational structure would be for the receiving regulators to decide.

Risks

Option 1: 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 the HTA

122. This analysis has assumed that there would be minimal loss in the value of functions, given the proposal to move the functions elsewhere in the sector or the health and social care system. CQC and the HRA would have a number of years to prepare for the transfer of these functions, during which time the Department would work alongside both organisations to ensure that they are ready to take the functions on prior to the changes being implemented. However, there could be a risk that the functions of HFEA and HTA would not be delivered as effectively during the transition stage and there could be a fall in productivity, while organisations adapt to changes. Furthermore, by increasing the functions of CQC, there is a potential risk that CQC would become overstretched and that this would detract from the essential delivery of their current functions. Finally, by the date of any transfer of functions, the HRA will be a relatively new organisation and may need time to further find its feet.

123. There is a risk to expertise through the loss of directly employed HFEA and HTA staff, as well as expert advisers. The HFEA came into operation in 1991 and the HTA in 2005. Both organisations have developed and built expertise. If existing HFEA and HTA expertise were not imported into the CQC and the HRA at the time of transfer, it may take CQC and the HRA some time to build their reputation and proficiency in these areas, which would be detrimental for the services they regulate and for public confidence.

124. A loss of expertise may occur through reputational mechanisms. An individual working at the HFEA and 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. There is a risk that CQC and the HRA would need time to build such a reputation in these areas of regulation. This could lead to a loss of skilled staff and their associated knowledge and expertise.

125. Currently the public know where to turn for the public advice provided by the HFEA and HTA (for example around where to go for fertility treatments, or how to donate one's body to science). With the transfer of functions, this service may alter in a way that reduces its accessibility to the public. Under this option, it would be for CQC and the HRA to decide how they would carry out this public information service in the future.

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 the HTA

126. In addition to all of the risks involved in option 1, there is a greater risk of fragmentation. HFEA and HTA expertise and knowledge would have to be dispersed across a greater range of ALBs than in option 1, which may result in a greater loss of reputation and proficiency in these areas if existing relevant staff from, and expert advisers to, the HFEA and HTA were not imported into the new bodies on transfer.

Option 3: HFEA and HTA retain their functions but deliver further efficiencies

127. There is a risk that the HFEA and HTA will not achieve the savings that they predict without a formal transfer of functions. It is difficult to assess the likelihood of this, as the likely outcome under option 3 could be linked to the Department of Health's announcement that it was proposing that HFEA and HTA functions be transferred to CQC and the HRA. If this proposal were dropped and the HFEA and HTA remained statutory independent organisations, there is a risk that the motivation to achieve further efficiency savings could be reduced. In the past, when the HFEA and HTA faced the prospect of being merged into the Regulatory Agency for Tissue and

Embryos (RATE), joint HR operations were in place to make efficiency savings. However, when the possibility of RATE disappeared, the HFEA and HTA moved back to separate HR systems.

Direct costs and benefits to business

128. Currently the HFEA, HTA and CQC charge fees to all providers they regulate, both public and private. Fees may change under options 1 and 2 (compared to option 3) due to (i) a fall in running costs (passed on in the form of reduced fees) or (ii) a fall in Government grant-in-aid (passed on in the form of increased fees). However, the level of grant-in-aid is not within the scope of this Impact Assessment. Therefore, the options do not incorporate the effects on private business of changes in grant-in-aid. There is additional uncertainty over how such changes in fees would be split between the public and private sectors.

129. If CQC and the HRA choose to change the way in which functions are carried out (with no loss in quality or safety), there may also be changes to the costs providers face in demonstrating compliance with regulations. However, these costs are unknown.

Summary and preferred option

130. The preferred option is option 1 - 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 the HTA.

131. Option 1 is preferred to option 3, as option 1 has the potential to provide greater scope for efficiency savings in terms of reduced running costs and delivers the policy objectives. The benefits of reduced salaries of regulatory staff and personnel could outweigh costs of redundancy and transition by roughly one order of magnitude. There may be further benefits in terms of streamlining registrations, licensing and inspections (with associated reductions in administrative burden for providers). However these cannot be quantified and remain uncertain.

132. Option 1 is preferred to option 2. Option 2 may provide alternatives for some functions that might be more appropriately delivered by another organisation than by CQC or the HRA. However, option 2 also faces a greater risk of fragmentation of expertise and knowledge. By splitting up the functions of the HFEA and the HTA across a wider range of organisations, there is a greater chance that relationships between the regulator and the regulated organisation would be damaged and expertise would be lost.

133. Further work to analyse the costs and benefits of the options will be undertaken using evidence gathered in response to this consultation exercise on the proposals prior to a decision on the way forward being made. At this stage, it is not certain what the final organisational structures would be or how organisations would operate and carry out their functions as under option 1 or option 2. Under option 1, this would be for CQC and the HRA to determine. Under option 2 it would be for CQC, HRA and potentially other organisations to determine. Responses to this consultation and further work will enable more robust predictions to be made around the final organisational structure and how functions are carried out. These will be incorporated into a subsequent Impact Assessment.

Annex. Methodology for Calculating Benefits and Costs for Options 1 and 2

Benefits

1. Four main scenarios are considered: (a) all staff or personnel continue to be employed, (b) the Chair and Chief Executive of the HFEA and HTA are no longer employed, (c) the Chair, Chief Executive, and half of all Directors and Members of the HFEA and HTA are no longer employed. A further figure (d) is presented, indicating the maximum scale of savings if all staff and personnel at the HFEA and HTA are no longer employed. It should be noted that (d) is not a plausible scenario, and provides only an indication of the scale of the benefits involved. All of these represent additional benefits over and above the efficiency savings proposed by the HFEA and HTA in the context of the Shared Services programme (i.e. option 3). These cost savings are presented in table A1 below (and table 1 in the main section).

Table A1. Savings from reduced salaries and remuneration

Staff made redundant	Salary and remuneration (£m)		Savings over 2014/15 to 2023/24 (£m)		
	2010/11	2014/15	Total	Average annual	Total discounted
(a) None	-	-	-	-	-
(b) Chair and Chief Executive	0.5	0.4	4.6	0.5	3.9
(c) Chair, Chief Executive, and half of all Directors & Members	1.0	0.9	9.4	0.9	8.1
(d) All Staff	7.7	6.2	67.8	6.8	58.0

2. For scenario (a) there are no savings, as it is assumed that there is no incremental change in staffing.

3. Under scenario (b), the second column shows the total expenditure in 2010/11 on the Chief Executive and Chair of the HFEA and HTA, as reported in their Annual Reports. This includes on-costs for Chief Executives (assumed to be 30% to cover pensions, national insurance and other benefits), but not for Chairs. In 2010/11, this was £0.5m (column 2). It is assumed that there is a pay freeze lasting roughly until 2014/15, so that salaries and remuneration remain the same in nominal terms. The following analysis assumes 2014/15 as the price base year, so salaries and remuneration in real terms in 2014/15 are £0.5m. However, from April 2012, the roles of Director of Strategy and Chief Executive are combined at the HFEA, reducing overall salaries. The final level of pay of the Chief Executive of the HFEA is not known, but is assumed to be the average of the two outgoing posts (reflecting that more responsibility garners a higher salary, but also that it is unlikely to be as high as the outgoing Chief Executive). This suggests the wage bill for Chairs and Chief Executive (including on-costs) may be in the region of £0.4m in 2014/15 (column 3).

4. The savings over ten years (column 4) are assumed to be the total salary and remuneration of the Chair and Chief Executive over ten years from 2014/15 to 2023/24. Over this period, salaries and remuneration are expected to grow by 2% per year in real terms (based on the Treasury GDP deflator that reflects long run productivity growth). This generates a total potential saving of £4.6m. Averaged over this period given an annual benefit of £0.5m per year (column 5). When discounted at 3.5% to the base year of 2014/15, the present value of the costs is £3.9m (column 6). If a longer time period is considered, more of the benefits would be taken into account. However, this would be associated with increased uncertainty, so the limit is drawn at ten years.

5. This assumes that the roles of Chair and Chief Executive can be undertaken by the relevant personnel at CQC and the HRA without having to take on additional staff. Other staff may need to

take on some of these responsibilities, implying this is an overestimate of the benefits. However, at this stage it is uncertain whether this would be the case and is something which would be determined by the recipient bodies.

6. The penultimate row provides indicative figures for savings for scenario (c), i.e. if the Chair, Chief Executive, and half of all Directors and Members are no longer employed. The half of directors and members does not assume which specific posts would no longer be required, rather it takes half of the overall savings that would arise if all Directors and Members are made redundant. This incorporates the part-time work of some posts. As Directors are salaried, their savings include 30% on-costs. Members only receive remuneration, so no on-costs are included. The savings over 2014/15 to 2023/24 (columns 4-6) are calculated as for scenario (b).

7. This figure may overestimate the final savings, as Directors of the HFEA and HTA may have a number of other responsibilities that may not be taken on by the Directors of the recipient bodies. These responsibilities may need to be taken on by other individuals. If these individuals are already at the recipient bodies, then the estimates would not need to be adjusted. However, if other staff members are required then the benefits would be an overestimate.

8. The last row shows results for scenario (d), i.e. if all staff are no longer employed. This is not a plausible scenario, and provides only an indication of the scale of the figures involved. Annual Reports state the total expenditure on staff totalled £7.7m in 2010/11 (£4.6m for the HFEA and £3.1m for the HTA, column 2). The HTA has estimated that it will reduce its staffing between 2010/11 and 2014/15 from 54 FTE to 44 FTE, and that its total expenditure on staff would be £2.6m in 2014/15 (implying an average salary of £46,000). The HFEA has estimated that that it will reduce its staffing between 2010/11 and 2014/15 from 86 FTE to 67 FTE, although does not suggest what its total expenditure on staff would be. Assuming the same average salary (i.e. £41,000), this would suggest a total spend of £3.6m in 2014/15. This suggests that total staff expenditure in 2014/15 may be in the region on £6.2m (column 3). The savings over 2014/15 to 2023/24 (columns 4-6) are calculated as for scenario (b).

Costs

9. The same four scenarios are considered as in the benefits section: (a) no redundancy payments are made, (b) redundancy payments are made to the Chief Executive of the HFEA and HTA, (c) redundancy payments are made to the Chief Executive and half of all Directors of the HFEA and HTA. Redundancy payments are not made to Chairs or Members since they are on fixed term contracts with specific exclusion of entitlement to compensation for loss of office through employment law. A further figure (d) is presented, indicating the maximum scale of redundancy payments if received by all staff at the HFEA and HTA. It should be noted that (d) is not a plausible scenario, and provides only an indication of the scale of the potential costs involved.

Table A2. Indicative costs of redundancy and reorganisation

Staff made redundant	Redundancy Costs (2014/15) (£m)	Transition Costs (2014/15) (£m)
(a) None	-	-
(b) Chair and Chief Executive	0.03	0.16
(c) Chair, Chief Executive, and half of all Directors & Members	0.06	0.34
(d) All Staff	0.86	5.08

10. Redundancy costs are assumed to be one-fortieth of the final salary of the individual multiplied by the number of years of employment at the organisation. Salaries for Chief Executives and Directors

are as calculated in the benefits section, as are the average salaries for all staff (£41,000 at the HFEA and £46,000 at the HTA).

11. Joining dates for Chief Executives and Directors were identified from Annual Reports, and service was assumed to continue until transition in 2014/15. Adjustments were made for part time working. Length of service for all staff was based on estimated 2014/15 staffing levels of 67 in the HFEA and 44 in the HTA. The HFEA and HTA were assumed to have the same number of FTEs at their creation (1991 and 2005 respectively) as at 2014/15. While this is unrealistic, it provides an overestimate of the length of service of the staff currently at these organisations, thereby overestimating the redundancy payments. Staff turnover was assumed at 10% per year (this could also be interpreted as the growth rate of the HFEA and HTA, avoiding the previous assumption). This generated the average length of service for staff at each organisation in 2014/15 – approximately 8 years for the HFEA and 6 years for the HTA. It is recognised that the average length of service may still be less, in which case the costs would be less.

12. Multiplying one-fortieth of the total salaries for each scenario by the length of service of the relevant individuals gives the total redundancy costs in column 2. These are approximately £0.03m for scenario (b), £0.06m for scenario (c) and around £0.9m for scenario (d). These are expressed in 2014/15 prices and are expected to occur over one year only. Therefore the discounted redundancy costs (to a base year of 2014/15) are identical.

13. Total reorganisation costs are calculated based on this estimate of redundancy costs. The National Audit Office (NAO) surveyed central government organisations that had been reorganised, identifying areas of expenditure incurred with the reorganisation process. The main areas of expenditure identified included staff, IT, property, corporate functions, branding & communications and indirect costs. Staff redundancy costs made up 17% of all costs incurred by organisations in their reorganisation. Redundancy payments reflect a real cost to those made redundant and so they are not treated as a transfer payment. Due to uncertainty around the final organisational structure, the associated reorganisation costs are highly uncertain.

14. Total reorganisation costs are assumed to be approximately six times (1/0.17) greater. It is important to note one major issue with this methodology: it assumes that costs other than redundancy (i.e. IT, property, corporate functions, branding & communications) are directly proportional to redundancy payments. Therefore, it assumes by implication that there are no fixed costs to reorganisation, which is implausible. All non-redundancy costs (IT, property, corporate functions, branding & communications) are likely to include fixed elements. Nevertheless, the methodology provides a rough approximation of the scale of the costs involved. Column 3 presents these rough reorganisation costs, assumed to be six times greater that redundancy costs alone.