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

Response by the Human Fertilisation and Embryology Authority

September 2012

1 Executive summary

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

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

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

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

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

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

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

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

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

- Transferring a small dedicated, expert regulator like the HFEA into a large, general regulator like the CQC presents real operational risks. Staff may leave and corporate memory be lost. Complex issues relating to assisted reproduction might get insufficient senior attention in the CQC, with the result that mistakes are made; or they might take a disproportionate amount of the Board's time at the expense of the important issues the CQC already regulates. This could undermine the public's confidence in the regulatory system. Once lost, restoring confidence would be difficult and expensive.

- The law will remain the same, so the detailed regulatory requirements set out in the Act will still need to be administered by the CQC. Those who hoped that this consultation would usher in a different regulatory regime will be disappointed.
- And while we understand the need to release savings for the front-line, abolishing the HFEA will not make a real difference. In the context of the expenditure on the NHS, the costs savings that are claimed to result would be miniscule.

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

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

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

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

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

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

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

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

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

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

Summary	
Our functions: We set and enforce standards, and safeguard people's information.	**Main points to note:** 1. These functions are fully integrated and each informs the other. 2. This joined-up model is critical in such a fast-moving and highly charged area of science and ethics. 3. Parliament was wise to set us up in this way. Anything else would be too slow to respond, and would have other risks attached too. 4. This model has the public's confidence – because it works.

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

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

Principally, the HFEA:

- **Licenses clinics:**

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

- **Makes policies:**

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

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

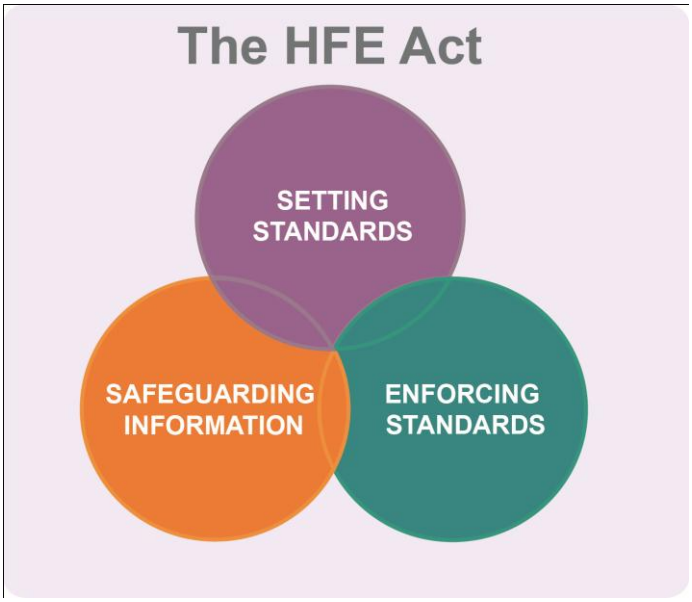
  We authorise screening for specific and serious conditions that can be diagnosed in embryos prior to implantation in a woman

- **Keeps personal and identifiable information:**

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

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

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



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

Setting standards

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

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

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

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

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

Enforcing standards

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

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

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

Safeguarding information

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

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

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

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

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

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

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

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

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

3 Response to the questions

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

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

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

Summary	
HFEA response: No.	**Main reasons:** 1. Many more risks than benefits. 2. The hoped-for benefits are few and optimistic, and any financial savings yielded would be tiny. 3. Too big a mis-match in terms of scale, nature, coverage and regulatory concerns. Our functions would either divert resources disproportionately or receive too little attention. 4. There are governance obstacles to overcome, owing to the HFEA's legal duties – which will not change, whoever delivers them.

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

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

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

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

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

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

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

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

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

Risks to delivery

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

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

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

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

Risks to governance

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

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

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

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

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

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

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

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

Summary	
HFEA response: Yes – in relation to proposals to reduce regulatory overlap.	**Main points:** 1. There is some regulatory overlap between HFEA and CQC and this is keenly felt by some licensed centres, although we think the extent is overstated in the consultation document. 2. We have already proposed ways in which this can be tackled, now and in the longer term. 3. Within the healthcare system there are many organisations responsible for ensuring quality – each must recognise the others' roles and co-operate productively.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Summary	
HFEA response: No.	**Main reasons:** 1. The regulation of embryo research is intimately bound up with the regulation of treatment. 2. We provide a tight/single oversight of the embryo from treatment to research. 3. There would be few if any savings and greater administrative burdens for some centres. 4. The application process for researchers can be streamlined by closer working between the HFEA and the HRA.

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

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

Warnock

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

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

The statutory framework

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

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

The policy and decision-making framework

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

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

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

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

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

Operational issues

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

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

The consequences of transfer

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

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

Improving the regulation of research

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

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

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

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

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

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

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

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

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

Summary	
HFEA response: No.	**Main reasons:** 1. Our Register information is about people's lives and genetic origins. It is also highly inter-dependent with our regulatory methods. There are risks associated with moving it, and we do not view it as a good fit into the HSCIC. 2. Our information provision role is critical, and must reside in the same place as the Register. 3. Moving donor remuneration policy to the Department of Health risks undermining the principle that such decisions are taken at arm's length from the Government of the day.

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

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

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

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

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

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

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

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

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

Transferring our information provision functions to the Department of Health

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

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

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

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

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

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

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

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

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

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

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

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

Summary	
HFEA response: Yes. This is our preferred option.	**Main reasons:** 1. We have put in place an efficiency programme that has reduced our costs by 30% since 2009. We have plans to make further savings by working with the 'shared service' programme. 2. We have been responsive to the public debate on the HFEA's future, and, where we can, we have made changes to the way we work – with more to come. 3. This is not a plea for the status quo. We accept and welcome the opportunity for a radical look at how we continue to improve and to deliver further efficiencies.

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

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

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

HFEA programme of efficiency

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

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

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

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

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

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

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

Public debate on the future of the HFEA

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

Changes in society's attitude to reproduction

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

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

Efficiency in regulation

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

Costs

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

The HFEA's 'brand'

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

Concern about the location of transferred functions

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

Response and way forward

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

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

Inspections

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

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

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

Data collection and validation

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

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

Research licensing

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

- Work closely with the HRA
- Join IRAS.

Future possibilities

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

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

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

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

Summary	
HFEA response: Yes.	**Main reasons:** 1. Since 2010 our expenditure has reduced from £8m to £6m, and the number of people who work for us has reduced from 86 to 70. 2. By the end of the year 2014/15 we will have reduced our expenditure to £5.8m and the number of people working for us to 67. 3. Taking into account our current functions, savings beyond those identified above could not realistically release *significant* sums of money, without directly impacting upon the delivery of core functions.

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

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

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

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

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

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

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

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

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

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

Summary	
HFEA response: No.	**Main reasons:** 1. It would damage effectiveness. The inter-linked nature of what we do is real and adds value. 2. Policy and operations benefit from being together; separation is known to be perilous.

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

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

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

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

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

Summary	
HFEA response: We have a number of comments, and we consider this a limited exercise on which to base decisions on the transfer of functions.	**Main reasons:** 1. The efficiencies expected from option 1 are far too small to meet the stated aim of contributing to reducing NHS costs by a third. 2. Less than £4m released in 10 years equates to about 3 minutes per year of NHS running time. 3. We believe there is overestimation of benefits and underestimation of costs of transfer. 4. We believe the assessment is based on a too narrow set of assumptions and variables; a small change in any of these can produce a very different outcome.

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

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

These are our observations on the impact assessment:

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

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

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

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

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

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

No.

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

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

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

No.