Department of Health

Triennial Review of the Human Fertilisation and Embryology Authority

Review Report

April 2017

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Executive Summary

The Human Fertilisation and Embryology Authority (HFEA) is an Executive Non-Departmental Public Body of the Department of Health (the Department or DH). The Triennial Review of the HFEA was conducted to provide assurance to the Department and the public that the HFEA's functions are required and the body is operating efficiently.

The HFEA was established under the Human Fertilisation & Embryology Act 1990. Its key function is the regulation of treatments and research using human embryos, eggs and sperm (gametes).

This Triennial Review was announced through a Written Ministerial Statement on 25 June 2015. Stage One of the review considered whether the functions undertaken by the HFEA are necessary and, if so, whether they could be better delivered through another organisational structure. Stage Two moved on to an assessment of the HFEA's performance, efficiency and governance. The review process included gathering evidence from stakeholders, interviews and analysis of written material.

Main findings

The review concluded that the HFEA is a well-run organisation, performing necessary functions effectively. Overall, the review team found considerable support for the HFEA, which is highly regarded by the large majority of stakeholders from whom we received views. There was a clear belief from stakeholders, with which the review team concurs, that there remains a need for a regulatory body with substantial expertise of operating in a specialised area of medical science that also raises complex moral and ethical issues.

The HFEA commands high levels of confidence from a wide range of stakeholders both in the UK and internationally. It has been the subject of a number of reviews in recent years and has responded proactively to issues raised in those reports to improve performance and reduce costs.

Stage One of the review concluded that the functions were necessary and that the current form of the HFEA is most appropriate.

Recommendation 1: that the functions of the HFEA continue to be required.

Recommendation 2: that the HFEA should continue to operate in its current form.

Stage Two of the review looked at performance, efficiency and governance issues. Particular areas of focus for the review included: the potential for the HFEA to further develop a coordinated approach with other regulators and inspection regimes; the management and

provision of information; and delivery of the recommendations set out in the 2013 report by Justin McCracken[1]. There are a further 15 recommendations.

Recommendation 3: that the HFEA works cooperatively with UKAS to ensure that incidents in laboratories that provide services to clinics are investigated effectively.

Recommendation 4: that the Department of Health coordinates arrangements to support the HFEA and other health and care system regulators to provide an even more joined-up regulatory framework.

Recommendation 5: that the HFEA continues to work with the MHRA and others to develop and manage an effective oversight process for culture media and other medical devices, and communicates this to relevant stakeholders.

Recommendation 6: that the HFEA continues to enforce consent requirements and applies robust penalties where appropriate. In doing so, that the HFEA works with clinics to share best practice arrangements and provide any necessary guidance; for example, encouraging clinics to adopt digital processes potentially safeguarding the completion of each stage in the process.

Recommendation 7: that the HFEA, as part of the Information for Quality programme, builds on the information and guidance it currently provides for prospective patients on the various IVF services and treatments that are available, including the evidence for medical efficacy, the potential risks, and the likely costs.

Recommendation 8: that the HFEA builds on its approach of working collaboratively with the other regulators to support further development of the Regulatory Advice Service for Regenerative Medicine to provide support to researchers to understand and manage the regulatory requirements.

Recommendation 9: that the HFEA publishes on its website an annual update on horizon scanning issues.

Recommendation 10: that the HFEA undertakes a follow-up stakeholder survey, as recommended in the McCracken report, to assess attitudes and satisfaction following implementation of its stakeholder engagement programme.

[1] Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority, Justin McCracken, April 2013.

Recommendation 11: that the HFEA considers the practicalities of inclusion, within its performance measures, of an assessment of comparative performance against relevant high-performing organisations.

Recommendation 12: that the Department of Health assists the HFEA by working to better manage information and reporting requests of all arm's length bodies, having regard to proportionality and reflecting differences in the size of, and resources available to, such bodies.

Recommendation 13: that the HFEA and the Department of Health, having regard to the outcome of wider decisions on policy, priorities and ensuring value for money, explore whether there are opportunities to work with stakeholders to provide further information and best practice on the commissioning of fertility treatments.

Recommendation 14: that the HFEA works with the Department of Health and other arm's length bodies to explore further opportunities to share services and develop implementation plans.

Recommendation 15: that the HFEA, working with the Department of Health, NHS Digital and the Government Digital Service as necessary, explores further the relative benefits of hosting its database with NHS Digital.

Recommendation 16: that the HFEA, working with the Department of Health and the Government Digital Service as necessary: (i) seeks to ensure that the replacement IT system is compatible with those in other organisations with whom it may share information; and (ii) agrees target efficiency savings to be delivered from the new IT system.

Recommendation 17: that the HFEA develops plans for non-executives and key staff that maximises knowledge retention and transfer.

Next steps

The HFEA, working with the sponsor team in the Department of Health, should produce a plan to take forward these recommendations over the next 12 months. It is acknowledged that not all recommendations can be completed in this period and that not all recommendations are for the HFEA to take forward. The sponsor team should monitor progress and ensure that the Department of Health is actively engaged in decisions taken.

Acknowledgements

The review team would like to thank everyone who contributed to the review process. Particular thanks go to Peter Thompson, Sam Hartley and Joanne McAlpine in the HFEA and to all those who took the time to meet with the review team or respond to the call for evidence.

1. Introduction and background

Aims of the Review

1.1. It is government policy that an arm's length body (ALB) should only be set up, or remain in existence, where there is clear evidence that this model is the most appropriate and cost-effective way of delivering the function in question.

1.2. In April 2011, the Cabinet Office announced that all Non-Departmental Public Bodies (NDPBs) still in existence following the first stage of public bodies reform would have to undergo a substantive review once in a three year cycle. Triennial Reviews (TRs) have two main stages:

- stage one tests the continuing need for the body, both in terms of the functions it performs and the model and approach in which they are delivered; and
- stage two considers the body's governance, performance and capability as well as exploring opportunities for efficiencies.

1.3. The health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, resulted in the devolution of functions and powers away from the DH to ALBs and local health and care organisations. As steward of this evolving system, the DH is using TRs to provide assurance that the system, and the ALBs within it, is fit for purpose.

1.4. Although the Cabinet Office requirement for government departments to undertake TRs currently applies only to NDPBs, the DH is including its Executive Agencies and Special Health Authorities within this process, with the reviews playing a key role in supporting effective stewardship and oversight of the Department's ALBs. The TRs are conducted in line with Cabinet Office guidance2 so far as is appropriate and relevant. This guidance states that all reviews should be conducted in line with the following principles:

- **Challenge** Reviews must be challenging. They should take a first principles approach to whether the function of a body is still needed, and if it is what the best form for delivery of that function is. Reviews should not just seek to evidence the status quo. They should be robust and rigorous and provide evidence for all recommendations. They must consider issues of efficiency, including the potential for efficiency savings, and make relevant recommendations. They should consider the performance of the body, and whether it could provide better value for money, including in terms of the body's contribution to economic growth. A description of how the review will be structured to meet this aim should be set out clearly in the

[2] Guidance on Reviews of Non Departmental Public Bodies, revised in 2014.

Terms of Reference, which will be agreed between the department and Cabinet Office.

- **Proportionality** Reviews must not be overly bureaucratic and should be appropriate for the size and nature of the NDPB being reviewed. Where appropriate, reviews of similar bodies should be combined or clustered to ensure the maximum benefit in terms of streamlining the review process, identifying synergies across departments and NDPBs, and considering efficiency.

- **Contextual** Reviews should not be undertaken in silos, but should wherever possible be integrated with other departmental policy initiatives, efficiency reviews or landscape reviews, and seek to look across departmental boundaries to cluster reviews of bodies to further enable informed discussions about potential efficiencies. Departments should consider the potential for integration when building their Triennial Review timetable and Cabinet Office will assist departments in doing this.

- **Pace** Reviews must be completed quickly to minimise the disruption to the NDPB's business and reduce uncertainty about its future. Reviews should normally take no more than six months. Timetables, including start and completion dates, for individual reviews will be agreed with Cabinet Office at the beginning of each review.

- **Inclusivity** Reviews must be open and inclusive. The NDPB being reviewed must be engaged and consulted at both an Executive and a Non-Executive level. Users and stakeholders must have the opportunity to comment and contribute. Parliament must be informed about the commencement and conclusions of reviews. Departmental Select Committees must be given the opportunity to input.

- **Transparency** All reviews must be announced formally, both to Parliament and to the public. All review reports must be published once clearance has been given by the Minister for the Cabinet Office. The results of reviews must be announced to Parliament.

Process and methodology of the HFEA Triennial Review

a) Governance

1.5. The review was conducted by a small Department of Health team working under direction of an impartial Senior Review Sponsor (SRS).

1.6. The review was overseen by a Project Board that was chaired by the SRS. The review was also subject to scrutiny by a Critical Friends Group. The Critical Friends Group looked also at the Triennial Review of the Human Tissue Authority (HTA). Details of the membership of the review team, the Project Board and the Critical Friends Group are set out in Annex A. The Project Board and Critical Friends Group each met 3 times during the review process.

1.7. The terms of reference for the review are set out at Annex B and a copy of the Written Ministerial Statement announcing the review is at Annex C.

b) Stakeholder engagement and call for evidence

1.8. Stakeholder engagement was a key element of the evidence gathering process. The review team sought to obtain views from a wide range of stakeholders to pick up key themes emerging from a variety of viewpoints. The full list of stakeholder respondents is provided at Annex D and a list of the call for evidence questions is at Annex E. Evidence was though gathered through a variety of means:

- a public call for evidence announced on the Department of Health website and open between 3 July and 31 August 2015. This included 12 questions seeking views on the HFEA;
- a total of 28 stakeholder interviews (including HFEA board members and staff, experts in the health and care system, regulated bodies and professional groups);
- two workshops to which stakeholders were invited to attend; and
- analysis of other published material (Annex F provides a list of the key papers used).

c) Previous reviews of the HFEA

1.9. Several reviews have taken place in recent years looking at various aspects of the HFEA and its functions:

- the Department of Health published a report[3] reviewing all of its arm's length bodies in 2010. This report proposed, for both the HFEA and the Human Tissue Authority, that the department should consider the practicalities of transferring functions to the Care Quality Commission (CQC), the Health and Social Care Information Centre and a new research regulator (now the Health Research Authority (HRA));
- this was followed by a public consultation, published in June 2012, on proposals to transfer the functions of the HFEA and HTA to the CQC and HRA. The response to this consultation process was published in January 2013[4]. There were 109 responses and a large majority were opposed to the transfer of functions; and

[3] Liberating the NHS: Report of the arm's-length bodies review - July 2010, Department of Health

[4] Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority – January 2013

- consequently, Justin McCracken (then Chief Executive of the Health Protection Agency) undertook a review[5] aimed at supporting the HFEA and HTA in delivering efficiencies in the way in which they undertake their functions. This Triennial Review considers the extent to which the recommendations made by Mr McCracken have been implemented.

1.10. It was agreed at the outset of this review that it would not reopen issues that have been covered recently in other reviews unless there was compelling evidence to do so. For example, the review has not re-opened consideration of a possible merger between the HFEA and HTA or the transfer of functions as considered in the 2012 consultation.

d) Estimated costs of the review

1.11. The review team started planning the review in May 2015. This report was drafted by December 2015 and cleared for publication by October 2016. The review team worked on other reviews simultaneously and an estimate has been made of the time allocated to this review. On this basis, the direct costs of the review, based on eight months duration, are set out in Table 1 below. There were no travel or other costs as interviews either took place in London or via telephone or video-conference. This estimate does not take account of indirect costs, such as the time contributed by HFEA members and staff.

Table 1: Estimated cost of the Triennial Review of the Human Fertilisation & Embryology Authority.

Role	Proportion of time spent on review	Estimated cost
SRS	0.05 * 0.66	£4,126
Lead Reviewer	0.4 * 0.66	£26,644
Assistant Reviewer	0.5 * 0.66	£13,510
Assistant Reviewer	0.3 * 0.66	£8,106
Total estimated cost		**£52,386**

About the HFEA

1.12. The HFEA is an Executive Non-Departmental Public Body of the Department of Health. The HFEA is responsible for licensing fertility treatments and research conducted using human embryos.

[5] Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority - Justin McCracken, April 2013

1.13. The HFEA was established in 1991, under powers in the Human Fertilisation & Embryology Act 1990 (HFE Act 1990). This followed a 1984 report, of the Committee of Inquiry into Human Fertilisation and Embryology, led by Dame (subsequently Baroness) Mary Warnock, which recommended setting up a body to regulate human embryo research and assisted reproduction treatment.

1.14. Its role is UK wide. It sets standards for, and issues licences to, fertility clinics. The HFEA is a statutory body and its main functions as a regulator under the HFE Acts 1990 and 2008, and associated secondary legislation, are to:

- license and monitor clinics carrying out in vitro fertilisation (IVF) and donor insemination;
- license and monitor establishments undertaking human embryo research;
- maintain a register of licences held by clinics, research establishments and storage centres;
- regulate storage of gametes (eggs and sperm) and embryos for treatment or research;
- as the UK's Competent Authority, implement the requirements of the European Union Tissue and Cells Directive (EUTCD) as far as gametes and embryos are concerned; and
- license intrauterine insemination (IUI), gamete intrafallopian transfer (GIFT) and other services.

1.15. The HFEA also provides guidance and advice. It has a statutory duty to produce and maintain a Code of Practice setting out quality and safety standards for treatment and research.

1.16. It also has a duty to maintain a formal register of information about donors, licensed treatments and children born as a result of those treatments and has a role in providing relevant advice and information to donor conceived people, donors, clinics, research establishments and patients, including servicing the statutory right of access to register information. It also reviews information about human embryos and developments in research involving human embryos.

1.17. The HFEA covers an area of activity that can raise complex and contentious legal, moral and ethical issues. To quote from the Warnock report[6], "The issues raised reflect fundamental moral, and often religious, questions which have taxed philosophers and

[6] http://www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into_Human_Fertilisation_and_Embryology_1984.pdf

others down the ages." In recommending its establishment the Warnock report said that it should not primarily be a medical or scientific body but should take a broader view and protect the public interest.

2. Stage One: Function

The HFEA's functions and supporting legislation

2.1. The HFEA is a statutory body and its functions are set out in the HFE Acts 1990 and 2008. Its responsibilities cover the whole of the UK, as recommended in the Warnock report.

2.2. The table below provides a detailed breakdown of the HFEA's functions, all of which have a statutory basis.

Table 2: Breakdown of HFEA functions

Breakdown of HFEA Functions				
	Function/Activity	**Legislative requirement**	**Purpose (objectives, beneficiaries)**	**Approximate spend**
1	To license and inspect fertility clinics and research establishments working with human embryos.	**Yes** - 1990 Act, Sections 11-21 & Schedule 2 (licensing) and Section 38A and Schedule 3B (inspection).	The HFEA's core function is the licensing and regulation of fertility clinics and research centres in the UK – this goes to the heart of the HFEA's strategic aim of ensuring high quality, safe care for patients, though its regulatory activities. There is a direct benefit to patients in relation to the safety and quality of the care they receive. The HFEA's role as a regulator is underpinned by its inspection and licensing activities. It extends to the monitoring of the performance of clinics and, further, to having in place a robust process for dealing with incidents and complaints about clinics, under the framework of the	£2.574m
2	To observe the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed.	**Yes** – 1990 Act, Section 8ZA.		
3	To investigate serious adverse events and reactions and take appropriate control measures.	**Yes** – 1990 Act, Schedule 3A.		

4	To share information with the competent authorities of other European states in relation to adverse incidents and to carry out inspections requested by such a competent authority relating to a serious adverse event or reaction, and to take any appropriate control measures.	**Yes** – 1990 Act, Section 8A.	compliance cycle. This work is supported by the need to maintain open lines of communication with other competent authorities across Europe, and other regulators in the UK.	

5	To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities. To promote compliance with the legislation and the Code of Practice.	**Yes** – 1990 Act, Sections 8 and 25.	The HFEA's Code of Practice is the vehicle through which its regulatory scheme and approach is communicated to clinics. It is intended to help and encourage its licensed establishments to understand and comply with their legal requirements. It also gives guidance on how centres are expected to go about meeting those requirements. The guidance in the Code also serves as a useful reference for patients, donors, donor-conceived people, researchers and those working in the fertility sector. This has a direct benefit to the staff at the clinics, in having clear and unambiguous advice on the requirements put in place, which allows for and encourages good practice resulting in better quality of care for patients.	£1.047m

6	To keep formal registers of: • Information about donors, treatments and children born as a result of those treatments. • Licences granted. • Certain serious adverse events or reactions	**Yes** – 1990 Act, Section 31.	This data is used to improve outcomes and research. It also has an essential role in supporting donors and donor-conceived people in accessing data as provided for in legislation. The improvements the HFEA is making to its data-collection and presentation work in the Information for Quality programme will directly benefit patients by ensuring that they have access to high-quality meaningful information through the HFEA website, allowing patients to take better-informed decisions.	£742k
7	To publicise the HFEA's role and provide advice and information to the donor conceived, donors, clinics, research establishments and patients.	**Yes** – 1990 Act, Section 8.	The HFEA aims to make its website, and its 'Choose a Fertility Clinic' tool, the authoritative location for all patient enquiries and needs. The IVF sector has a majority of private treatments and it is considered essential that the HFEA provides authoritative and independent information for patients seeking treatment. Additionally, the HFEA publishes a 'guide to fertility' for new patients seeking treatment, and maintains the 'Lifecycle' campaign, which provides information about donor conception. This information is of direct benefit to patients.	£846k

8	To review information about: • Human embryos and developments in research involving human embryos. • The provision of treatment services and activities governed by the legislation. And to advise the Secretary of State for Health on developments upon request.	**Yes** – 1990 Act, Section 8.	The HFEA's statutory role as expert advisor on matters of fertility treatment and research is well-established. Most recently, it convened an expert panel to provide advice relating to the use of Mitochondrial Donation as a treatment. This advice, led to Parliament's decision to approve the use of Mitochondrial Donation as a treatment.	£507k

Are the functions necessary?

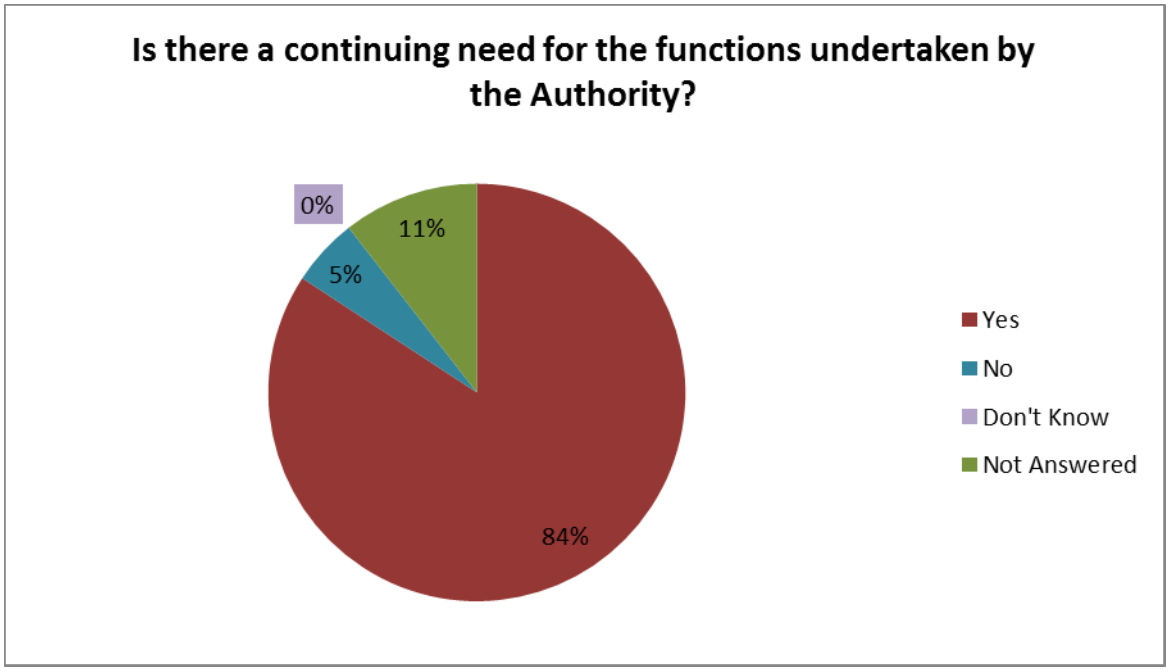
2.3. The first birth through in vitro fertilisation occurred in 1978. It demonstrated the rapid advancement of medical science but raised ethical and moral questions about the extent to which what was technologically possible should nevertheless be regulated. This led to the review, led by Baroness Warnock, which was established in July 1982 and reported in July 1984. This comprehensive report made a number of recommendations surrounding the regulation of treatments and research, the legal and consent arrangements for donors, patients and other parties, and the establishment of a regulatory body. This led directly to the HFE Act 1990 and establishment of the HFEA.

2.4. Since that time the treatment of infertility through in vitro fertilisation has become commonplace. Worldwide, an estimated five million babies have now been born following IVF treatment, with more than 225,000 born in the UK. As such, it could be argued that IVF has, for the most part, become a standard medical procedure that is much less at the cutting edge of medical science than many unregulated treatments. That is not, though, to suggest that all IVF treatment has become routine and the boundary of what is possible is continually being expanded.

2.5. However, the fundamental difference between IVF and other medical treatments remains that fact that the purpose and end result is the creation of new human life. It may also lead to new family forms and legal relationships that could not exist previously. This was the point made again and again in stakeholder interviews. As such,

stakeholders strongly supported (see Figure 1 below as an example) the continued need for the functions carried out by the HFEA).

Figure 1: Call for evidence responses - Functions



2.6. There were nevertheless some areas where a minority of stakeholders expressed the view that the HFEA regulates activity beyond its clear legislative remit. In particular, these concerns centred on the extent to which the HFEA should gather and share information about the relative performance of fertility clinics and whether such information should incorporate patient feedback.

2.7. Consideration of the benefits or otherwise of the HFEA providing information is covered in more detail in Section Two of the report. For the purposes of considering its functions it was clear that areas of disagreement among stakeholders related not to the function per se, which was largely seen as necessary, but rather to the scope of that function. However, the legislation clearly provides for the HFEA to make its own judgement on the extent of information made available:

"The Authority shall - provide to such extent as it considers appropriate, advice and information for persons to whom licenses apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act..."

2.8. Additionally, notwithstanding the formal legislative powers, the review found clear evidence that the collection of data to help inform and support patient decisions was highly valued.

2.9. The other area of HFEA activity that was questioned by a small number of stakeholders related to the work undertaken in supporting a reduction in multiple births resulting from IVF treatment. For many stakeholders this is an example of the HFEA using its position as regulator to encourage practices that reduce health risks to both mothers and babies but a few argued that this falls outside the legislative remit.

2.10. Multiple births following pregnancy is regarded as the biggest single risk of fertility treatment, increasing the risk of stillbirth, neonatal death and disability. The primary cause of the increased rate of multiple births is the practice of transferring multiple embryos during IVF treatment. The natural rate of multiple births in pregnancy is under 2% but in 2005 the rate following IVF treatment was around 24%.

2.11. The HFEA launched a review in 2005 to consider what more could be done to reduce multiple birth rates. This resulted in a policy aim to reduce multiple birth rates to 10% over a period of time. This policy was introduced in 2009. It allowed clinics to develop their own policy for reducing multiple births through the use of elective single embryo transfer (where appropriate), though until 2014 the HFEA enforced this through applying a licence condition that a clinics multiple birth rate must be below the HFEA target. By 2013 the rate of multiple births following IVF treatment had fallen to around 15%.

2.12. The statutory basis for this activity is provided in sections 12 and 13 of the HFE Act 1990. This gives the HFEA the power to issue Directions. HFEA Directions 0003 require centres to have a multiple births minimisation strategy, and section 17 of the Act allows the HFEA to issue regulatory sanctions for non-compliance with the multiple births policy. In addition, the review team found clear evidence that the policy on multiple births provided significant beneficial public health outcomes.

2.13. There was also one area that some stakeholders were concerned was not currently sufficiently regulated. This relates to culture media, which is a solution used to support embryo development in a petri dish prior to transfer to the womb. A number of stakeholders suggested that the HFEA should be given responsibility for regulating use of culture media through the licensing process. This issue is covered further in Section Two of this report and, from the viewpoint of the HFEA's functions, concludes that this issue can be adequately addressed through effective engagement between the HFEA and the Medicines and Healthcare Products Regulatory Agency.

2.14. In conclusion, the review team found a clear and continuing need for regulation of the treatment and research related to human fertility and embryology. Where questions were raised by stakeholders regarding the scope of the functions, the HFEA has already been engaging with stakeholder groups to agree a consensual approach where possible.

Recommendation 1: that the functions of the HFEA continue to be required.

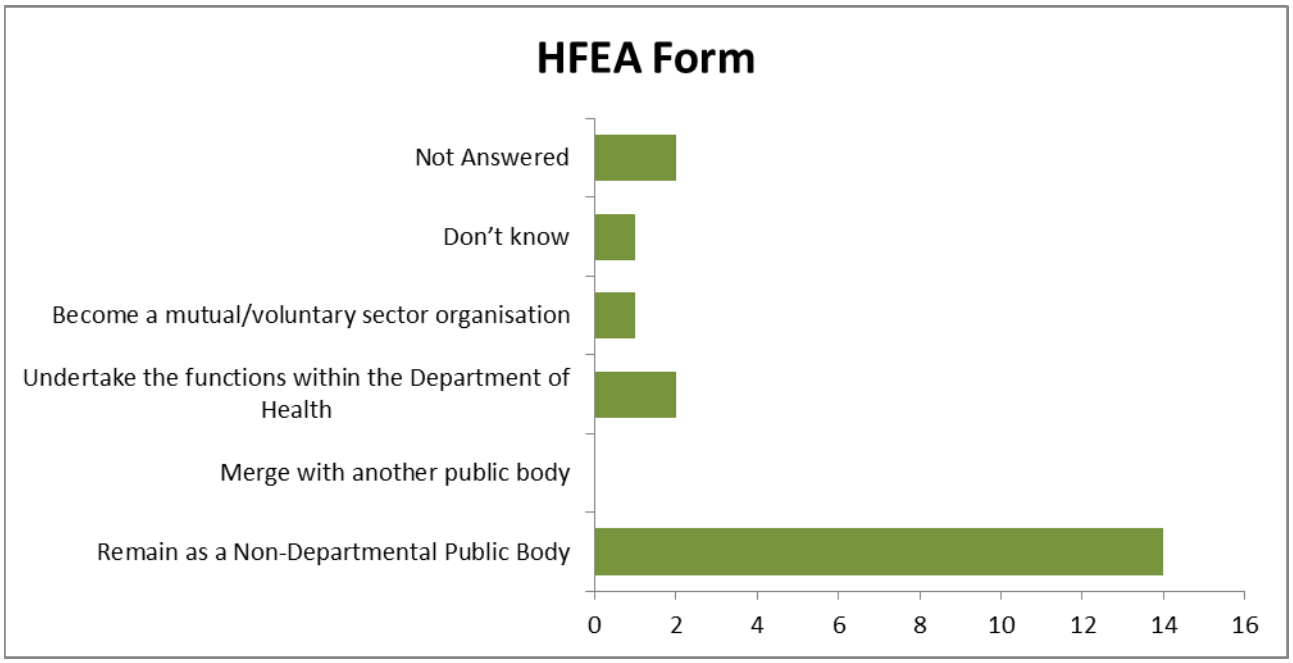
3. Stage One: Form

3.1. The HFEA is an Executive NDPB of the Department of Health. Such a body operates at arm's length from the Department and Ministers but there must nevertheless be an appropriate degree of support, oversight and scrutiny.

3.2. The form of the HFEA has been considered a number of times in recent years (see paragraphs 1.9-10 above). This review has considered a range of options, as set out below, but did not seek to re-open conclusions reached in recent reviews unless compelling evidence was provided to do otherwise.

3.3. The Call for Evidence responses (as shown in Figure 2 below) and stakeholder interviews indicated that the large majority of stakeholders felt that the HFEA should retain its current independent structure as a NDPB. There was very limited desire among stakeholders to see any change to the form of the HFEA, though a small number expressed concerns about overlapping regulatory functions or suggested that the functions should be brought within the Department of Health.

Figure 2: Call for evidence responses - Form



International Comparisons

3.4. The Review Team sought to make comparisons between the HFEA and equivalent bodies internationally. Information was obtained primarily through checking websites online, though it was also sought through stakeholder interviews. Such comparative information is valuable in helping to assess alternative approaches to the functions and

form of the HFEA, and in determining whether there are any lessons that could be drawn.

3.5. The research undertaken revealed no clear direct international comparisons to the HFEA; though the approaches in some other countries are briefly summarised below.

3.6. Many countries (in Europe this includes Ireland, Poland and Luxemburg for example) have no legislation in place regarding assisted reproduction and therefore no comparator organisations. In contrast, countries such as Belgium, the Netherlands and Finland, have well developed processes with highly regarded clinics and low multiple birth rates.

3.7. The Assisted Human Reproduction Agency of Canada (established 2004) seemed the closest comparator but the body was wound down in 2012 in response to changes in legislation and its responsibilities were assumed by Health Canada.

3.8. In Australia, the Reproductive Technology Accreditation Committee has established a Code of Practice for Assisted Reproductive Technology (ART) that is an essential compliance requirement for ART organisations. Additionally, an Embryo Research Licensing Committee regulates research activities involving the use of human embryos. Its functions in relation to research closely reflect those of the HFEA, involving licensing, inspections and maintaining a database.

3.9. There are also several international organizations that seek to share knowledge and sometimes to set standards: the International Federation of Fertility Societies (which was established in 1968 and itself grew out of the International Fertility Association); the European Society of Human Reproduction and Embryology (established in 1985 to stimulate study and research): and the International Committee Monitoring Assisted Reproductive Technologies (which focuses on providing information on the availability, effectiveness and safety of treatments). In the EU, a ‘Tissues and Cells Directive’ sets out the quality and safety standards that should be met by all EU/EEA countries.

3.10. In summary, there is a very mixed approach to the provision and regulation of fertility treatment and research internationally. Stakeholders who commented on international comparisons generally indicated that the HFEA was an international leader in this field, helping to set the standard for regulation and, through this, providing a framework that supports innovation and research.

Alternative delivery models

3.11. Triennial Reviews are required to consider whether the functions of an ALB, if still required, could be delivered more effectively through a different organisational delivery model.

3.12. In considering alternative delivery models the review team was looking for evidence that any recommended changes would deliver net benefits compared to the HFEA's current structure. The assessment was not simply whether the functions could be delivered by another delivery model but also about how well that model would support the HFEA's core aims and functions. The review team consider that any changes to the delivery model should deliver clear benefits, such as reduced costs or improvements in the quality of service provision.

3.13. The review team considered and rejected a number of potential delivery models that were clearly inappropriate:

- abolition – given the conclusion that the functions were necessary then abolition would only be appropriate if those functions were moved elsewhere. The options for that are discussed below;
- contracting out – regulated bodies, who are required to share sensitive and commercial information with the regulator, place great store in the independence, impartiality and expertise of the HFEA. This would almost certainly be undermined by any contacted-out service provision. Stakeholder responses also suggested that the wider public, who are beneficiaries of the regulation, would have less confidence in an organisation operating under a commercial contract. There are no obvious providers of such a service; and
- commercialisation/privatisation – the HFEA generates income from regulatory licence fees. Under Treasury rules[7] the HFEA can only charge full cost recovery for such activities. There is some small scope to charge for other services, such as guidance material and conferences, but this is limited and could not justify any commercial status.

Bring the functions within the Department

3.14. Departmental oversight of the HFEA remains necessary but the core regulatory functions of the HFEA are entirely appropriate for an arm's length body operating with a degree of day-to-day independence from the DH and Ministers. Stakeholders were largely supportive of the HFEA remaining as an independent arm's length public body that was seen to operate independently of any direct political influence.

3.15. Regulated bodies can see what their fees are paying for in the HFEA but this would be undermined if it became a part of the Department. In addition, the HFEA provides a high level of expertise to support the regulatory function that could be lost within the Department.

[7] See Managing Public Money (https://www.gov.uk/government/publications/managing-public-money)

3.16. The HFEA does though play a central role in developing policy and advising on policy issues relation to embryology and fertility. This is a function that would normally be performed in a Department or Executive Agency rather than an NDPB (which operates more at arm's length from ministerial oversight and control). However, retaining this function in the HFEA links it to the staff with the scientific and practical expertise that is necessary to fully understand the issues involved and to exert influence effectively in negotiations. Feedback from stakeholders clearly indicated that the Authority is highly regarded in this role and the work undertaken to see through the provisions allowing mitochondrial donation was almost universally praised.

3.17. It is nevertheless important that the HFEA works closely with Department of Health on any policy issues and it is clear that the Department has been fully sighted and involved in policy setting. As such, the review found no benefit in transferring functions to the Department.

Merge with another public body

3.18. Merging the HFEA with other ALBs has been considered before: most recently the potential merger of HFEA and HTA in the McCracken review, which concluded that the relatively modest benefits were outweighed by the risks of a loss of focus and specialist expertise, and could anyway be delivered through closer cooperation and sharing of appropriate back-office functions. This review found no evidence to suggest that position had changed and moreover, although close and effective working between the HFEA and HTA is important, both organisations have the need to maintain close ties to a range of other bodies.

Continued delivery by the existing NDPB

3.19. This was the option stakeholders supported. The regulatory functions of the HFEA would appear to be most appropriate for delivery through an NDPB. This was the conclusion reached by Justin McCracken in his 2013 review and there is no evidence to support revising that conclusion.

3.20. The Cabinet Office set out three tests for NDPB status. A body only has to meet one test but in practice many will meet more than one. The three tests are:

- is this a technical function (which needs external expertise to deliver)?
- is this a function which needs to be, and be seen to be, delivered with absolute political impartiality? and
- is this a function which needs to be delivered independently of Ministers to establish facts and/or figures with integrity?

3.21. A strong argument can be made that the HFEA meets all of these tests. The need for technical expertise to deliver the regulatory function is clear; such regulation requires political impartiality and independence from direct ministerial control; the HFEA is required to maintain records and provide information and guidance to patients, donors and regulated bodies.

3.22. A summary of the options considered is set out in Table 3 below.

Table 3: Assessment of alternative delivery models

Delivery Option	**Assessment**
Abolish	Rejected – functions are needed.
Contract out the service	Rejected – could undermine independence and expertise, no obvious providers.
Commercialisation/privatisation	Rejected – income is from regulatory fees and scope to expand into other income streams is extremely limited.
Bring-in house (DH takes on the function)	Rejected – not ideal for a regulatory function and may undermine independence and expertise.
Merger with another body	Rejected – no clear benefits that couldn't be achieved outside of a merger and risks to loss of expertise.
Continued delivery by an NDPB	Accepted – HFEA meets the tests for NDPB status.

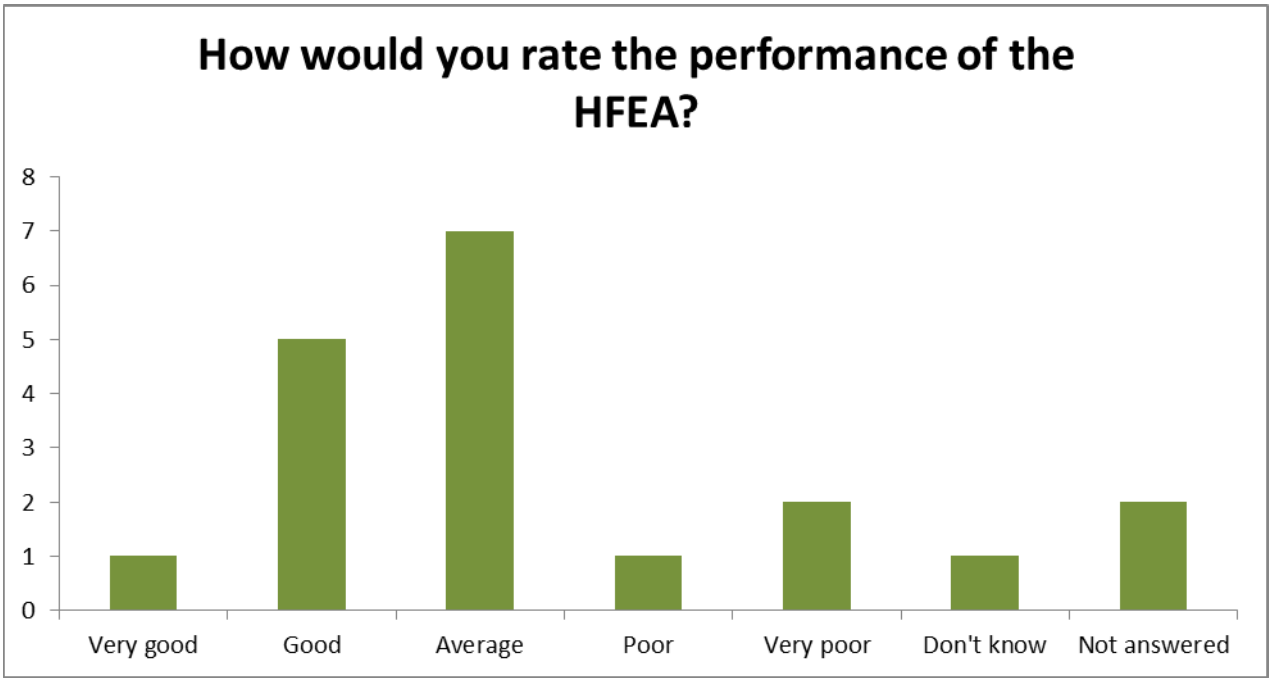
Recommendation 2: that the HFEA continues to operate in its current form.

4. Stage Two: Performance

4.1. If the conclusion of Stage One is that the organisation should be maintained in its current form, then the review moves on to Stage Two and considers the scope for improving performance or delivering efficiencies, as well as adherence with the principles of good corporate governance.

4.2. The HFEA is highly regarded as an effective regulator, and this review supports that view, but all organisations need to continually adapt and develop to keep pace with change. Stakeholder responses to the call for evidence were largely positive (see Figure 3 below) but there were nevertheless areas where changes were sought. The sections below pick out the key issues identified by the review process where it is considered that the HFEA can make changes to improve performance further but they are often building upon actions that the Authority has either already planned or are in progress.

Figure 3: Call for Evidence responses - performance rating



Regulation and Inspection: working with other regulators

4.3. Given its specialised regulatory role the HFEA might be expected to have fewer areas of interconnection with other regulatory activity than most other regulators. Even so, the HFEA needs to work closely with a wide range of other regulatory and accreditation bodies, such as the CQC, the MHRA, the HRA, the HTA and the UK Accreditation Service (UKAS). Maximising coordination across the regulatory framework offers great potential benefit for regulated bodies by reducing the burden of regulation through better

information sharing, coordinating the timing of inspections and ensuring that consistent standards are applied wherever possible.

4.4. It should to be acknowledged that the HFEA has already done much to develop engagement with other regulatory bodies: for example, since 2013 it has agreed memoranda of understanding, primarily covering the sharing of information and good practice, with the CQC, the MHRA and the HTA. More recently, the HFEA has worked with UKAS during investigation of two serious adverse events. HFEA licences require laboratories used by those establishments to have UKAS accreditation and so there is potential for greater cooperation, particularly where UKAS accredited services used by clinics are involved in incidents that impact negatively on licensed activities.

Recommendation 3: that the HFEA works cooperatively with UKAS to ensure that incidents in laboratories that provide services to clinics are investigated effectively.

4.5. Despite the work that has already been undertaken, a number of stakeholders wanted to see more done to align the regulatory processes. There are limitations to what can be achieved since regulators may well be required to undertake inspections within a given timeframe and to apply standards appropriate to that regulated activity. However, within such restrictions, there is further potential to reduce the regulatory burden while at the same time having a positive impact on the quality of regulation. Particular issues that stakeholders would welcome include:

- regulators coordinating their information requirements and sharing information (within the requirements of legislation such as the Data Protection Act 1998) so that regulated bodies are subject to fewer requests;
- the timetable for inspections being better coordinated, where possible and appropriate, between regulators so that they can either take place together or as part of a clear process. Many regulated bodies would prefer joint inspections or, better still, one body inspecting on behalf of another also; and
- to the extent possible, the standards required by stakeholders should be consistent. It is understood that this will not always be easy and that different standards are often necessary for different activities. What is most important is that standards are mutually consistent.

4.6. Although it is possible for the HFEA to engage further with regulators and accreditation bodies to coordinate arrangements, it is nevertheless difficult for any individual regulator to achieve this goal. The Department of Health is well placed to support this work among regulators and we recommend that consideration is given to establishing the necessary processes.

Recommendation 4: that the Department of Health coordinates arrangements to support the

HFEA and other health and care system regulators to provide an even more joined-up regulatory framework.

Regulation and inspection: culture media

4.7. Embryo culture medium is the solution used to support the development of embryos (in a petri dish) before they are transferred to the womb. In vitro fertilisation seeks to imitate the conditions an embryo would encounter in vivo, and as such optimising the culture environment during IVF treatment is fundamental to its success.

4.8. In the past, UK clinics often made their own embryo culture media but the majority now use commercially manufactured culture media. Questions remain about the safety and potential long-term impact of these products. Varying concentrations of components such as growth factors, amino acids, energy substrates and antibiotics may potentially impact early embryo development and the long-term health of the children born after treatment. The components of embryo culture media therefore require scrutiny to ensure that risks are minimised and embryo health is enhanced.

4.9. This product is regarded as a medical device under the Medical Devices Regulations 2002 (as amended) and the European Medical Devices Directive 93/42/EC. Such devices are regulated by the Medicines and Healthcare Products Regulatory Agency, which classifies culture media as a high risk device (Class III). In practice, this requires culture media to be CE marked by a Notified Body following assessment of the quality of the manufacturing process and any known safety issues. The MHRA will then monitor reports of any adverse reactions or other incidents. The Class III status means that manufacturers are required to note and justify any changes to culture media composition in their technical documentation, and are also expected to ensure that post-market surveillance is carried out to monitor the long-term safety of the culture media.

4.10. This issue is not new and the HFEA has been engaging with others for some years (see for example the 2009-10 report on Scientific Horizon Scanning at the HFEA[8]). More recently, a paper for the HFEA's Scientific and Clinical Advances Advisory Committee in October 2015 provided a detailed update and concluded both that long-term studies are needed to properly assess the impact of culture media and that those commercial companies producing culture media should provide explicit information regarding the precise formulation. This meeting also considered what needed to be communicated to the MHRA as a result of the analysis.

4.11. The McCracken review also raised the issue of cooperation between the HFEA and the MHRA and made the following recommendation:

[8] http://www.hfea.gov.uk/docs/Horizon_Scanning_Report_2009-10.pdf, Pages 13-15.

McCracken review, recommendation 11 – The HFEA should clarify to all concerned how it cooperates with the MHRA to achieve effective joint working on matters falling within the latter's regulatory oversight but which take place within premises regulated by the HFEA.

4.12. Given that this product is used exclusively by establishments regulated by the HFEA it is well placed to hear of any adverse incidents or other concerns with culture media. As such, close engagement between the HFEA and the MHRA is vital in this area. As mentioned above, the HFEA has since agreed a memorandum of understanding with the MHRA. In relation to culture media, the HFEA and MHRA have not only been sharing information on this subject but have been engaging jointly with the clinics and commercial manufacturers with the aim of reaching agreement on ensuring greater transparency regarding the content and an effective monitoring process.

4.13. Some stakeholders did argue that the HFEA should take on responsibility for the regulation of culture media but this would neither seem possible (given European and UK legislation relating to medical devices) nor beneficial provided the HFEA and MHRA work together, whether in relation to culture media or other medicines and medical devices, and make progress in developing an oversight process that manages the risks effectively.

Recommendation 5: that the HFEA continues to work with the MHRA and others to develop and manage an effective oversight process for culture media and other medical devices, and communicates this to relevant stakeholders.

Regulation and inspection: managing the risks

4.14. The legislation requires that all clinics are inspected at least once every two years and that licences can be issued for a maximum of five years in the case of treatment licences and three years in the case of research licences. However, in order to align the licensing and inspection cycle the HFEA agreed with stakeholders that it would issue treatment licences for a maximum period of four years. To align the licensing and inspection cycle of research licences, where a licence renewal occurs in the year after the last inspection then this renewal is carried out by desk based assessment if the research centre was considered compliant with requirements.

4.15. Those inspections undertaken just before granting or renewing a licence involve a full compliance and quality check. The interim inspections usually involve a focused, risk-based, assessment, looking at common non-compliances and focusing on areas of practice that are considered to carry a high risk. This process also incorporates consideration of how licensed clinics and research centres respond and learn from incidents and complaints.

4.16. Such a risk-based approach provides for best use to be made of limited resources and reduces unnecessary burdens on regulated bodies. This was recommended in the McCracken review:

McCracken review, recommendation 10 – The HFEA should conduct a review of the balance of its regulatory focus to ensure that it reflects the relative risks of the different activities that it oversees. Its approach should reflect the relative maturity of the sector it regulates now, the need to ensure appropriate oversight of technical developments in the field of ART, the need to ensure that appropriate standards of practice are implemented consistently throughout the sector, and the continuing need for a high degree of public assurance regarding the sensitive activities that it oversees. This should not lead to any overall increase in regulatory activity or cost, but a rebalancing of activity.

4.17. Following this recommendation the HFEA undertook a public consultation on its future strategy[9] that led to an approach that emphasises quality of care and outcomes. This ensures, for example, that inspections talk directly to patients and use their input to inform the areas of focus.

4.18. The HFEA also faces the constant risk of legal challenge to its approach and decisions. This has a significant impact on its spending profile, with legal costs amounting to 5% or more (roughly £300,000-£400,000 per annum) of its budget. Such costs can be minimised by, as the Authority strives to do, ensuring that the decision-making process is thorough and that all necessary steps are taken but some such challenges will inevitably occur.

4.19. In responding to legal challenges, or the threat of them, the HFEA has to consider the range of options open to it and aim to keep costs down without undermining the regulatory controls. The decision to remove the multiple births licence condition was made at least in part in order to avoid further costs associated with a legal challenge but the HFEA concluded that it could deliver the policy aims through providing support, sharing best practice and continuing to work with its stakeholder group.

a) Legal parenthood and consent

4.20. Whilst this review supports this risk-based inspection approach, there are areas where some stakeholders argued for tighter regulatory oversight. Perhaps the key example relates to the processes needed to ensure that all parties have given informed consent and that legal parenthood is clearly established, where donated gametes are used and the patient couple are not married or in a civil partnership. Several recent court cases[10] have highlighted that many clinics failed to ensure that a small number of patients provided informed consent in advance of treatment in such cases. A recent audit by the

[9] Our future strategy (http://www.hfea.gov.uk/8572.html)

[10] E.g., https://www.judiciary.gov.uk/judgments/in-the-matter-of-the-human-fertilisation-and-embryology-act-2008-cases-a-b-c-d-e-f-g-and-h/

HFEA suggests that around 80 cases are now known to be of concern. The judicial judgements have been critical of this whole process.

4.21. The taking of such consents is the responsibility of clinics and the problem only came to light through HFEA inspections and a request in 2013 that all clinics audit their records. However, the HFEA fully acknowledges that it could have been more robust in requiring the clinics to address the failings quickly and comprehensively. Since the extent of the problem has been fully established the HFEA has been working with clinics to minimise the risk of any future recurrence.

4.22. Since the establishment of fully informed consent is partly an administrative process it may not have previously been given the appropriate level of attention and priority by clinics when compared with the clinical procedures that follow. However, the impact of these errors is significant; requiring legal action to address, causing great distress to those affected and potentially damaging reputations.

4.23. The HFEA already produces detailed guidance on the consent requirements. The HFEA's Code of Practice[11] covers legal parenthood and record management and document control. The Code of Practice also provides detailed information about what information needs to be provided to patients and donors prior to consent, and the HFEA additionally published guidance on consent forms for staff working in clinics in April 2015[12]. This is separate from, and in addition to, the requirement to offer them counselling. Some clinics make the take-up of counselling a requirement but this is not mandatory under the legislation.

4.24. Many clinics are private, commercial, entities and the HFEA should ideally, as it does, leave them to decide how they implement the licence conditions. However, the implications of a failure to manage the consent arrangements properly are significant and recent history demonstrates that current processes have not been sufficient to prevent serious breaches of the requirements. Ensuring that legal parentage is properly established is clearly fundamental to the welfare of all parties.

4.25. There are no clear and simple solutions to address these concerns. Robust rules requiring the adoption of systematic processes to ensure consent requirements have been fully covered are already a licence condition. The consequences for breach of this condition reflect the seriousness of the impact it has on those involved and the HFEA already publishes Indicative Sanctions Guidance[13] which sets out the various categories of breaches and the penalties they might attract.

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[11] http://www.hfea.gov.uk/code.html

[12] http://www.hfea.gov.uk/docs/Consent_forms_-_a_guide_for_clinic_staff.pdf)

[13] http://www.hfea.gov.uk/10261.html?utm_source=jan16&utm_medium=email&utm_campaign=clinicfocus

4.26. To support clinics in taking forward the necessary changes, the HFEA must continue to play a valuable role in providing guidance to clinics on best practice arrangements. Moreover, the sharing of best practice arrangements between clinics should be possible in relation to such administrative processes supporting regulatory requirements. It is recognised that clinics operate in a competitive market situation but their competitive advantage will lie very largely with their clinical approaches rather than with their administrative processes. Although requiring any specific approach would seem inappropriate, the HFEA might seek to encourage clinics to adopt digital processes that could apply automated safeguards, whereby electronic consent forms require completion of all sections appropriate to that case before it can proceed to the next stage.

> **Recommendation 6:** that the HFEA continues to enforce consent requirements and applies robust penalties where appropriate. In doing so, that the HFEA works with clinics to share best practice arrangements and provide any necessary guidance; for example, encouraging clinics to adopt digital processes potentially safeguarding the completion of each stage in the process.

b) Novel and innovative practices or treatments

4.27. Around 60% of IVF treatment is privately funded and costs normally range between £3,000-5,000 for a full cycle. A number of stakeholders expressed concerns at the range of supplementary treatments or innovative processes being offered by clinics. The perceived risk is that patients may be offered expensive treatments unaware that they may have little or no evidence of efficacy or safety to support their use. Stakeholders referred to the fact that IVF patients will often be desperate for success and therefore susceptible to taking on any additional procedures if they believe it might increase their chances.

4.28. There are many examples: intra-cytoplasmic sperm injection (ICSI) involves the embryologist selecting sperm to be injected directly into the egg; it has now been around for over 20 years and is widely used but the precise nature of the risks and impact remains uncertain. ICSI adds around £1,000 or more to the standard cost of IVF treatment.

4.29. A more recent development is time-lapse imaging, which involves regular photographs of the embryo to help identify those with the best chance of success. This approach has been pushed by some clinics[14] and adds around £500 or more to the cost of treatment. Although the early indications suggest that may be a helpful tool this remains a new procedure with risks, if any, as yet unclear.

4.30. There are many other possible treatments, such as in vitro maturation (IVM), which removes eggs at an early stage and matures them in an incubator, thereby reducing the

[14] See http://www.bbc.co.uk/news/health-22559247

need for fertility drugs. IVM is relatively new and any risks are not yet clear. The cost of IVM is generally a little lower than for IVF treatment, though the success rates are also lower.

4.31. The HFEA provides some information to patients on its website and is planning to develop this further as part of its Information for Quality (IfQ) programme (dealt with further below). It also has a horizon scanning panel and a Scientific and Clinical Advances Advisory Committee that consider new techniques and advise on whether or not they should be approved and what inspection or monitoring might be necessary.

4.32. The HFEA's role in providing information and guidance to patients and in protecting the health and welfare of patients and IVF conceived children would suggest that provision of information to patients that explains the extent of the evidence for medical efficacy, the potential risks, and the expected costs, is a necessary function. The HFEA has to carefully balance its involvement in providing appropriate levels of advice and guidance to patients without going beyond its role and capacity. However, the potential benefits to patients are significant and the HFEA should seek to further develop this service as part of the IfQ programme.

Recommendation 7: that the HFEA, as part of the Information for Quality programme, builds on the information and guidance it currently provides for prospective patients on the various IVF services and treatments that are available, including the evidence for medical efficacy, the potential risks, and the likely costs.

Regulation and inspection: research

4.33. This section does not seek to suggest that the regulatory framework acts as a barrier to research. It is almost certainly the fact that Parliament approved regulations in February 2015 enabling mitochondrial donation to take place precisely because it had confidence in the regulatory framework. This made the UK the first country in the world to approve such a process.

4.34. The McCracken review made several recommendations aimed at supporting research:

McCracken review, recommendation 7 – On completion of the review of information requirements the HFEA should establish inclusive projects (a) to review whether further use could be made of the information in its statutory Register to promote public understanding and facilitate more research into issues pertaining to ART; and (b) to identify the best means of providing information from the register, together with appropriate support, to people born as a result of ART.

McCracken review, recommendation 8 – In order to improve the approval process for research projects involving gametes and embryos, the HFEA should commit to

participating fully in the new Integrated Research Application and Approval System (IRAaS) from its launch in 2014, (and to cooperating fully with the other bodies involved), and should make adequate resources available now to prepare for it.

McCracken review, recommendation 9 – In the legislation establishing the HRA the Department of Health should ensure that it has a duty to provide a "one stop shop" for advice for those intending to undertake health research, and should ensure that the legislation includes a "duty to cooperate" among all regulatory bodies.

4.35. Recommendation 7 of the McCracken review links to recommendation 6, which deals with what information is collected and held by the HFEA and is addressed below. Supporting quality research requires the right information to be collected and stored in the first place.

4.36. The legislation requires that written consent must be obtained from the donor before any embryos or gametes can be used for research purposes. Prior to giving consent the donor must be provided with relevant information, such as the nature of the research project. The requirement for informed consent remains central to the use of human tissue across the health system.

4.37. Research on embryos and gametes requires a licence from the HFEA, which can be issued for up to three years. Research ethics approval from a properly constituted ethics committee is required before a licence application is made. As recommended in the McCracken review, the HFEA has improved engagement with the HRA and linked the approval process for research projects to the Integrated Research Application and Approval System (IRAS). In addition, the HFEA has helped to establish – through the MHRA and working also with the HRA and HTA – a 'One Stop Shop' for research and development professionals (the Regulatory Advice Service for Regenerative Medicine). This offers a single point of access to expert support and advice in response to queries about the regulation of regenerative medicines. There remains scope to utilise this service to provide wider support to researchers to help them manage within the regulatory framework

> **Recommendation 8:** that the HFEA builds on its approach of working collaboratively with the other regulators to support further development of the Regulatory Advice Service for Regenerative Medicine to provide support to researchers to understand and manage the regulatory requirements.

4.38. The HFEA holds a register of sensitive personal data (the Register) on IVF conceived children, parents and donors. This is the world's largest national data set on regulated fertility treatments, including the handling and storage of embryos, eggs and sperm. It holds valuable information for research purposes and has already been used to support research (such as into childhood cancer rates in IVF conceived children) but a number of stakeholders wanted to see greater use made of this data to support research, in particular providing a better understanding of the health risks to IVF conceived children.

4.39. The confidentiality of the information held on the Register is strictly protected but the HFE Act 2008 (which amended the 1990 Act) made it easier to share some of this information under tightly defined conditions. This has allowed the HFEA to publish anonymised data from the register for use in research and it is working with the National Information Board to determine how identifying register information can be made available for research purposes provided strict ethical conditions are met. How the register is managed is also covered under the efficiency section below.

Supporting innovation and horizon scanning

4.40. Some of the activity regulated by the HFEA is at the cutting edge of medical science. If the regulatory framework is to remain relevant, carefully balancing wider ethical and moral views with appropriate support for new innovations, then the HFEA must remain on top of new developments. The introduction of regulations allowing mitochondrial donation (as mentioned above) was held out by a number of stakeholders as an example of the HFEA managing this balance extremely effectively.

4.41. The HFEA has long undertaken horizon scanning activities to ensure that it is aware of new scientific and clinical developments. Much of that work is conducted in-house by executive staff, but the HFEA also uses outside expertise and a Horizon Scanning Panel was established in 2004, bringing together an international panel of experts to advise the Authority on such issues. The aim is to provide an early warning system that identifies new developments that may impact on the field of assisted reproduction or embryo research. The panel meets once a year but aims to identify issues for consideration throughout the year. The priorities identified through all of this horizon scanning work are usually then considered in depth by the HFEA's Scientific and Clinical Advances Advisory Committee (SCAAC). The SCAAC meets three or four times a year. The HFEA needs to ensure that these processes are sufficient to enable it to anticipate future developments that might affect its regulatory landscape.

4.42. The HFEA published an annual report of its horizon scanning activities through to 2009-10 but this then stopped, apparently to reduce costs. Although an annual report may well be unnecessary, and SCAAC papers and minutes of the Horizon Scanning panel are still provided, it would be valuable, and transparent, for the HFEA to publish an annual update on horizon scanning on its website.

> **Recommendation 9:** that the HFEA publishes on its website an annual update on horizon scanning issues.

Stakeholder communication and engagement

4.43. The HFEA has invested a great deal of time and effort in improving its stakeholder engagement. Stakeholders are represented on a wide range of HFEA committees and the HFEA has undertaken a number of consultation processes to involve stakeholders in

policy development. Feedback received from stakeholders on HFEA engagement was largely positive, with most respondents saying it has performed well and none ranking it below average. This section looks at a few specific areas of stakeholder engagement. It also seeks to demonstrate how three recommendations in the McCracken review have been addressed:

McCracken review, recommendation 4 – In order to improve transparency, both the HFEA and the HTA should review and strengthen their arrangements for consulting with stakeholders on their approach to regulatory activities, and should ensure that issues raised with them and their responses are publicly available and discussed regularly in open Authority meetings.

McCracken review, recommendation 6 – To reduce unnecessary regulatory burden the HFEA should proceed without delay with its planned fundamental review of information requirements, using the British Fertility Society (BFS) and Association of Clinical Embryologists' (ACE) paper3 as the basis for discussion, and adopting for the project an inclusive approach similar to that used successfully in the "One at a Time" project. The HFEA should publish the Project Initiation Document for this work by July 2013 and then make quarterly progress reports available to open meetings of the Authority. It is estimated that this will yield savings of approximately £1m.

McCracken review, recommendation 13 – The HFEA should review its approach to engagement with its stakeholders and should publish an action plan within 6 months. In 12-18 months' time the HFEA should undertake a structured and anonymous stakeholder attitude and satisfaction survey, and publish the results and associated action plan.

4.44. In responding to recommendations 4 and 13 of the McCracken report the HFEA commissioned a survey of stakeholder views in 2013, agreed a new stakeholder engagement plan in May 2014 and appointed a Head of Engagement in October 2014. This post has responsibility for implementation of the engagement plan, including increasing face-to-face meetings with stakeholders and making sure that Authority decisions are properly communicated. However, the stakeholder survey conducted in 2013 was too early to judge views on the impact of the engagement plan (it rather helped to inform the development of that plan) as recommended in the McCracken report. It would therefore be appropriate for the HFEA to undertake a further survey on stakeholder attitudes and satisfaction. In taking forward further stakeholder engagement approaches the HFEA should also look to learn from best practice approaches elsewhere.

Recommendation 10: that the HFEA undertakes a follow-up stakeholder survey, as recommended in the McCracken report, to assess attitudes and satisfaction following implementation of its stakeholder engagement programme.

a) Public opinion

4.45. This report has referred several times to the requirement on the HFEA to balance wider public ethical and moral concerns with the ever-changing scientific landscape of what it is possible to achieve. However, precisely what the views of the wider public are is difficult to ascertain. There have been many public consultation processes (as has already been outlined, this review undertook one) seeking such views but the danger with placing too much reliance on the outcome is that the respondents are usually those who have a particular interest in the topic. The vast majority of the public do not engage with such consultations.

4.46. There are examples of more comprehensive surveys (the HFEA commissioned a survey of 2,615 adults in 2002) but even with this approach the responses might well vary depending on the amount of information provided in advance of the question. As well, therefore, as reflecting public opinion, the HFEA has a role in supporting public education and understanding of these issues.

4.47. During the review process the issue of genetic manipulation of embryos, usually in order to treat inherited medical problems, was raised in the media on numerous occasions. The recent approval of mitochondrial donation is clearly only a further stage in the process of what is medically possible and the HFEA has a vital role in supporting informed debate and ensuring that the regulatory framework is informed by all relevant factors.

b) Provision of Information

4.48. The HFEA has a responsibility to provide information to patients and donors to support them to make informed decisions. In responding to recommendation 6 of the McCracken report the HFEA established the 'Information for Quality' (IfQ) programme in 2013. The aim is to ensure that the information the HFEA collects, stores and publishes is necessary and valuable. The key activities intended to achieve this are:

- redevelopment of the 'Choose a fertility clinic' tool on the HFEA website;
- redevelopment of the clinical portal on the HFEA website that allows clinics to submit information and the HFEA to provide them with performance data; and
- an improved system for determining data requirements and then for collecting and reviewing that data.

4.49. This work is being informed by an Advisory Group that is chaired by a HFEA Non-Executive Director and includes a range of stakeholder representatives. The Group met eight times in 2014. Part of its work has been to consider what information needs to be requested of clinics and held by the HFEA. At its meeting in February 2015[15] the Group

[15] http://www.hfea.gov.uk/docs/12_Feb_IfQ_Advisory_Group_meeting_minutes.pdf

agreed to stop collecting several types of data (such as whether the patient travelled from overseas) and also considered what additional data might be required for research purposes and recommended obtaining data on culture media subject to a suitable research proposal coming forward. This whole process of dataset consideration includes representatives from clinics and will allow researchers and others to put forward proposals for consideration.

4.50. Stakeholders welcomed the IfQ work, though some wanted to see faster progress to a conclusion. The area of greatest interest related to the provision of information to patients to support their choice of a fertility clinic. This process is, of course, vitally important to the clinics themselves and the HFEA has been taking great pains to reach the right conclusion. Over the past 18 months the HFEA has engaged extensively with patient groups and others in the sector about the provision of a ratings system on its website. This system was referred to by a number of stakeholders as a 'Tripadvisor' type system in that it would potentially allow for rankings and one to five star markings. The review heard very differing views about this issue. Many clinics, and some others, were concerned that important factors in determining outcomes (such as the age of the patient) would not be adequately reflected in any scoring process, leading clinics to seek to minimise the risk profile of the patients they take or that patients own views would be based very largely on the outcome rather than the quality of the service provided. On the other hand, such review and rating systems have indeed been popular and valuable to customers on many online websites and there is no fundamental reason why, particularly when accompanied by wider information and caveats, it should not been seen as useful in this area too.

4.51. However, the HFEA's actual proposals are now closer to NHS England's 'Friends and Family Test' rather than Tripadvisor: this will provide for feedback from patients on whether they would recommend the clinic but will not provide a direct ranking system. The HFEA is providing reassurance to the sector that it will be putting in safeguards to prevent any abuse of the system, ensuring that it becomes a valuable resource for patients.

c) Disseminating best practice

4.52. Some stakeholders suggested that they would welcome more support from the HFEA through the provision of training to support better understanding of the regulation and sharing of best practice (also mentioned above in relation to consent arrangements). Stakeholders indicated that they would be prepared to pay for relevant training or conferences and so this would be self-financing.

Performance measurement

4.53. Key Performance Indicators should reflect and support the strategic priorities of an organisation. They help organisations understand how well they are performing in relation to their strategic goals and objectives. Below this, an organisation might use a number of further targets or measures. There are a wide variety of types of performance indicators but some core examples are:

- **cost:** the money spent to acquire the resources;
- **input:** the resources (staff, materials and premises) employed to provide the service;
- **output:** the service provided, for example, in terms of tasks completed; and
- **outcome:** the impact and value of the service delivery.

4.54. The HFEA's Strategy 2014-17[16] sets out the HFEA's objectives, how they will be achieved, and what the benefits will be. This is a good example of clear objectives. At the lower level, the Annual Report and Accounts 2014-15[17] provides a number of activity measures and performance indicators (largely outputs).

4.55. The HFEA seeks continuous improvement and value for money. To assess performance against this the HFEA needs to make appropriate comparisons. It should therefore seek to benchmark performance against comparator organisations. This might include a selection of bodies from other regulators, similar organisations in other countries, and high-performing organisations in other sectors. However, the availability of such comparative data is a consideration that will need to be assessed further to determine whether this could be implemented.

Recommendation 11: that the HFEA considers the practicalities of inclusion, within its performance measures, of an assessment of comparative performance against relevant high-performing organisations.

[16] HFEA Strategy 2014-17, http://www.hfea.gov.uk/docs/Strategy_2014-17_FINAL.pdf

[17] HFEA Annual Report and Accounts 2014-15, page 10, http://www.hfea.gov.uk/docs/HFEA_Annual_Report_and_Accounts_2014-15.pdf

5. Efficiency

Summary of HFEA income, expenditure and resources

5.1. The HFEA is a very small organisation and has made significant reductions in its size and spend over recent years. Many stakeholders commented on the savings already achieved and expressed concern at the scope for such a small organisation to go much further whilst retaining sustainability and resilience.

5.2. Table 4 below summarises HFEA resources.

Table 4: HFEA Income, Expenditure and Staff

(£000s)	2010/11 (outturn)	2011/12 (outturn)	2012/13 (outturn)	2013/14 (outturn)	2014/15 (outturn)	2015/16 (plans)
Income	5,916	5,661	3,979	4,123	4,035	4,126
Grant-in-Aid	2,251	435	778	1,018	920	1,120
Expenditure	7,043	5,928	5,132	5,028	5,716	5,246
Staff (FTE)	95	76	67	66	64	67[18]

5.3. The HFEA sets licence fees to cover the costs of regulation and this income now covers around 80% of its expenditure. The HFEA's licence fees are generally considered fair by stakeholders and a Fees Group has been established to provide a forum for discussing fees. This forum is intended to be representative of the various types and sizes of licensed clinics. This implements a further recommendation from the McCracken review:

McCracken Recommendation 5 – Both the HFEA and the HTA should establish and operate a permanent fees review group to improve accountability and facilitate dialogue with licence fee payers.

5.4. The HFEA is foremost a successful regulatory body. However, the demands placed upon a small ALB such as the HFEA by the DH and other departments can be challenging, both in terms of time and cost. It would be helpful to such bodies if information requests and reporting requirements were proportionate to the ALB's size

[18] This is the full staff complement and does not represent an increase on the previous year (which reflects staff in post).

and resources wherever possible. This issue will become increasingly significant as ALBs seek to manage resources effectively under tight fiscal controls.

5.5. This will be best achieved where there is close communication with the Department. As well as the HFEA responding to the priorities of the Department, the role of the sponsor team is pivotal in ensuring that the Department understands what it is possible for the HFEA to achieve and the competing priorities that need to be balanced.

> **Recommendation 12:** that the Department of Health assists the HFEA by working to better manage information and reporting requests of all arm's length bodies, having regard to proportionality and reflecting differences in the size of, and resources available to, such bodies.

NHS funding of IVF treatments

5.6. Around 60% of IVF treatment is privately funded, with the rest provided through the NHS. The NHS funding comes through Clinical Commissioning Groups (CCGs) but the review team heard various concerns that this process did not necessarily ensure best value for money. NHS England, alongside NHS Improvement where appropriate as the economic regulator, provides commissioning guidance to CCGs. The National Institute for Health and Care Excellence (NICE) already provides best practice guidance19 but this is not mandatory and is not necessarily followed by clinics.

5.7. Stakeholder concerns related primarily to a view that CCGs do not necessarily understand what treatments are likely to offer best value and success rates, and what fees are appropriate for the services. If CCGs applied appropriate conditions to their funding of fertility treatment it should be possible not only to better ensure that costs are minimised and success rates maximised but this could also be a useful tool in encouraging clinics to adopt these best practice arrangements.

5.8. The review team is aware that the Department of Health is already in the process of considering these issues and nothing in this report seeks to pre-empt the outcome of such discussions. However, it would be potentially helpful in delivering efficiencies and improved outcomes for the HFEA to work with DH and stakeholders to explore whether, having regard to wider policy decisions and resource allocations, there might be an opportunity to support CCGs in obtaining value for money from their funding of fertility treatments.

> **Recommendation 13:** that the HFEA and the Department of Health, having regard to the outcome of wider decisions on policy, priorities and ensuring value for money, explore whether there are opportunities to work with stakeholders to provide further information and

[19] http://www.nice.org.uk/guidance/cg156

best practice on the commissioning of fertility treatments.

Accommodation

5.9. The HFEA is currently located in Finsbury Tower, alongside the CQC. The lease for this office expires in May 2016 and the HFEA has been exploring alternative options. The McCracken review also covered this issue and focused on the wider benefits of co-location with other regulatory bodies:

McCracken Recommendation 3 – The Department of Health's future estates strategy should take into account the clear operational benefits in terms of facilitating seamless regulation of co-locating in one building all the bodies engaged in regulation and oversight of health care and related research.

5.10. The HFEA had been planning for a move to 151 Buckingham Palace Road, a building already occupied by the MHRA, HTA and the NHS Litigation Authority. However, the lease holder for that building (the Department for Business Innovation and Skills) is not now releasing the expected amount of floor space and so moving to this office would only be possible by sharing the space currently occupied by the HTA. The HFEA have considered this option against an alternative of co-locating with the National Institute for Health and Care Excellence (NICE) at 10 Spring Gardens.

5.11. The HFEA's assessment was that both options meet Cabinet Office requirements for desk occupancy rates but the NICE co-location option offered slightly more space, greater flexibility (including access to their offices in Manchester for the HFEA's home-based inspectors who live in the North) and an opportunity to bring Authority meetings in-house, which should deliver savings of up to £100,000 per annum by removing the need to book external meeting rooms. In addition, rental costs were estimated to be £50,000 pa lower at Spring Gardens. Co-location with NICE therefore offered significant cost savings.

5.12. However, as the McCracken review noted, the potential benefits of co-location go wider than simply the direct costs. Co-location with the HTA, the MHRA and others in 151 Buckingham Palace Road would potentially allow for easier collaboration with those bodies, though the HFEA's assessment is that many of the benefits of close working relations can be achieved regardless of co-location and the only particular benefit is that it would allow the HFEA and HTA Finance teams to be brought together (see below). The HFEA therefore decided to co-locate with NICE from spring 2016. The HFEA will now need to ensure that the wider potential synergies from close cooperation with other health regulators are not lost. In addition, the Department of Health should aim to ensure that its accommodation strategy for its arm's length bodies gives full consideration to the wider potential benefits of appropriate co-location.

Back and middle-office functions

5.13. The HFEA has relatively low overheads and the scope for further savings is relatively limited but some benefits ought to be achievable.

a) Finance

5.14. The McCracken review recommended that the HFEA and the HTA combine finance functions:

McCracken Recommendation 2 – The support services of the two bodies should be combined and managed by a single Director of Finance and Resources, supporting both Chief Executives. This will facilitate the achievement of further significant efficiency savings, estimated at £2.8M over 10 years.

5.15. In response, the post of Director of Finance and Resources has been combined with the HTA since early 2014. However, the two organisations have retained separate (albeit small) finance teams; reflecting the different software systems they currently use. This has been justified on the basis that the costs of moving to a unified system at this stage would outweigh the savings any merger would produce.

5.16. The decision to locate the HFEA with NICE, rather than co-locating with the HTA, further complicates any wider merger of this function but it need not act as a barrier. It will be important for the HFEA to consider the relative merits of establishing shared functions with any of a range of other health regulators, or indeed other bodies. To achieve this it should work with the Department of Health to explore the best options and produce an implementation plan. If the finance function is still to be merged with the HTA then a decision should be taken on the most appropriate timing, the staff resources required, and the most appropriate location of the function.

> **Recommendation 14:** that the HFEA works with the Department of Health and other arm's length bodies to explore further opportunities to share services and develop implementation plans.

b) Information Technology

5.17. The HFEA is in the process of updating its IT system and is working with the Government Digital Service, NHS Digital and others to ensure that replacement system delivers the necessary service and provides flexibility to respond to changing future requirements. The HFEA plans to use a cloud-based system for its general functions but, for security reasons, does not plan to move its register (the database that holds sensitive personal information on patients, donors, children and treatments referred to previously in this report) to a cloud based system. As an alternative, the HFEA is in discussion with NHS Digital about hosting this database, although the statutory responsibility for the data would remain with the HFEA. This would offer a number of

potential benefits: increased cyber security; lower costs; and the potential, subject to necessary safeguards being in place, for combining data with other health databases to support research. The HFEA will need to ensure that appropriate service level agreements, such as in respect of access to the data, are included in these discussions.

5.18. In respect of the replacement of its general office systems, the HFEA should also aim to ensure compatibility with the IT/software systems of other bodies with whom they share information or might share back/middle office functions in the future. It should also agree, with the Department and the Government Digital Service, target efficiency savings to be delivered from the move to the new IT system.

Recommendation 15: that the HFEA, working with the Department of Health, NHS Digital and the Government Digital Service as necessary, explores further the relative benefits of hosting its database with NHS Digital.

Recommendation 16: that the HFEA, working with the Department of Health and the Government Digital Service as necessary: (i) seeks to ensure that the replacement IT system is compatible with those in other organisations with whom it may share information; and (ii) agrees target efficiency savings to be delivered from the new IT system.

Procurement and contract management

5.19. HFEA contract and procurement spend is relatively small, with accommodation and IT, both covered above, being much the largest. The HFEA has a detailed procurement policy that operates alongside DH and Crown Commercial Service controls. Any purchase over £500 requires at least two oral quotations and any purchase over £2,000 requires at least three written quotations. Anything above £25,000 requires a formal tendering process.

5.20. There are mandated suppliers for a range of services (travel, couriers, legal, etc) that are provided through contracts managed by other public bodies. The HFEA policy also covers the need for contract management, tailored to the individual contract.

6. Governance

Principles of good corporate governance in ALBs

6.1. Every arm's length body needs clear arrangements for overseeing its strategic direction, performance monitoring and review. The variety of organisations means that one solution will not fit all and departments, in discussion with the arm's length body, are able to decide on the precise structure of governance arrangements as long as the key principles are met. Such arrangements are then normally outlined in the Framework Agreement.

6.2. Cabinet Office guidance states that Triennial Reviews must assess the controls, processes and safeguards in place against the principles and supporting provisions set out in the Code of Good Corporate Governance. The Cabinet Office publishes a range of guidance on governance issues for public bodies[20].

6.3. The full assessment for each principle is detailed in tabular form in Annex G. It reflects both self-assessment by the Authority and analysis of the review team. Non-compliance is acceptable where this is justified by the particular circumstances and where appropriate alternative arrangements are in place.

6.4. The HFEA is fully compliant with all of the principles. The sections below summarise the detail in the table and pick up particular issues in relation to the principles.

Accountability

6.5. The Authority complies with the principles. The Chief Executive is formally appointed as the Accounting Officer.

6.6. The HFEA provides the Secretary of State for Health with advice and information when requested to do so. It has a duty to seek approval from the Secretary of State for its Code of Practice and provides him with copies of annual reports.

Role of the sponsor department

6.7. The Authority and Department comply with the principles. In addition to the SDS, there is a departmental sponsor team which has regular contact with HFEA and a team member attends board meetings as an observer.

[20] www.gov.uk/government/publications/public-bodies-information-and-guidance

6.8. The Framework Agreement between the department and the HFEA sets out clear accountability arrangements and the roles and responsibilities of senior parties in both organisations. It is reviewed at least every three years.

6.9. Oversight by the Departmental Board is provided through a quarterly performance report that includes an indicator on overall ALB assurance and occasional consideration by the Audit and Risk Committee, which has an ongoing programme of inviting ALB sponsor teams and audit chairs to meetings.

Role of the Board, Chair and Non-Executive Board Members

6.10. The Authority complies with the principles.

a) Board structure

6.11. The HFEA has an independent Chair who is appointed by, and can provide advice directly to, the Secretary of State.

6.12. The HFEA's board is made up of 12 non-executives, who are Authority members and appointed by the Secretary of State under Schedule 1 of the HFEA Act 1990. The Chief Executive and other staff attend meetings but not as board, or Authority, members. Although the Corporate Governance Code[21] recommends that non-executives make up the majority of the board, it is also expected that a mixed board of executives and non-executives would normally provide the best balance. Such a structure should best ensure that the board has a full understanding of the key issues affecting the Authority, is subject to appropriate scrutiny and challenge, and is able to take forward outcomes effectively.

6.13. However, the review found that the HFEA board operates effectively, with good two-way communications with the executive that provides oversight, challenge and a close connection to decision-making processes. It seems unlikely that a mixed executive and non-executive board structure could be established whilst meeting the requirements for the Authority as set out in legislation and without creating a complex and bureaucratic structure. As such, no change to the current structure is recommended.

b) Planning for changes to key posts

[21] Corporate governance in central government departments – HM Treasury & Cabinet Office (https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments)

6.14. The specialist nature of the HFEA's responsibilities is reflected in the knowledge and expertise brought by non-executive authority members. The board reviews its composition to ensure relevant skills and experiences are covered.

6.15. Nevertheless, for a relatively small organisation such as the HFEA, the loss of board members or key staff can result in a loss of knowledge and ability. Some stakeholders expressed concerns that the small size of the HFEA led to inherent risks that the loss of key staff could have a significant adverse impact on performance. The HFEA recognises that retaining experienced staff can be difficult when private companies welcome their experience and can offer higher salaries. It responds to this by offering flexible packages, good training and development opportunities and accepting a flow of turnover. Indeed, there are clear benefits from having ex-staff operating in the regulated sector. The challenge is to ensure that sufficient knowledge and experience is maintained.

> **Recommendation 17:** that the HFEA develops plans for non-executives and key staff that maximises knowledge retention and transfer.

Effective financial management

6.16. The Authority complies with the principles.

Communications

6.17. The HFEA operates a very open and transparent process. All board meetings are conducted in public and audio transcripts are made available on its website.

Conduct and behaviour

6.18. The Authority complies with the principles.

7. Annexes

Annex A - Membership of the Project Board and Critical Friends Group

a) Review team

Senior Review Sponsor	Kathryn Tyson	DH, Director of International Health and Public Health Policy
Lead Reviewer	David Dipple	DH
Assistant Reviewer	David Malcolm	DH

b) Project Board

The purpose of the Project Board was to provide oversight of the review process, clearing the approach and documentation.

Chair	Kathryn Tyson	Senior Review Sponsor (DH, Director of International Health and Public Health Policy)
Member	Peter Thompson	Chief Executive Officer, HFEA
Member	Edward Webb	DH Sponsor Team
Member	David Dipple	Lead Reviewer
Secretariat	David Malcolm	Assistant Reviewer

c) Critical Friends Group

The purpose of the Critical Friends Group was to rigorously and robustly test and challenge the scope of the reviews, the process (particularly the robustness of the approach to evidence gathering and analysis), and emerging conclusions and draft reports.

Chair	Justin McCracken	Previously Chief Executive of the Health Protection Agency
Member	Professor Bobbie Farsides	Professor of Clinical and Biomedical Ethics, Brighton and Sussex Medical School
Member	Hugh Whittall	Director, Nuffield Council on Bioethics

Member	Kathryn Tyson	Senior Review Sponsor (DH, Director of International Health and Public Health Policy)
Member	David Dipple	Lead Reviewer
Secretariat	David Malcolm	Assistant Reviewer

Annex B - Terms of Reference for the Review

Stage One

Stage one of the review will verify the functions of the HFEA, assess how the functions contribute to the core business of the health and care system, and consider whether they are still needed.

The McCracken review looked at most aspects of the HFEA's functions. This included the keeping of records and information requirements (e.g., on donors, conception outcomes, offspring) and regulation of research, and other, activity. The Triennial Review will take full account of the outcome of the McCracken review's assessment of functions. Within this context, the review will consider:

1. Whether delivery of the functions contributes to wider government policy and constitutes a justifiable use of public money.
2. The benefits of delivering the function or activity for users and wider stakeholders.
3. The cost and effects of not delivering the function.
4. How the functions interact with other parts of the health and care system or the wider public sector.

Where it is concluded that functions are still needed, stage one will go on to examine how this function might best be delivered. The review will first examine whether the functions would be better delivered by either of the following delivery models:

1. To be delivered by the private sector, the voluntary and community sector, under contract by the private or community sector, or as a mutual, Community Interest Company, or social enterprise.
2. Merged with another body, either another area of central government or another public body. (This will exclude the assessments made in recent reviews regarding merger with the HTA or transferring functions to the CQC and HRA.)

If it were decided that the HFEA should remain as a separate public body then the McCracken review has relatively recently assessed the Authority against the three tests set by the Cabinet Office and determined that NDPB status was appropriate. This assessment would be accepted.

Stage Two

If the outcome of stage one is that the HFEA should retain its current status, stage two will go on to review its performance, governance and efficiency. Within this context, the review will consider the following key lines of enquiry:

1. Whether the HFEA makes the best use of public money and maximises revenues (where appropriate and possible).
2. An assessment of the implementation of the recommendations in the McCracken review.
3. Whether internal processes are sufficiently lean and whether further efficiencies and synergies, outside of those in the McCracken review, could be delivered.
4. The balance between grant-in-aid and regulatory fee income.
5. Whether regulatory activity is efficient and risk-based (having regard to the legislative requirements).
6. The capacity and capability to respond effectively to changing demands or a changing regulatory/policy/scientific environment. The quality of strategic plans and horizon scanning.
7. Collaboration with partners across the health and social care system, and elsewhere.
8. Relations and communications with stakeholders, including understanding of regulated bodies, patients, and wider interests. Building and maintaining public confidence.
9. Whether the governance is appropriate. To whom is the HFEA accountable and how is this exercised?

Annex C - Written Ministerial Statement announcing the review

Made on 25 June 2015:

DEPARTMENT OF HEALTH

Arm's Length Bodies (Triennial Reviews)

The Parliamentary Under Secretary of State for Public Health, Department of Health (Jane Ellison): I am today announcing the start of the Triennial Reviews of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, the Human Fertilisation and Embryology Authority, the Human Tissue Authority, and NHS Blood and Transplant.

The Triennial Review programme ensures that all Government Departments review their Non-Departmental Public Bodies on a regular basis. In order to ensure that the Department of Health is operating as an effective system steward and can be assured of all the bodies it is responsible for, it has extended the programme of reviews over the period 2014-17 to include all of its arm's length bodies.

The reviews are conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.

Copies of the reports of the reviews will be placed in the Libraries of the House.

Annex D – Stakeholder Engagement

a) List of respondents to Call for Evidence

The review team published an online call for evidence that was made available on the Department of Health pages on Gov.Uk and was publicised on the HFEA website also. In addition, the team emailed a wide range of stakeholders to inform them of this process and encourage wider dissemination. The call for evidence opened on 3 July 2015 and ran until 31 August 2015. The respondents are listed below.

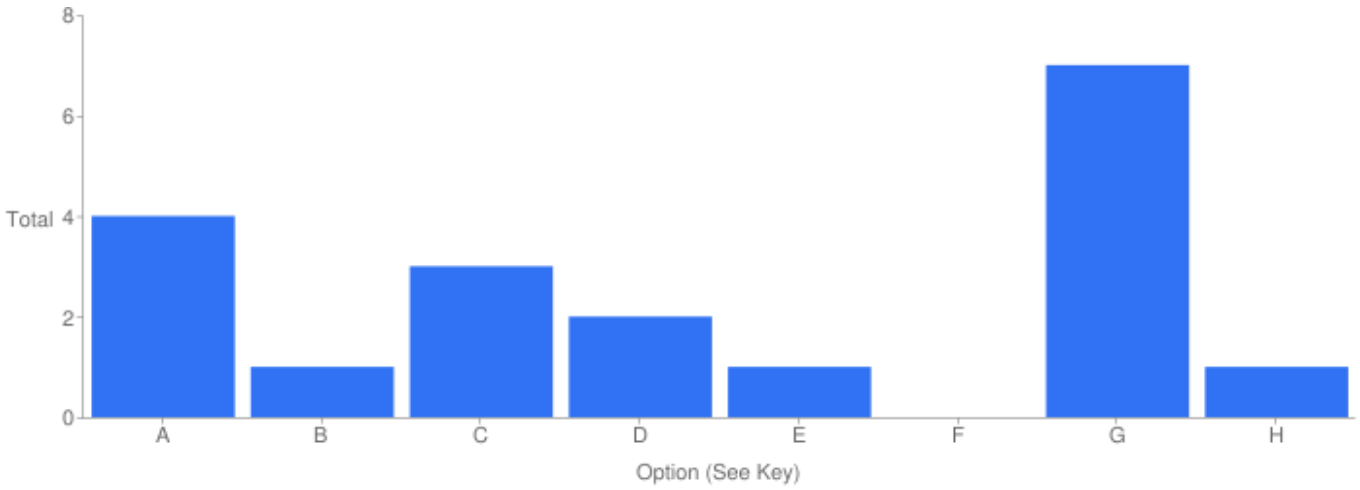
Call for Evidence Respondents

	Name	Grouping and Organisation/Individual
1	Gulam Bahadur	Individual
2	Siriol Griffiths	Individual
3	Dr Jyoti Taneja	Private Sector - Healthcare
4	Anonymous (ex-employee)	Individual
5	Karl Swann	Academic/Research
6	Bonnie Collins	Public Sector
7	Daniel Brison	Academic/Research
8	PROGAR	Public Sector
9	Association of Biomedical Andrologists	None (Professional healthcare organisation)
10	Nuffield Council on Bioethics	None (Independent body)
11	Royal College of Physicians	None (Professional healthcare organisation)
12	Graham Phillips	Individual
13	Jane Denton (Multiple Births Foundation)	Charitable/voluntary sector healthcare organisation
14	Frances C Rawle	None (Medical Research Council)
15	Hilary Lloyd	None (British Medical Association)
16	Peter D Williams	Charitable/voluntary sector healthcare organisation
17	Progress Educational Trust	Charitable/voluntary sector healthcare organisation

18	Association of Clinical Embryologists	None
19	British Fertility Society & Royal College of Obstetricians and Gynaecologists	None

Figure 4 below provides a breakdown of respondents self-classification of the various sectors represented.

Figure 4: Breakdown of call for evidence responses



Key	Option	Total	Percentage
A	Individual	4	21.05%
B	Public sector	1	5.26%
C	Charitable/voluntary sector healthcare organisation	3	15.79%
D	Academic/research institution	2	10.53%
E	Private sector – healthcare related	1	5.26%
F	Private sector - other	0	0%
G	None of the above	7	36.84%
H	Not Answered	1	5.26%

A number of the respondents to the call for evidence indicated that they were representing views of a wider membership. In addition, some respondents, or their organisations, were also included within stakeholder interviews or attended a workshop. The review team took this into account but did not attempt to formally weight responses in any way.

b) List of workshop attendees

The review team also offered two sessions where interested stakeholders could book places. These were held on 30 July and 13 August 2015. The attendees were:

Attendees at workshops

1	Sarah Norcross	Progress Educational Trust
2	Virginia Bolton	British Fertility Society
3	Susan Avery	British Fertility Society
4	Clio Korn	Academy of Medical Sciences
5	Jane Denton	Imperial College Healthcare NHS Trust / Multiple Births Foundation
6	Sarah Rappaport	Wellcome Trust
7	Geeta Nargund	Create Fertility
8	Stuart Campbell	Create Fertility
9	Praful Nargund	Create Fertility
10	Lucy Jenner	Care Fertility

c) List of interviews

In addition, the review team conducted interviews with a range of stakeholders as set out below:

Interviews conducted

Department of Health

1 Director General for Public Health

2 DH Sponsor Team

Human Fertilisation and Embryology Authority

3	Sally Cheshire	Chair
4	Sue Gallone	Director of Finance and Resources
5	Juliet Tizzard	Director of Strategy and Corporate Affairs
6	Nick Jones	Director of Compliance
7	Yacoub Khalaf	Non-Executive Director
8	David Archard	Non-Executive Director

9	Margaret Gilmore	Non-Executive Director
10	Andy Greenfield	Non-Executive Director
11	Kate Brian	Non-Executive Director
12	The Rt Reverend Dr Lee Rayfield	Non-Executive Director
13	Debra Bloor	Chief Inspector

Other public and private sector

14	Jane Denton	Multiple Births Foundation
15	Adam Balen	British Fertility Society
16	Susan Seenan	Infertility Network UK
17	Laura Witjens	National Gamete Donation Trust
18	Nina Barnsley	Donor Conception Network
19	Sheila McLean	Professor of Law and Ethics in Medicine at Glasgow University
20	Janet Wisely	Health Research Authority
21	Ian Hudson	Medicines and Healthcare Products Regulatory
22	Mostafa Metwally	Royal College of Obstetricians and Gynaecologists
23	Alex Baylis	Care Quality Commission
24	Linda Whalley	NHS Digital
25	Marilyn Crawshaw	PROGAR, BASW
26	Tracey Chester	British Infertility Counselling Association
27	Ruth Wilde	British Infertility Counselling Association
28	Lorraine Turner and Stephen Mitchell	UK Accreditation Service

Annex E - Public Call for Evidence Questions

Call for Evidence Question (Majority response shown in **bold**)	**Yes**	**No**	**Don't know**	**Not Answered**
1. Is there a continuing need for the functions undertaken by the Authority?	**16 (84%)**	1 (5%)	0	2 (11%)
2. How well do you think that the Authority fulfils each of its functions at present?	Very Well – 3 (16%) **Well – 7 (37%)** Average - 5 (26%) Poor – 1 (5%) Very Poor – 1 (5%)		0	2 (11%)
3. Outside of the options that have previously been considered, which of the following organisational forms would you support?	**NDPB – 14 (74%)** Merge – 0 DH – 2 (11%) VCS - 0		1 (5%)	2 (11%)
4. How would you rate the performance of the Authority?	Very Good – 1 (5%) Good – 5 (26%) **Average – 7 (37%)** Poor – 1 (5%) Very Poor - 2 (11%)		1 (5%)	2 (11%)
5. Does the Authority have a positive impact on patient and donor care?	**Yes – 9 (47%)** No – 3 (16%)		3 (16%)	4 (21%)
6. Do you think that the functions of the Authority, regulatory or otherwise, impose burdens that are:	**Proportionate – 9 (47%)** Disproportionate – 3 (16%)		3 (16%)	4 (21%)
7. How effectively does the Authority operate within and support the rest of the health and care system?	Very Well – 0 **Well – 4 (21%)** Average – 2 (11%)		5 (26%)	6 (32%)

Call for Evidence Question (Majority response shown in **bold**)	**Yes**	**No**	**Don't know**	**Not Answered**
	Poor – 1 (5%) Very Poor – 1 (5%)			
8. Could the Authority do more to support innovation and new approaches in the area of human fertilisation and embryology?	**9 (47%)**	6 (32%)	1 (5%)	3 (16%)
9. How effectively does the Authority maintain public confidence that the area of human fertilisation and embryology is regulated appropriately?	Very Well – 2 (11%) **Well – 8 (42%)** Average – 1 (5%) Poor – 3 (16%) Very Poor – 1 (5%)		2 (11%)	2 (11%)
10. How well does the Authority communicate and engage with stakeholders?	Very Well – 2 (11%) **Well – 9 (47%)** Average – 5 (26%) Poor – 0 Very Poor – 0		0	3 (16%)
11. Is the Authority sufficiently forward-looking and responsive to new challenges and opportunities?	**8 (42%)**	3 (16%)	2 (11%)	6 (32%)
12. Are there any measures you believe the Authority could take to deliver further efficiencies (whether reduced costs or improved use of resources)?	Not applicable – text responses only.			
13. Does the Authority follow best practices in its governance arrangements?	**6 (32%)**	0	7 (37%)	6 (32%)

Annex F – Other Sources of Evidence

The review team referred to a range of published documents and other material as part of the evidence gathering and analysis process. The key documents are listed below:

Published sources of information and evidence	
1	HFEA Website (: http://www.hfea.gov.uk/)
2	HFEA Annual Report and Accounts 2014-15 (http://www.hfea.gov.uk/docs/HFEA_Annual_Report_and_Accounts_2014-15.pdf)
3	Human Fertilisation & Embryology Acts 1990 and 2008 (http://www.legislation.gov.uk/ukpga/1990/37/contents and http://www.legislation.gov.uk/ukpga/2008/22/contents)
4	Liberating the NHS: Report of the arm's-length bodies review - July 2010 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216278/dh_118053.pdf)
5	Government response to the consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority - January 2013 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212742/Consultation_HFEA_and_HTA_government_response.pdf)
6	Review of the Human Fertilisation & Embryology Authority and the Human Tissue Authority - Justin McCracken, April 2013 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216947/Justin_McCracken_report_of_review_of_HFEA_and_HTA.pdf)
7	Review of the balance of competences between the UK and the European Union – Health (https://www.gov.uk/government/consultations/review-of-the-balance-of-competences-health)
8	HFEA Horizon Scanning Committee Report 2009-10 (http://www.hfea.gov.uk/docs/Horizon_Scanning_Report_2009-10.pdf)
9	Legal judgement in the High Court of Justice Family Division (https://www.judiciary.gov.uk/judgments/in-the-matter-of-the-human-fertilisation-and-embryology-act-2008-cases-a-b-c-d-e-f-g-and-h/)
10	Managing Public Money – HM Treasury (https://www.gov.uk/government/publications/managing-public-money)
11	Who's accountable? Relationships between Government and arm's-length bodies - House of Commons, Public Administration Select Committee, First Report of Session 2014–15 (http://www.publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/110/110.pd

12	Corporate governance in central government departments – HM Treasury & Cabinet Office (https://www.gov.uk/government/publications/corporate-governance-code-for-central-government-departments)
13	Joint Accreditation Committee ICT Europe and EBMT (JACIE): http://www.jacie.org/
14	UK Accreditation Service (UKAS): http://www.ukas.com/
15	Economist articles (http://www.economist.com/news/leaders/21661651-new-technique-manipulating-genes-holds-great-promisebut-rules-are-needed-govern-its and http://www.economist.com/news/briefing/21661799-it-now-easy-edit-genomes-plants-animals-and-humans-age-red-pen)
16	One at a time website covering multiple birth issues (http://www.oneatatime.org.uk/index.htm)
17	Integrated Research Application System (https://www.myresearchproject.org.uk/)
18	NICE guideline on Fertility (http://www.nice.org.uk/guidance/cg156/chapter/introduction)
19	Report of the Joint Committee on the Human Tissue and Embryos (Draft) Bill – August 2007 (http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/169.pdf)
20	Nuffield Bioethics paper on germline therapies (http://nuffieldbioethics.org/wp-content/uploads/Germline_therapies_background_paper.pdf)
21	Guardian article (http://www.theguardian.com/lifeandstyle/2015/sep/12/couples-who-used-sperm-donors-win-right-to-be-called-legal-parents)
22	Memoranda of Understanding or joint working agreements between the HFEA and other bodies: HTA - http://www.hfea.gov.uk/docs/HFEA_HTA_MoU_and_JWP.pdf CQC - http://www.hfea.gov.uk/docs/HFEA_CQC_MoU_and_JWP.pdf MHRA - http://www.hfea.gov.uk/docs/Joint_working_with_the_MHRA.pdf
23	European Society of Human Reproduction and Embryology (https://www.eshre.eu/)
24	International Federation of Fertility Societies (https://iffs.site-ym.com/)
25	International Committee Monitoring Assisted Reproductive Technologies (http://www.icmartivf.org/)

Annex G - Compliance with the Principles of Good Corporate Governance

PRINCIPLES OF GOOD CORPORATE GOVERNANCE **Accountability**			
Statutory Accountability		**Compliant (Yes/No)**	**Review Findings**
Principle	**The public body complies with all applicable statutes and regulations, and other relevant statements of best practice.**		
Supporting Provisions	The public body must comply with all statutory and administrative requirements on the use of public funds. This includes the principles and policies set out in the HMT publication “Managing Public Money” and Cabinet Office/HM Treasury spending controls.	Yes	
	The public body must operate within the limits of its statutory authority and in accordance with any delegated authorities agreed with the sponsoring department.	Yes	
	The public body should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000. It should have a comprehensive Publication Scheme. It should proactively release information that is of legitimate public interest where this is consistent with the provisions of the Act.	Yes	
	The public body must be compliant with Data	Yes	HFEA also administers a statutory data protection

	Protection legislation.		scheme, which applies a higher level of confidentiality, as set out in the Human Fertilisation & Embryology Act 1990, as amended, applicable to all activities, treatments and services governed by the Act.
	The public body should be subject to the Public Records Acts 1958 and 1967.	Yes	
Accountability for public money		**Compliant (Yes/No)**	**Detail**
Principle	**The Accounting Officer of the public body is personally responsible and accountable to Parliament for the use of public money by the body and for the stewardship of assets**		
Supporting Provisions	There should be a formally designated Accounting Officer for the public body. This is usually the most senior official (normally the Chief Executive).	Yes	
	The role, responsibilities and accountability of the Accounting Officer should be clearly defined and understood. The Accounting Officer should have received appropriate training and induction. The public body should be compliant with the requirements set out in “Managing Public Money”, relevant Dear Accounting Officer letters and other directions. In particular, the Accounting Officer of the NDPB has a responsibility to provide evidence-based assurances required by the Principal Accounting Officer (PAO). The PAO requires these to satisfy him or herself that the Accounting Office responsibilities are being appropriately discharged. This includes, without reservation, appropriate access of the PAO’s	Yes	

	internal audit service into the NDPB.		
	The public body should establish appropriate arrangements to ensure that public funds: • are properly safeguarded; • are used economically, efficiently and effectively; • are used in accordance with the statutory or other authorities that govern their use; • deliver value for money for the Exchequer as a whole.	Yes	
	The public body's annual accounts should be laid before Parliament. The Comptroller and Auditor General should be the external auditor for the body.	Yes	
Ministerial Accountability		**Compliant (Yes/No)**	**Detail**
Principle	**The Minister is ultimately accountable to Parliament and the public for the overall performance of the public body.**		
Supporting Provisions	The Minister and sponsoring department should exercise appropriate scrutiny and oversight of the public body.	Yes	
	Appointments to the board should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The Minister will normally appoint the Chair and all non-executive board members of the public body	Yes	

	and be able to remove individuals whose performance or conduct is unsatisfactory.		
	The Minister should be consulted on the appointment of the Chief Executive and will normally approve the terms and conditions of employment.	Yes	Ministers do not appoint the Chief Executive, HFEA is a statutorily independent regulatory body, but consultation does take place.
	The Minister should meet the Chair and/or Chief Executive on a regular basis.	Yes	
	A range of appropriate controls and safeguards should be in place to ensure that the Minister is consulted on key issues and can be properly held to account. These will normally include: • a requirement for the public body to consult the Minister on the corporate and/or operational business plan; • a requirement for the exercise of particular functions to be subject to guidance or approval from the Minister; • a general or specific power of Ministerial direction over the public body; and • a requirement for the Minister to be consulted by the public body on key financial decisions. This should include proposals by the public body to: (i) acquire or dispose of land, property or other assets; (ii) form subsidiary companies or bodies corporate; and (iii) borrow money; a power to require the production of information from the public body which is needed to answer satisfactorily for the body's affairs.	Yes	HFEA is a statutorily independent regulatory body, however it has a statutory function to provide the Secretary of State for Health with advice and information when requested to do so. It has a duty to seek approval from the Secretary of State for its code of practice and provides him with copies of annual reports. All corporate and business plans are cleared through the prescribed channels. As is any expenditure outside centrally prescribed financial delegations.

	There should be a requirement to inform Parliament of the activities of the public body through publication of an annual report.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Roles and responsibilities			
Role of the Sponsor Department		**Compliant (Yes/No)**	**Detail**
Principle	**The departmental board ensures that there are robust governance arrangements with the board of each arm's length body. These arrangements set out the terms of their relationship and explain how they will be put in place to promote high performance and safeguard propriety and regularity.** **There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the public body.**		
Supporting Provisions	The departmental board's regular agenda should include scrutiny of the performance of the public body. The departmental board should establish appropriate systems and processes to ensure that there are effective arrangements in place for governance, risk management and internal control in the public body.	Yes	
	There should be a Framework Document in place which sets out clearly the aims, objectives and functions of the public body and the respective roles and responsibilities of the Minister, the sponsoring department and the public body. This should follow relevant Cabinet Office and HM Treasury guidance. The Framework Document should be published. It should be accessible and understood by the sponsoring department, all board members and by the senior management team in the public body. It should be regularly reviewed and updated.	Yes	

	There should be a dedicated sponsor team within the parent department. The role of the sponsor team should be clearly defined.	Yes	
	There should be regular and ongoing dialogue between the sponsoring department and the public body. Senior officials from the sponsoring department may as appropriate attend board and/or committee meetings. There might also be regular meetings between relevant professionals in the sponsoring department and the public body.	Yes	
Role of the Board		**Compliant (Yes/No)**	**Detail**
Principle	**The public body is led by an effective board which has collective responsibility for the overall performance and success of the body. The board provides strategic leadership, direction, support and guidance.** **The board – and its committees – have an appropriate balance of skills, experience, independence and knowledge.** **There is a clear division of roles and responsibilities between non-executive and executives. No one individual has unchallenged decision-making powers.**		
Supporting Provisions	The board of the public body should: • meet regularly; • retain effective control over the body; • effectively monitor the senior management team.	Yes	
	The size of the board should be appropriate.	Yes	
	Board members should be drawn from a wide range of diverse backgrounds.	Yes	

	The board should establish a framework of strategic control (or scheme of delegated or reserved powers). This should specify which matters are specifically reserved for the collective decision of the board. This framework must be understood by all board members and by the senior management team. It should be regularly reviewed and refreshed.	Yes	
	The board should establish formal procedural and financial regulations to govern the conduct of its business.	Yes	
	The board should establish appropriate arrangements to ensure that it has access to all such relevant information, advice and resources as is necessary to enable it to carry out its role effectively.	Yes	Sub-committees of the board all have external co-opted members with expertise in the relevant area. Some committees provide advice to the Board. The HFEA also has a horizon scanning panel made up of internationally recognised experts to keep it abreast of development in the fields of assisted reproduction and embryology.
	The board should make a senior executive responsible for ensuring that Board procedures are followed and that all applicable statutes and regulations and other relevant statements of best practice are complied with.	Yes	Duty of Chief Executive.
	The board should make a senior executive responsible for ensuring that appropriate advice is given to it on all financial matters.	Yes	Duty of Finance Director.
	The board should establish a remuneration committee to make recommendations on the remuneration of top executives. Information on	Yes	

	senior salaries should be published. The board should ensure that the body's rules for recruitment and management of staff provide for appointment and advancement on merit.		
	The Chief Executive should be accountable to the board for the ultimate performance of the public body and for the implementation of the Board's policies. He or she should be responsible for the day-to-day management of the public body and should have line responsibility for all aspects of executive management.	Yes	
	There should be an annual evaluation of the performance of the board and its committees – and of the Chair and individual board members.	Yes	
Role of the Chair		**Compliant (Yes/No)**	**Detail**
Principle	**The Chair is responsible for leadership of the board and for ensuring its overall effectiveness.**		
Supporting Provisions	The board should be led by a non-executive Chair.	Yes	
	There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments. The Chair should have a clearly defined role in the appointment of non-executive board members.	Yes	

	The duties, role and responsibilities, terms of office and remuneration of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include: • representing the public body in discussions with Ministers; • advising the sponsoring Department and Ministers about board appointments and the performance of individual non-executive board members; • ensuring that non-executive board members have a proper knowledge and understanding of their corporate role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members' performance; • ensuring that the board, in reaching decisions, takes proper account of guidance provided by the sponsoring department or Ministers; • ensuring that the board carries out its business efficiently and effectively; • representing the views of the board to the general public; and • developing an effective working relationship with the Chief Executive and other senior staff.	Yes	
	The roles of Chair and Chief Executive should be held by different individuals.	Yes	

Role of Non-Executive Board Members		Met (Yes/No)	Detail
Principle	**As part of their role, non-executive board members provide independent and constructive challenge.**		
Supporting Provisions	There should be a majority of non-executive members on the board.	Yes	HFEA has no executive members on its board
	There should be a formal, rigorous and transparent process for the appointment of non-executive members of the board. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The duties, role and responsibilities, terms of office and remuneration of non-executive board members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The corporate responsibilities of non-executive board members (including the Chair) will normally include: • establishing the strategic direction of the public body (within a policy and resources framework agreed with Ministers); • overseeing the development and implementation of strategies, plans and priorities; • overseeing the development and review of key performance targets, including financial targets; • ensuring that the public body complies with all	Yes	

	statutory and administrative requirements on the use of public funds; • ensuring that the board operates within the limits of its statutory authority and any delegated authority agreed with the sponsoring department; • ensuring that high standards of corporate governance are observed at all times. This should include ensuring that the public body operates in an open, accountable and responsive way; and • representing the board at meetings and events as required.		
	All non-executive board members must be properly independent of management.	Yes	
	All non-executive board members must allocate sufficient time to the board to discharge their responsibilities effectively. Details of board attendance should be published (with an accompanying narrative as appropriate).	Yes	
	There should be a proper induction process for new board members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Effective Financial Management			
Effective Financial Management		**Compliant (Yes/No)**	**Detail**
Principle	**The public body has taken appropriate steps to ensure that effective systems of financial management and internal control are in place.**		
Supporting Provisions	The body must publish on a timely basis an objective, balanced and understandable annual report. The report must comply with HM Treasury guidance.	Yes	
	The public body must have taken steps to ensure that effective systems of risk management are established as part of the systems of internal control.	Yes	
	The public body must have taken steps to ensure that an effective internal audit function is established as part of the systems of internal control. This should operate to Government Internal Audit Standards and in accordance with Cabinet Office guidance.	Yes	
	There must be appropriate financial delegations in place. These should be understood by the sponsoring department, by board members, by the senior management team and by relevant staff across the public body. Effective systems should be in place to ensure compliance with these delegations. These should be regularly	Yes	HFEA complies with centrally issued financial delegations. It also maintains regularly updated Financial Standing Orders.

	reviewed.		
	There must be effective anti-fraud and anti-corruption measures in place.	Yes	
	There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure compliance with these rules. The public body should proactively publish information on expenses claimed by board members and senior staff.	Yes	
	The annual report should include a statement on the effectiveness of the body's systems of internal control.	Yes	
	The board should establish an audit (or audit and risk) committee with responsibility for the independent review of the systems of internal control and of the external audit process.	Yes	
	The body should have taken steps to ensure that an objective and professional relationship is maintained with the external auditors.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Communications			
Communications		**Compliant (Yes/No)**	**Detail**
Principle	**The Public Body is open, transparent, accountable and responsive.**		
Supporting Provisions	The public body should have identified its key stakeholders. It should establish clear and effective channels of communication with these stakeholders.	Yes	
	The public body should make an explicit commitment to openness in all its activities. It should engage and consult with the public on issues of real public interest or concern. This might be via new media. It should publish details of senior staff and boards members together with appropriate contact details.	Yes	
	The public body should consider holding open board meetings or an annual open meeting.	Yes	All board meetings are conducted in public. Audio transcripts are available on its website.
	The public body should proactively publish agendas and minutes of board meetings.	Yes	
	The public body should proactively publish performance data.	Yes	
	In accordance with transparency best practice, public bodies should consider publishing their spend data over £500. By regularly publishing	Yes	

	such data and by opening their books for public scrutiny, public bodies can demonstrate their commitment to openness and transparency and to making themselves more accountable to the public.		
	The public body should establish effective correspondence handling and complaint procedures. These should make it simple for members of the public to contact the public body and to make complaints. Complaints should be taken seriously. Where appropriate, complaints should be subject to investigation by the Parliamentary Ombudsman. The public body should monitor and report on its performance in handling correspondence.	Yes	
	The public body must comply with the Government's conventions on publicity and advertising. These conventions must be understood by board members, senior managers and all staff in press, communication and marketing teams.	Yes	
	Appropriate rules and restrictions must be in place limiting the use of marketing and PR consultants.	Yes	
	The public body should put robust and effective systems in place to ensure that the public body is not, and is not perceived to be, engaging in political lobbying. This includes restrictions on board members and staff attending political conferences in a professional capacity.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Conduct and behaviour			
Conduct and behaviour		**Compliant (Yes/No)**	**Detail**
Principle	**The board and staff of the public body work to the highest personal and professional standards. They promote the values of the public body and of good governance through their conduct and behaviour.**		
Supporting Provisions	A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all board members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.	Yes	
	The public body has adopted a Code of Conduct for staff. This is based on the Cabinet Office model Code. All staff should be aware of the provisions of the Code. The Code should form part of the terms and conditions of employment.	Yes	
	There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of Interests for board members and senior staff. This is regularly updated.	Yes	
	There are clear rules and guidelines in place on political activity for board members and staff. There are effective systems in place to ensure	Yes	

	compliance with any restrictions.		
	There are rules in place for board members and senior staff on the acceptance of appointments or employment after resignation or retirement. These are effectively enforced.	Yes	Board and Executive are also bound by confidentiality provision in the HFEA's primary legislation.
	Board members and senior staff should show leadership by conducting themselves in accordance with the highest standards of personal and professional behaviour and in line with the principles set out in respective Codes of Conduct.	Yes	