Triennial Review of the Human Fertilisation and Embryology Authority

Call for evidence
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Prepared by: David Dipple, Lead Reviewer.
Overview

In recent years, the health and social care system in England has undergone substantial change. The Health and Social Care Act 2012 and the Care Act 2014 have devolved functions and powers away from the Department of Health to local and arm’s length bodies.

The Department has a key stewardship and assurance role in respect of arm’s length bodies within the health and care system. The Department needs to ensure these organisations have appropriate functions and are performing to a high standard.

To perform this stewardship function, the Department is undertaking Triennial Reviews of all of its arm’s length bodies. This includes all Executive Non-Departmental Public Bodies (ENDPBs), Advisory Non-Departmental Bodies (ANDPBs), Executive Agencies and Special Health Authorities. The Human Fertilisation and Embryology Authority (HFEA), an Executive NDPB, is subject to review in 2015-16.

The programme of reviews builds on the approach developed by the Cabinet Office as part of their work on public bodies reform.

Purpose of the review

As noted above, this review is part of a wider programme the Department of Health has developed as part of its stewardship and assurance function. The review will have two main stages:

- The first is to provide a robust challenge of the continuing need for the Authority both in terms of the functions it performs, and the way in which these are delivered.

- If it is agreed that the HFEA should retain its current functions and utilise the same delivery model, the second stage of the review will then consider its performance, capability and governance, as well as considering opportunities for efficiencies.

The Department of Health published a report into a review of all of its arm’s length bodies in 2010. This report recommended that both the HFEA and the Human Tissue Authority (HTA) should have their functions transferred to the Care Quality Commission and a new research regulator. However, the majority of responses to a consultation on this proposal in 2012 were opposed to such a move and this led to a further review by Justin McCracken in early 2013. This review considered a range of options, including merging the HFEA and HTA, but concluded that they should remain as separate Non-Departmental Public Bodies. This was agreed by the Department of Health and the Cabinet Office. The review also made a number of recommendations about the scope for efficiencies and improvements in the way the HFEA and HTA undertook their functions.
This Triennial Review will take full account of these previous reviews and will not seek to reopen recent decisions. The Triennial Review will also include an assessment of the implementation of the recommendations in Mr McCracken’s review.

This Call for Evidence seeks views from respondents to assist its consideration of both of the above stages. The evidence is being gathered simultaneously for stage one and stage two in the interests of timeliness and value for money only, and is not an expression of pre-judgement as to the outcome of stage one of the review.

About the HFEA

The Human Fertilisation and Embryology Authority (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.

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 are set out in the Human Fertilisation & Embryology Acts 1990 and 2008, and associated secondary legislation. The key functions 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) for treatment and embryos;
- implement the requirements of the European Union Tissue and Cells Directive (EUTCD) as far as gametes and embryos are concerned;
- license intrauterine insemination (IUI), gamete intrafallopian transfer (GIFT) and other services.

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.

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.

Useful links

Cabinet Office Triennial Review guidance
HFEA website
Timeline

The Triennial Review commenced on 25 June 2015 and is expected to conclude by the end of December 2015. The conclusions of the review will be announced in both Houses of Parliament and a copy of the final report will be published on the Department of Health pages on gov.uk.

Responding to the call for evidence

In order to conduct the review in an open and transparent manner and ensure that the findings are rigorous and evidence-based, the review team is seeking the views of a wide range of stakeholders. We are interested in the views of individuals and organisations that engage with the HFEA or have a wider interest in its operations.

The call for evidence is running from 3 July 2015 to 31 August 2015. Responses can be provided by completing the online questionnaire below.

The review team will also accept responses or material in different forms provided it is relevant to the purpose of the review (detailed above) and/or the questions detailed below. The review team is unable to respond to individual cases or consider complaints other than as part of the evidence for the review where it falls within the terms of reference.

Workshops

Interested stakeholders are also invited to attend a workshop to share their views on this call for evidence. You can book a place (places are limited and allocated on a first-come first-served basis) through the links below.

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
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<tbody>
<tr>
<td>30 July 2015</td>
<td>14:00-16:00 hours</td>
<td>Richmond House, London</td>
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<td><a href="https://www.eventbrite.co.uk/e/human-fertilisation-embryology-authority-hfea-workshop-tickets-17299573490">https://www.eventbrite.co.uk/e/human-fertilisation-embryology-authority-hfea-workshop-tickets-17299573490</a></td>
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<td>13 August 2015</td>
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Annex A: Call for Evidence Questions

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FoIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that under the FoIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain why you regard the information you are providing as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Questions

There is no need to answer all of the questions unless you wish to do so. For those which you do answer, please provide evidence to support your answers wherever possible. If you wish to send us supporting documentation please email as an attachment to TR-HFEA@dh.gsi.gov.uk. Information where relevance is not demonstrable will not be accepted as evidence. The review team is unable to respond to individual cases or consider complaints other than as part of the evidence for the review where it falls within the terms of reference.

About you

| Name: Hilary Lloyd
| Address: British Medical Association, BMA House, Tavistock Square, London WC1H 9JP
| Telephone: 020 7383 6286
| Email: ethics@bma.org.uk

Would you categorise your response as from:

Professional Association
If your response is from an umbrella organisation representing a wider membership, please indicate the number of members consulted and the number of responses received:

Please indicate what interactions you have with the Authority:

A number of BMA members are regulated by the HFEA. The BMA is represented on the HFEA's Professional Organisations Group and has intermittent contact with the HFEA regarding ethical and policy issues of mutual interest.

Functions

<table>
<thead>
<tr>
<th>1. Is there a continuing need for the functions undertaken by the Authority?</th>
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<tr>
<td>Yes</td>
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Are there any functions you believe could be dropped or undertaken by another organisation?

| No |

Are there any functions that you think are needed but are not currently being undertaken?

| No |

Are there gaps or overlaps in the HFEA’s role which should be addressed?

| No |

Could the function be merged with those of another public body?

| No |

Please briefly explain your answer:

The HFEA continues to have an important role in maintaining public confidence in the very sensitive areas it regulates. Although IVF may now be considered a routine treatment, the use of embryos for research, the development of new technologies and some issues around the donation of gametes and embryos remain controversial and subject to strongly opposing views. The public and professional consultations on mitochondrial transfer over the last few years have demonstrated the benefit of having a respected, independent regulatory body for assisted reproduction and related research.

The HFEA needs to work closely with the Health Research Authority to ensure a seamless approach to the regulation of embryo research to minimise overlap and repetition.

There should also be continued strides towards collaborative policy working with other professional groups along the lines of the 'one at a time' project which was well designed, executed and received.
2. How well do you think the Authority fulfils each of its functions at present?

Well

Please briefly explain your answer:

We represent a large number of doctors and it is not possible to seek views from them all but we are not aware of any significant concerns about the work of the HFEA and our overall impression is that the HFEA is carrying out its functions well and continues to have the support of the medical profession.

Form

3. Recent reviews have considered and rejected possible merger of the HFEA with both the Human Tissue Authority and a combination of the Care Quality Commission and the Health Research Authority.

Outside of the options outlined above that have previously been considered and rejected, which of the following organisational forms would you support:

Remain as a Non-Departmental Public Body

Please briefly explain your answer:

It is very important the HFEA is, and is seen to be, independent from Government. It regulates a discrete area of practice and has developed considerable expertise since its inception. The current system appears to be working well and we can see no reason to change it.
## Performance and Efficiency

4. How would you rate the performance of the Authority?

Good

In what areas, if any, could the HFEA improve its performance?

What key indicators should be used to effectively measure the HFEA’s performance?

Please briefly explain your answer:

The HFEA continues to maintain public confidence in this sensitive area of practice and has taken positive steps to improve its stakeholder engagement.

Requests to engage on policy issues have been positively received. The development of a pilot support and intermediary service for people affected by gamete or embryo donation is an example of the HFEA’s positive response to concerns raised by the BMA and others.

5. Does the Authority have a positive impact on patient and donor care?

Yes
No
Don’t know

Please briefly explain your answer:
6. Do you think that the functions of the Authority, regulatory or otherwise, impose burdens that are:
   - Proportionate
   - Disproportionate
   - Don’t know

Are risks managed appropriately?

How does the approach compare to other regulators?

Please briefly explain your answer:

<table>
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<tr>
<th>7. How effectively does the Authority operate within and support the rest of the health and care system:</th>
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<tbody>
<tr>
<td>Very well</td>
</tr>
<tr>
<td>Well</td>
</tr>
<tr>
<td>Average</td>
</tr>
<tr>
<td>Poor</td>
</tr>
<tr>
<td>Very Poor</td>
</tr>
<tr>
<td>Don’t know</td>
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Please briefly explain your answer:

<table>
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<tr>
<th>8. Could the Authority do more to support innovation and new approaches in the area of human fertilisation and embryology?</th>
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<td>Yes</td>
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Please briefly explain your answer:

It would be helpful if the HFEA could help to raise awareness of bodies willing to provide funding to support innovation and new approaches to treatment.

9. How effectively does the Authority maintain public confidence that the area of human fertilisation and embryology is regulated appropriately:

Well

Please briefly explain your answer:

Despite the sensitivity and controversial nature of some of the activities regulated, we believe there is a high level of public confidence in assisted reproduction. The HFEA has a reasonably high profile and has taken steps to improve the information provided to and for the public and potential patients and donors. The generally positive response to the public dialogue on mitochondrial transfer indicated a high level of support for the safeguards and regulatory mechanism in place to allow new technologies to be developed and used in clinical practice.
10. How well does the Authority communicate and engage with stakeholders?

**Well**

Are relationships with stakeholders (including regulators and professional bodies and other organisations in the health and care system) effective?

How effective is engagement with the public and wider stakeholders?

How well does the HFEA influence nationally and internationally?

Please briefly explain your answer:

The BMA is represented on the HFEA’s Professional Organisations Group and so is kept up to date with developments and ongoing work. It is important that this group is not just used to keep stakeholders informed but also to engage relevant organisations at an early stage; this happens on some issues but less well on others.

The HFEA has been receptive when we have raised issues of concern - such as around embryo freezing policies - although the response has not always been as speedy as we would like. We accept however, that the HFEA has other competing priorities and limited resources.

11. Is the Authority sufficiently forward-looking and responsive to new challenges and opportunities?”

**Yes**

**No**

**Don’t know**

Does the HFEA have the capability and capacity to respond to future challenges?

Does the HFEA have a robust and effective strategy for responding to changing demands and technologies?

Please briefly explain your answer:
Efficiency

12. Are there any measures you believe the Authority could take to deliver further efficiencies (whether reduced costs or improved use of resources)?

Governance

13. Does the Authority follow best practice governance arrangements?
   - Yes
   - No
   - Don't Know

Is the HFEA sufficiently open and transparent?
Are effective financial management processes in place?
Does the HFEA recruit through open and fair processes?

Please briefly explain your answer:

Other Comments

Are there any other issues or evidence you think the review team should take into account?
Contact Details

Please send responses to these questions by 31 August 2015 either by email to TR-HFEA@dh.gsi.gov.uk or by post to HFEA Triennial Review Team, Room 220, Department of Health, Richmond House, 79 Whitehall, Room 220, London SW1A 2NS.