

Response to the HFEA triennial review

August 2015

About you

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Would you categorise your response as from:

- Individual
- Public sector
- Charitable/voluntary sector healthcare organisation
- Academic/Research institution
- Private sector – healthcare related
- Private sector – other
- None of the above. Please state:

Independent bioethics council

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:

The Nuffield Council on Bioethics' remit is to explore ethical issues arising out of developments in medicine and biology. Many of the topics we have covered in recent years relate to matters falling within the remit of the HFEA. We have therefore both ongoing informal contact with HFEA staff/members, and have made specific recommendations as to future HFEA action (e.g. with respect to information sharing in [donor conception](#), and the ethical aspects of introducing novel techniques for the prevention of [mitochondrial DNA disorders](#)).

There has, additionally, been some cross-membership between members of the HFEA and of its advisory committees, and the Council and its Working Parties.

Functions

1. Is there a continuing need for the functions undertaken by the Authority?

Yes

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?

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

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

Please briefly explain your answer:

The area in which we overlap with HFEA interests lies in consideration of the ethical issues arising out of developments in reproductive medicine and scientific research. These developments continue to excite considerable public controversy, as confirmed by our own work in this field.

A dedicated body that is able to consider these issues, at arm's length from government but accountable to Parliament, and one that is capable of gathering input from a wide range of external organisations and the general public, is very valuable. As currently constituted, the HFEA is well-placed to fulfil these functions.

The HFEA's record of sensitive but robust regulation, its specialist knowledge and the public trust it has earned over a long period underwrite public confidence in responsible progress in the field of reproductive medicine and research. This is particularly important in such a contested area.

The presence of the HFEA also helps to maintain the position of the UK as a leader in innovation, good practice and policy internationally.

2. How well do you think the Authority fulfils each of its functions at present?

Very well

Please briefly explain your answer:

The Council has interacted with HFEA colleagues in a number of recent projects: the role of payment/reward for [donation](#) (2011); novel techniques for the prevention of [mitochondrial DNA disorders](#) (2012); and the sharing of information in the context of [donor conception](#) (2013).

These issues were/are clearly important for the HFEA, and staff have been positive and proactive in engaging with external bodies such as ourselves, both in terms of contributing to evidence-gathering and sharing information,

and in terms of serious consideration given by the HFEA to subsequent recommendations.

There appears to be a genuine willingness to work with external stakeholders such as ourselves, with the aim of ensuring HFEA policy is well informed.

The review advice on mitochondrial DNA disorders has shown that the HFEA is capable of being a responsible leader in orderly processes of public policy development, capable of holding a steady course in the face of lobbying from all sides.

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:

In areas as contested as reproductive healthcare and research, an arm's length body is invaluable to ensure that consideration of these issues is (and is seen to be) independent both of the day-to-day business of government and of particular interest-groups.

The HFEA benefits from these functions being concentrated within a professional regulatory body that has earned the trust of the sector, patients and the wider public.

While the HFEA should look for efficiencies through working with related organisations, dilution or loss of identity within a merged or absorbed organisational structure would risk the confidence that the progressive IVF and embryology field enjoys in the UK and internationally.

Performance and Efficiency

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

Don't know

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:

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

Yes

Please briefly explain your answer:

Careful and serious consideration of policy issues affecting patients and donors (such as in information sharing in donor conception, and reward/payment of donors) is important for patient/donor care, and is carried out well. The HFEA has shown itself willing and able to respond sensitively and meaningfully to evolutions in underlying social conditions, for example, with regard to changing understandings of parenthood and family structure.

6. Do you think that the functions of the Authority, regulatory or otherwise, impose burdens that are:

Proportionate

Are risks managed appropriately?

How does the approach compare to other regulators?

Please briefly explain your answer:

Given the controversial nature of innovation in medically assisted conception and their social consequences, and especially human embryo research, there is a potential for substantial harm to individuals and to research if these are not managed effectively. The regulatory burdens imposed on clinics and research centres, along with the policy constraints, are a justifiable cost of reassurance in this field.

7. How effectively does the Authority operate within and support the rest of the health and care system:

Don't know

Please briefly explain your answer:

8. Could the Authority do more to support innovation and new approaches in the area of human fertilisation and embryology?

No

Please briefly explain your answer:

The term 'support' is unclear and potentially contested. As a regulator, the HFEA's role should not be to promote innovation and new approaches, since this raises a potential conflict with its essential purpose, which we take to be to regulate the conduct of assisted conception services so as to protect the interests of patients and those born as a result of assisted conception treatments, and to oversee the use of human embryos in research, in a way that is consistent with public morality. Though the broad parameters are encoded in the framework legislation, public morality is an indistinct and shifting notion, which the Authority has done well to take into account in its consideration of specific instances of innovation.

It is an important consideration that innovation in assisted conception and embryological science may itself contribute substantially to public good (although it might, equally, diminish it). All other things being equal the HFEA should therefore enable innovation in a way that is consistent with its primary functions. To go beyond this risks the public confidence that the HFEA enjoys as an 'ethical regulator'.

Insofar as the HFEA should be subject to any duty relevant to research and innovation, it should be to promote public good consistent with public morality and the protection of the interests of patients and their offspring, not to promote research and innovation *per se*.

We would have grave concerns if, for example, a 'economic growth duty' (such as provided by s.108 of the Deregulation Act 2015) should apply to the HFEA. Such a duty would be either unnecessary (no regulatory action should be disproportionate with respect to the purposes of regulation) or pernicious (justified and proportionate action should not be modified in consideration of its economic impact).

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:

Through its efforts to engage early and proactively with public opinion on matters of controversy, its use of public dialogue and broad consultation, and

its open meetings and reasoned decisions, the HFEA has taken significant steps to maintain public confidence. The HFEA naturally has its detractors but these are often those who take polar positions. By international comparisons, the HFEA has done well to maintain public confidence and an enabling environment for responsible research, innovation and safe treatment.

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 HFEA's engagements with the Council have been timely, open and constructive. Consultation and engagement with the broader public appears to be earnest, well managed and methodologically innovative. The HFEA's model is much admired internationally and their policy outputs are widely analysed and used in support of the work of other bodies.

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

Yes – to a degree

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:

The HFEA has recently appeared to focus on its core regulatory activities rather than future issues, although it has well established networks and mechanisms to consider future issues (e.g. the Horizon Scanning Panel, which, however does not appear to have published an annual report since 2010) and the Scientific and Clinical Advances Advisory Committee. We are

not aware, however, that it has, so far, been overtaken by an issue that it might have been better prepared to consider.

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

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:

As an arm's length body, accountable to Parliament, the HFEA is well placed to consider controversial issues in reproductive medicine and research. The HFEA is capable of gathering input from a wide range of external organisations and the general public, and there appears to be genuine willingness to work with external stakeholders, such as ourselves, to ensure HFEA policy is well informed.

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.