Consulation on the transfer of functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

Response from the Christian Medical Fellowship
September 2012

The Christian Medical Fellowship (CMF) has over 4,000 doctor members and around 1,000 medical student members and is the UK’s largest faith-based group of health professionals. A registered charity, we are linked with like-minded colleagues in more than 90 other countries. Our doctrinal beliefs and ethical values are outlined on our website: [http://www.cmf.org.uk/](http://www.cmf.org.uk/).

CMF regularly makes submissions on ethical and professional matters to Government committees and official bodies. All submissions are on our website ([www.cmf.org.uk/ethics/submissions/](http://www.cmf.org.uk/ethics/submissions/)).

Consultation Question 1:
Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.

CMF does not support this proposal. We are concerned that this option is being driven primarily by a desire to reduce costs, it is not primarily to improve regulation:

‘Option 1, our preferred option, is based on the aim of making additional savings in relation to overall costs of the regulating bodies by reducing the number of regulators in the field, and of reducing the burden of regulatory activity and associated costs on providers.’ (consultation paper, p46)

The splitting of individual HFEA functions will lead to a fragmentation of the roles currently undertaken by the HFEA, which will lessen the quality and effectiveness of oversight of assisted reproduction technology (ART) regulation and embryo research.

We disagree with the key objectives stated in the consultation paper:

1. That this option (and indeed the second option) will: ‘Strengthen the effectiveness of regulation in this area’ (consultation paper, p12).

The HFEA has had experience over many years (longer than the CQC and HRA) in regulating and inspecting clinics and in oversight of data collection. Neither the CQC nor the HRA have this level of expertise. Neither has the specialist knowledge, expertise and experience in most of the areas that the HFEA regulates. Indeed, as the consultation paper acknowledges, several of the current duties of the HFEA would be completely new for the CQC (such as the data registers): ‘and would require new skills and experience as well as an extension of their focus on service providers to include more work in particular areas on the individual needs of patients.’ (consultation paper, p50).
The CQC already has several different roles and adding to these will confuse its duties further, increase its regulatory burden and stretch its capabilities.

2. We disagree with the objective that: ‘A reduction in the total number of regulatory bodies provides an opportunity for the regulators that remain to clarify their roles with providers and where possible reduce the regulatory burden on providers’ (consultation paper, p12).

The most important role of HFEA in overseeing research and data collection and regulation of ART activities at clinics is both clear and well established. This proposed option would not lead to a reduction in the number of overseeing bodies that would be involved in regulating the current activities that the HFEA carries out. Instead, it is likely to be more confusing and overly complicated if the DoH also has to take on some specialist oversight roles and/or contract them out to others.

If one of the drivers behind this option is to reduce the regulatory burden, it would suggest that pursuing this option is likely to lead to increasingly lax regulation over a specialist area that requires tight control and oversight (see our comments at Q2).

Reducing the regulatory burden on research bodies for the (assumed) benefit of the wider economy (consultation paper, p7) would be at the expense of reducing regulation over the creation, use and storage of human embryos and admixed embryos. CMF strongly opposes reducing the regulation of research using human embryos, as well as the storage of gametes and the oversight of ART. Human embryos and gametes are not the same as other body tissues. Embryos are nascent human lives, deserving of special treatment and protection, as specified in the HFE Act. It is imperative that there is particularly tight regulation of all embryo research.

The consultation paper acknowledges that the CQC does not have to monitor compliance regularly and is left to itself to make decisions on when to monitor. It has to ensure that any action it takes is targeted and is proportionate to the risk, which exacerbates our concern that the CQC will not regularly monitor research (as the HFEA currently does, at least every two years) unless there is a specific reason or request to do so.

**Consultation Question 2:**
Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?

For donor conceived people who choose to seek information about their genetic heritage, the answers they receive have the potential to change their lives dramatically. The HFEA has a duty to keep registers, in order to record every treatment cycle, patient, gamete/embryo donor and all resulting offspring. The Human Fertilisation and Embryology Act 1990 also sets out the circumstances in which identifying information held on this register may be disclosed to third parties. On the whole, the HFEA has carried out this important duty reasonably successfully.

Transferring oversight and regulation of this sensitive and essential duty would represent a significant new activity for CQC, unlike any other it currently carries out.

The Department of Health suggests it may therefore have to contract out this service to an external provider which would introduce another layer of complexity and cost, one which is avoidable by retaining the HFEA. Contracting out to another body (or more) would introduce the strong possibility that important personal data might be lost, mislaid, inaccurately collected or not even collected at all.
We also question whether a transfer of duties, and consequent cutting of costs, will hinder essential research into the long-term health implications of fertility treatments.

**Consultation Question 3:**
Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this.

See comments above.

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

N/A

**Consultation Question 5:**
Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this.

We support this option. There are options to reduce costs (including reducing salaries) while at the same time benefitting from the expertise and long-term experience that the HFEA has in the following areas:

- Regulation of ART treatment cycles;
- Regulation of creation, donation, testing, use and storage of human embryos and admixed embryos;
- Licensing and regulation of the donation, procurement, testing, processing, preservation and distribution of gametes;
- Collection of data on children born of donated gametes and ART;
- Ensuring the welfare of child born from treatment;
- Regular inspections of clinics.

**Consultation Question 6:**
Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify

N/A

**Consultation Question 7:**
Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?

The following functions of the HFEA are best served by the HFEA, as a specialist and experienced body:

- Regulation of the creation, use and storage of human embryos and admixed embryos;
- Licensing and regulation of the donation, procurement, testing, processing, preservation and distribution of gametes and embryos;
- Regulation of data on children born of donated gametes and IVF;
- Ensuring the welfare of children born from treatment;
- Regular inspections of clinics.
However all policy functions and decision-making activities of the HFEA would be best transferred to Parliament and then to the Department of Health. For example, the setting of compensation for donors of gametes, decisions on recipients of ART, and on the welfare of the child etc should be transferred to Parliament which would have overall responsibility for setting policy such as remuneration limits, in consultation with stakeholders and the general public.

Consultation Question 8:
Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 above and in the accompanying consultation Impact Assessment?

N/A

Consultation Question 9:
This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.

N/A

Consultation Question 10:
Do you have any further comments on the consultation options that you would like to share with us?

N/A