Legislative Reform Advisory Group: outline work programme

Introduction

1. In recent speeches to Fertility 2022, and to the Progress Educational Trust Annual conference in 2021, the HFEA Chair, Julia Chain, has set out three broad areas in which we believe the Human Fertilisation and Embryology Act 1990 (as amended) should be modernised:
    - Patient protection
    - Scientific developments
    - Consent, data sharing and anonymity
2. We intend to engage with the Legislative Reform Advisory Group to consider elements of these three broad areas over the coming months.

Outline work programme

3. The outline work programme is set out below. Several of the issues under 'Patient Protection' are considered in the paper on licensing which is to be considered at this meeting. At this stage the work programme should be treated as indicative and as discussion gets underway, individual issues may change.

Patient protection

The Act risks not being focused enough on patient protection in an increasingly commercial and competitive environment – in areas including the HFEA's regulatory powers, information provision and advertising. How best should the Act take account of:

Issues of principle:

- Should the Act include an over-arching statutory objective regarding patient care?
- Should HFEA have statutory powers around investigating complaints?
- Should financial penalties be available to the HFEA?

Practical administrative issues:

- Should sanctions for serious non-compliance be re-ordered to be more proportionate?
- Should the HFEA have greater freedom over timing of inspections?
- Regulatory tools around the role of PR and of Licence holder

Scientific developments

The Act risks being overtaken by new knowledge which might delay potential benefits to patients unnecessarily – how best should the Act take account of:

Issues of principle:

- Regulating in-vitro derived gametes and embryos
- The '14 day rule' time-limit on embryo research
- Interventions on the nucleus/germline genetic engineering
- Artificial simulations of the womb environment
- Creating a statutory requirement for clinics to be active in research or to facilitate research

Practical administrative issues:

- How to define 'gametes' and 'embryos' in legislation?
- How to licence 'necessary' human embryo research when alternative models may become available?
- How to regulate the responsible implementation of AI and data-driven technologies?
- 'Regulatory sandbox' type powers to encourage innovation through trial approvals

Consent, data sharing and anonymity

The Act overly complicates patient consent- how best should the Act take account of:

Issues of principle:

- Variations in consent after embryos have been created, posthumous consent, consent to donate embryos for the purpose of research rather than to a specific research project
- Online DNA testing and 'matching' services enable donor conceived people, donors and their close genetic relatives to find each other in an identifiable way online. What should the HFE Act require of donors, recipients and the HFEA, in these new circumstances?
- Should fertility patients' treatment details no longer be kept confidential from their other medical treatment data?

Practical administrative issues:

- How legal parentage is administered, electronic consent, the ten-family limit.

Note: we do not propose to make recommendations on:

- Surrogacy law reform: in advance of the joint Law Commissions' report expected in November
- Shared motherhood and partner-to-partner donation and screening: we are in discussion with DHSC on this issue
- The Gender Recognition Act: and the tension of GRC holders' legal status with the HFE Act's definitions of woman and man


Human
Fertilisation &
Embryology
Authority