Legislative Reform Advisory Group (LRAG) Meeting notes

6 June 2023

Teleconference (Teams meeting)

Advisory Group	Present	Catherine Hill, Nina Barnsley, Robin Lovell-Badge, Raj Mathur, Emily Jackson, Tim Child, Jackson Kirkman-Brown, Angela Pericleous-Smith Peter Thompson (HFEA Chief Executive) Julia Chain (HFEA Chair, and Chair of LRAG meeting)
	Apologies	Adam Balen, Francesca Steyn
Members of the executive	Present	Clare Ettinghausen (Director of Strategy and Corporate Affairs) Dina Halai (Head of Policy (Scientific)) Ana Hallgarten (Public Policy Manager) Beth Lockwood (Policy Manager) Beth Rowbottom (Social Research Manager)

1. Welcome

1.1. The Chair welcomed members to the fifth meeting of the Legislative Reform Advisory Group and thanked them for their involvement.

1.2. The Chair stated that the focus of the discussion would be on specific issues arising from the HFEA consultation which ran between 28th February and 14th April 2023 on prospective changes to the Human Fertilisation and Embryology Act 1990 (as amended 2008).

2. Public consultation update

2.1. A brief overview of the responses to the consultation was presented by the Public Policy Manager. It was noted that the consultation was designed to collect a wide range of views on the HFEA's proposals, but was neither intended to be representative, nor a vote.

2.2. LRAG members were made aware that qualitative and quantitative analysis of the consultation was still ongoing and that the proposals for legislative change continue to be refined prior to being presented to the Authority in July.

2.3. The Chief Executive introduced four key areas for discussion and explained that these were the areas that required further detailed consideration.

2.4. The four areas for discussion were:

- The regulation of fertility services outside of licenced clinics
- Donor anonymity/identification
- Simplifying consent
- Future proofing the Act so it can better adapt to scientific developments

3. The regulation of fertility services outside of licenced clinics

3.1. The Chief Executive explained that some activities outside of the HFEA's regulatory powers are being marketed as fertility treatments, these include, for example, online clinics. It was noted some online clinics may publish their own success rates despite not being an HFEA licensed clinic. Patients may not be aware that elements of these services are unregulated or that they are unable to complain to the HFEA or seek support about these services. Continuing, the Chief Executive highlighted that this is a market which has emerged in recent years (long after the Act was initially passed) and which continues to grow.

3.2. From the consultation responses it was noted that respondents may have found the terminology 'allied fertility services' confusing and this may have affected the responses received. For clarity, the Chief Executive explained that the HFEA did not use the term to cover medical procedures already covered by other regulatory regimes, for example the GMC or the CQC. Any proposals to amend the Act should concern only treatments/services that are falling outside of other regulation.

3.3. LRAG members were asked to consider whether the regulatory scheme should be adapted to take into consideration of fertility services taking place outside of licenced clinics and if members thoughts about terminology to reflect this.

3.4. LRAG members gave some examples of where patients had been confused between different services they had accessed and who is responsible for overseeing them. Some members welcomed the clarification that the medical procedures already regulated elsewhere were not to be included in this proposal.

3.5. Members agreed this area was complex and it would be useful for the HFEA to better explain what it meant in this proposal.

4. Donor anonymity

4.1. The Chief Executive explained that it is increasingly possible for people to find out donor information without coming to the HFEA by using DNA testing sites and social media. When donors donated 18 years ago it wasn't foreseen that this would happen.

4.2. The Chief Executive highlighted that the responses to the consultation were mixed. Some respondents wanted to retrospectively 'open the register' while others wanted to mandate early identification from the birth of the donor conceived individual (DCI).

4.3. LRAG members were asked to discuss whether the existing regime of only releasing identifying information when the DCI has turned 18 has been so undermined by social and technological developments that a shift is necessary.

4.4. The last time this topic was discussed LRAG members felt a 'dual-track' approach seemed a reasonable compromise (and this option was part of the consultation exercise). This approach would allow donors to choose whether they wanted to be identifiable before the child turned 18 and recipients could choose their donor based on this information.

4.5. LRAG members mentioned the following points:

- Members noted that the dual-track approach initially proposed was to allow flexibility and prevent putting donors off donating. However, many members now felt this approach might be too complex and difficult to work smoothly.
- One member noted the welfare of the child maybe more significant than the age at which the DCI can request identifying information about their donor.
- A member felt the 10-family limit and the ability of donor gametes to be used globally should be revisited as it appears the more genetic siblings a DCI has the greater the risk of a negative outcome.
- Members felt the HFEA should continue to hold the register and ensure information is accurate and the process to request information is as smooth as possible. However, some members felt that the HFEA should not be involved in setting age limits at when donor information can be accessed.

4.6. Overall LRAG members agreed that the promise of anonymity for the donor until the DCI turns 18 is no longer a certainty due to the availability of DNA testing and social media. There was, however, no consensus on what option should replace the existing regime.

5. Simplifying consent

5.1. The Chief Executive highlighted that consents in fertility treatment will always be more complex than most other medical treatment.

5.2. Accepting that fact, the Chief Executive asked the group for their thoughts on whether fertility consent could be simplified and whether consent could be triaged to accommodate different individual circumstances.

5.3. LRAG members noted that:

- There is a case for simplification of consent as the more complex the consent, the more chance for human error and in turn legal challenge.
- There is a lot of GMC guidance around informed consent now that wasn't there when the Act was passed, so additional layers of consent for these areas is arguably unnecessary – although it was noted that there was no overlap between the consent required by the HFE Act and consent to medical treatment. The areas which aren't covered by GMC guidance include intention to be the legal parent or intention to donate, and storing and using embryos, which is why consent is fundamental in fertility treatment.
- Consent in relation to parenthood is particularly confusing and parenthood provisions only relate to treatment involving donated gametes. Parenthood for those using their own gametes is more straightforward. There was some discussion as to whether such consents could be simplified by moving away from the long-standing registration categories of 'mother' and father' to a 'parent' model similar to that used in surrogacy orders.

5.4. Members then discussed the proposal regarding the creation of embryo banks, allowing patients to provide broader consent to research of their embryos. An increasing number of people are freezing their eggs or embryos and there is disparity amongst clinics about how those eggs or embryos can be used if they are no longer going to be used by the patient.

- Some members felt projects involving the creation of immortal cell lines would require more complex consents and people may wish for their embryos only to be used in specific types of projects.

- There was a suggestion that there could be two categories of embryo research consent – a generalised consent for all research and one in which the patient could choose which areas of research they wanted their eggs or embryos to be used for.

6. Future proofing of the Act so it can better adapt to scientific developments

6.1. The Chief Executive explained that this topic was included in the consultation because it is clear that some of the framework in the Act is being put under pressure due to recent scientific developments such as in relation to the 14-day rule, nuclear germline genome editing and embryo-like entities.

6.2. The Chief Executive outlined the potential tension between a legal framework that is inherently fixed and scientific developments move rapidly and continuously. It was proposed that a better way of approaching this problem would be to allow more flexibility within the Act, enabling change to take place more rapidly in line with these developments.

6.3. However, it was highlighted that some of these decisions have wide reaching ethical and social implications and more consideration of what should stay in primary legislation may be needed.

6.4. The Chief Executive asked LRAG members to consider which decisions or issues should remain in primary legislation and which decisions could be allowed more flexibility through, for example, secondary legislation.

6.5. LRAG members discussed the following points:

- One member noted that it usually takes a minimum of two years to change the Act and then a further two years for any change to come into effect. Legal changes in line with scientific developments may therefore need to happen at a faster timescale than is currently taking place.
- Regulations could be used to regulate changes that require a more urgent change and others which are not as urgent could remain under primary legislation.
- Some members felt that embryo models were a development that required an urgent review on regulation as it is an area that lacks clarity in the Act.

6.6. LRAG then considered the 14-day limit on embryo research. They noted the following:

- Members felt even if the current limit was extended, there would always need to be a limit in place in legislation.
- Some members felt uneasy about the 14-day limit being extended. However, others felt that the limit could be extended to 28-days as there are already some countries taking embryo research beyond 14-days.
- However, there was consensus that there needed to be a wider discussion around this topic before any recommendation could be proposed, and that public engagement would be essential.

6.7. Overall, members felt there was a case for building greater flexibility into the Act. Some members felt there are a small minority of issues such as the 14-day limit for embryos which require more work, but that this should not prevent legislative reform in other areas.

6.8. The majority of members agreed that it was important to press ahead with the proposal for legislative reform for scientific developments.

7. Any other business

7.1. The Chair thanked members for their input into the HFEA law reform proposals.