

# Legislative Reform Advisory Group (LRAG) Meeting notes

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6 May 2022

Teleconference (Teams meeting)

Attendance		
Advisory Group	Present	David Archard, Adam Balen, Nina Barnsley, Kate Brian, Tim Child, Emily Jackson, Jackson Kirkson-Brown, Robin Lovell-Badge, Raj Mathur, Francesca Steyn. Peter Thompson (HFEA Chief Executive) Julia Chain (HFEA Chair, and Chair of LRAG meeting)
	Apologies	Nina Barnsley (Jo Davidson attending instead), Gwenda Burns (Kate Brian attending instead), Eddie Morris (Adam Balen attending instead).
Members of the executive	Present	Clare Ettinghausen (Director of Strategy and Corporate Affairs) Catherine Drennan (Head of Legal) Laura Riley (Head of Policy- Scientific) Ana Hallgarten (Public Policy Manager) Amanda Evans (Head of Intelligence)

## 1. Welcome

- 1.1.** The Chair welcomed members to the second meeting of the Legislative Reform Advisory Group and thanked them for their involvement. The Chair briefly restated the context to this important work.

## 2. Update since the last meeting

- 2.1.** The HFEA's Director of Compliance and Information, Rachel Cutting had taken part in a Progress Educational Trust event [on a future review of the Act](#). The discussion was lively, sometimes focused on the present rather than the future, but offering useful opportunity to outline our work generating ideas for modernisation of the Act.
- 2.2.** The Chair also reminded the meeting that HFEA is planning small roundtable expert feedback meetings on topics that LRAG have already explored, or will discuss together before July's planned consultative exercise. The aim is to help to surface any further issues for update in the HFE Act. These are not

representative meetings of any professional or patient groups, but aim to gain a snapshot of some specialists' views from their close working with the Act. A short note of these meetings will be placed on the HFEA website together with some themes raised in the meeting. Examples of groups will include:

- Data researchers who use HFEA Register data
  - Ethicists
  - Researchers working with human embryos under HFEA license
  - Family Lawyers
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### 3. Consent

- 3.1.** The HFEA Chief Executive outlined the issues in the discussion paper on Consent. The LRAG noted that consent is one of the cornerstones of the Act, but there are inconsistencies, and the law is not always clear. Consent in assisted reproduction and in the creation of embryos is unique as more than one person may need to consent. At times the two people involved in creating, storing, or donating their embryos might have opposing views.
- 3.2.** An ongoing court case regarding the [posthumous use of gametes was highlighted](#).
- 3.3.** Continuing, the Chief Executive noted how complex the issue of consent is, in particular when considering the broad range of issues that fall under the topic, including treatment, storage, donation, training, research, and disclosure of information.
- 3.4.** The Chief Executive highlighted the current emphasis in the Act of consent being both informed and in writing. The discussion paper assumes that informed consent would still be central to any changes to the Act.
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### 4. Legal parenthood

- LRAG agreed that legal parenthood continues to be a complex area for patients and challenging to administrate in practice. Legal parenthood forms are complex, because the law is complex, but often delegated to less experienced nurses to discuss with patients, to free up more senior staff's time for other aspects of care.
- 4.1.** LRAG members raised that:
- The Act should be amended so that consent forms for legal parenthood are not stored over decades only at clinics, which is suboptimal, and potentially risky for practical reasons. Forms should be mandated to be stored for much longer than 30 years under new amendments to the Act. There was however, no consensus on where else such forms should be stored.
  - Because complex family and parenthood arrangements also exist outside of patients seeking fertility treatment. It was suggested that legal parenthood in fertility clinics could be removed from the Act entirely and be dealt with as part of wider family law. One approach would be that (given some members also felt that a review of birth registration legislation would be beneficial), family law questions about legal parenthood could be dealt with in a new, separate Act also covering birth registration. However, it was accepted that any wider review would take years and therefore there was a strong case to improve the position within the constraints of the Act. An alternative view was that the family courts could iterate around legal parenthood via case law, avoiding this area being dealt with by legislation at all.

- Consenting to medical treatment and consenting to legal parenthood under the current Act can become 'muddled' for patients. In future, it was suggested that while patients could consent to become legal parents to a resulting child, their consent to treatment could be taken as implied, by the patients' presence in the clinic.
- Some suggested further that individuals seeking fertility treatment at clinics could be considered by default as wanting to be parents, rather than needing to explicitly give their consent to legal parenthood. Others were concerned by the idea of implied consent and felt strongly that a legal process is needed to agree and evidence who the legal parents are, for example by the patient ticking a box that s/he agrees to be the parent of any child born. Without a clearly recorded consent following specific mandated information-giving, this could raise issues for patients or their families if there were a change of circumstances, for example, with the posthumous use of gametes and embryos.
- All agreed that legal parenthood is often not considered a key issue by patients who are understandably sometimes more focused on starting their fertility treatment as soon as possible. The Act's requirements in this area must be therefore kept as simple as possible to avoid issues for patients about legal parenthood further down the line, for example when registering a child's birth.

## **5. Electronic consent**

**5.1.** LRAG agreed that the use of electronic consents in a clinic setting could be helpful to both clinicians and patients. Benefits included reducing admin errors, requiring identity authentications, creating flexible forms for different situations, automatically requiring information to be entered correctly, and offering drop-down details to explain complex issues, or providing mandatory video explanations of consent prior to completion. Patients can easily save electronic consent forms for their own records.

**5.2.** LRAG members raised that:

- The Act could in future require clinics to be able to demonstrate evidence of informed consent, but need not specify what method (electronic or otherwise) must be used for recording this consent. The HFEA could determine the appropriate consent recording regimes for clinics.
- The Act's focus should move to minimising the risks of patients misunderstanding consent requirements, eg requiring staff to make it clear what patients are being asked to consent to, and making it clear how patients can provide their consent.
- Nurse consultations should still be compulsory where electronic consent forms are used outside of the clinic, so that patients can seek professional explanations easily, including patients who need more help to understand written information or whose first language isn't English.

## **6. Consent for storage and use of testicular and ovarian tissue**

**6.1.** LRAG members raised that:

- The Act should be amended to resolve complications regarding the statutory responsibilities for the two regulators over these tissues. At the point of treatment the samples are the HFEA's responsibility, but when stored, the responsibility of the Human Tissue Authority, causing occasional non-compliances to occur. These might mean that tissue stored for future fertility preservation eg by a child having cancer treatment in hopes of eventual fertility restoration by autologous transplantation, in fact can't be used.

- Furthermore, there has also been significant research progress with in-vitro derived gonads which will require appropriate regulation in law.
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## 7. Family limits

**7.1.** LRAG agreed that the Act should be amended to specify that a family limit must be placed on donation and that HFEA should be given responsibility to determine the specific number for this limit.

**7.2.** LRAG members raised that:

- Given sometimes complex family relationships, defining 'family' can be challenging. There were varied opinions regarding whether using the term 'families' was optimal when setting limits.
  - A suggestion was for the Act to specify that the limit could pertain to the 'children born, plus their siblings and half siblings' per donor via licensed donation treatment, as a simpler expression of the principle. The relevant number of children per donor could then be set in directions by HFEA.
  - Donations from the same donor can be used in the UK under family limits, but also without limit in other countries, for example in the US. Strong concerns for donor-conceived people and recipients were felt about lack of restrictions on family limits overseas, for donations imported into the UK from abroad.
  - Some felt the Act should be amended to require increased transparency on the number of children/families already created overseas by donors whose gametes have been imported into the UK for treatment use. Others questioned how achievable this transparency might be, given that overseas clinics and donors may not know of these numbers themselves.
  - There were similar concerns about UK clinics' practice of exporting any unused stocks of donations overseas for use, after an individual UK donor has reached the current ten family limit. This was similarly felt to be a breach of patients' or donor-conceived people's expectations.
  - The principle for placing limits should be around limiting the risks of consanguinity for donor-conceived people in sexual relationships, but also around allowing donor-conceived people who wish to, to form relationships with a donor and/or relationships with their siblings from the same donor. This relationship-building becomes increasingly difficult where family numbers are very high.
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## 8. Payment arrangements coupled with consent

**8.1.** LRAG agreed that the Act should be amended such that consent (to storage, for example) should be given and recorded independently without tying it to any time-limited financial arrangements agreed for storage.

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## 9. Posthumous consent

**9.1.** LRAG noted the difficulty in regulating posthumous consent. The example of a current ongoing [court case](#) has demonstrated the problems that can arise posthumously when consent forms are not properly completed.

**9.2.** LRAG members raised that:

- Clinic consultations do discuss posthumous consent, but at that time, patients may be stressed or anxious to proceed to treatment, hence errors being made on the forms, or insufficient consideration being given to wishes around posthumous use.
- Consent forms continue to be essential as consent choices must be clearly documented regarding posthumous use.

- For clarity, all forms need to provide a required yes/no choice to be recorded. ‘I do not want X to happen’ should be required to be recorded as an active choice, not, as sometimes currently happens, leaving the ‘yes’ box blank for a presumed ‘no’, with no box provided, because forms have only provided a box to tick for ‘yes’.
  - The number of consent forms regarding the use of gametes could be reduced, with consent to different types of uses combined together in one form, to simplify the process and reduce the chance of errors between several forms.
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## 10. Clarity on consent requirements for procurement/harvesting of gametes and partner treatment of sperm

**10.1.** LRAG were content that in a fresh cycle of treatment (without processing and storing), a new Act requirement for consent before using a person’s own gametes for their own/their partner’s treatment could reduce difficulties if circumstances change in the course of treatment.

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## 11. Consent to research

**11.1.** LRAG noted that most embryo research already falls into easily defined purposes. Because the Act does not currently explicitly permit broad consent to donation of embryos for defined research purposes, this has resulted in at least one instance of wastage of large numbers of embryos donated for research. At present the Act implies that consent must be to donate to specific research projects. Reconsent to any amended individual research project can be very difficult logistically to obtain from patients.

**11.2.** If for example, a renewed research licence is not granted to a project due to changing views at the HFEA licensing system or the [Research Ethics Service](#) Research Ethics Committee (REC) then the embryos already consented to that project must be destroyed, which is a waste and a reputational risk to research. Research funding ceases with the licence stopping.

**11.3.** LRAG members raised that:

- All concurred that amending the Act to explicitly permit broad consent could allow for more research and less wastage of donated embryos. Recontact should be required as part of this. Patients with stored embryos are already recontacted regularly by their clinic.
  - Research gamete and embryo banks could be created under broad consent. Many patients will welcome the opportunity to donate to more than one specified project.
  - Specific opt-outs for different research uses must be available within any broad consent. Eg opting out of all research generating an enduring stem cell line, or creating a chimeric embryo.
  - The Act must provide under new consent arrangements, that patients must still be able to donate their embryos directly to specific projects only, if they prefer that. Some patients will only want to donate to a project that resonates with them personally.
  - More information should be provided about donating to research and the purposes of research in the Code of Practice and on the HFEA website.
  - Some members felt that the Act may not need significant change around consent to research, dependent on how the Act and the Code of Practice are interpreted.
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## 12. Data sharing

**12.1.** The HFEA Chief Executive outlined the discussion paper.

**12.2.** LRAG members agreed that amending the Act to permit easier sharing of fertility patient data in medical settings outside the fertility clinic would aid patient protection and safety, improving care, speeding up diagnosis, and providing important centralised records for research or commissioning. The group were concerned that when a patient has a miscarriage for example, were hospital staff not to have access to their fertility clinic records adds unnecessary risk. Clinicians said that they had almost never experienced patients saying this would be problematic (though occasionally if patients have a social relationship with their GP they might say they don't want their GP to know).

**12.3.** LRAG members raised that:

- The Act's imposition of an extra layer of confidentiality around fertility treatment above standard medical confidentiality should not be retained.
- HFE Act amendments should dovetail with GMC guidance around confidentiality and data sharing within research as well as care, such as the 'no surprises' test.
- Although many patients consent to data sharing of medical data for research, they may at times not feel clear who this information is being shared with. Maximum transparency should be provided.
- When sharing medical data between professionals, clinicians must be mindful and sensitive about disclosing information. A few fertility patients do not tell anyone at all that they are having treatment.
- Caution was raised where patients using donated gametes did not want their medical record to show donor gametes, which for some patients, particularly from some underserved communities, would be felt to be sufficiently stigmatising for the patients and their potential child that they would seek treatment outside the UK to avoid it.

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## 13. Sharing patient data in a research setting

**13.1.** LRAG members were content that that the Act should be amended to allow register information from the donors of gametes and embryos to be shared for all kinds of research, beyond anonymised research.

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## 14. Incentivising the use of HFEA Register data in research

**14.1.** LRAG members were content that the HFEA should be able to charge full cost recovery to researchers for access to our register data, regardless of how identifiable it may be, and at a rate set by the Authority (not the Act).

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## 15. Any other business

**15.1.** None raised.

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