LRAG discussion paper – June 2023

Introduction

1. Following decisions by the Authority and discussions held with LRAG in 2022, the HFEA held a public consultation between February and April 2023 on prospective changes to the Human Fertilisation and Embryology Act. The consultation document can be found **here**.
2. A summary of the impact of the consultation and next steps can be found in the **Authority paper** presented in May.
3. A brief overview of the responses to the consultation will be presented at the LRAG meeting. 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.
4. The Authority will review the final shape of our recommendations to Government in July.
5. The consultation asked 16 questions which are set out at Annex A. The responses indicate broad support (expressed as 'strongly agree' and 'agree') to most questions. In some areas it is clear that although the proposal was supported, it would be helpful if we could provide more detail when we submit recommendations to the Government. For example, the proposal that a revised Act should have an explicit duty on patient care (question 5) was interpreted by some as an indication that the protection of the embryo should no longer matter; whereas we see a greater focus on the patient as complementing the existing focus on the embryo and providing targeted regulatory tools to address inappropriate use of, say, multiple embryo transfer or treatment add-ons.
6. However, many respondents also provided detailed written responses and an analysis of those suggests that there are four areas where despite overall support there was less consensus. The aim of this LRAG meeting is to discuss those areas in more detail.
7. The areas for discussion are:
    - The regulation of fertility services outside of licensed clinics (question 6)
    - Donor anonymity / identification (question 10)
    - Simplifying consent (question 12)
    - Future proofing the Act so it can better adapt to scientific developments (question 16)
8. This paper sets out a summary of the key issue(s) under these four areas and poses questions for discussion. As noted above, on most issues the direction of travel is clear as set out in the consultation and we have not therefore sought to re-visit those issues.

Wider regulation of services outside of fertility clinics

The HFEA consultation said:

More fertility services are being offered that fall outside the remit of the Act

Some activities marketed as fertility treatments, but not covered by the Act, take place outside of HFEA licensed clinics. Some of these services might be in 'wellness' clinics, or they might be offered by

introduction services advertised online. From the perspective of the patient going through fertility treatment it is all part of their treatment journey and the HFEA should have powers in these areas.

Additionally, there has also been a growth in private arrangements, including online sperm donation where the risks to a woman's health can be serious. However, it is difficult to see how any regulatory regime could effectively tackle such arrangements.

9. We found some respondents took such 'fertility services' to include a variety of things including other gynaecological procedures not associated with licenced treatments. Others were unclear whether it included price regulation. Neither of these things were intended in the proposal we consulted on.
10. We need to better define the sorts of services we have in mind, but in the meantime the following sets out the sector developments we are most concerned about. The modern fertility market is increasingly offering services in settings which are outside of the regulated scheme – i.e., physical licensed premises. These can include, for example, online 'clinics' offering pre-treatment workup(s) and egg donor agencies. Patients have reported to us that when they find a service provider offering 'fertility services', it is immaterial what part of that service takes place in an HFEA licensed clinic. For example, some virtual clinics consider patients as 'their own' even though licensed treatments take place in HFEA licensed clinics, and they publish their own success rates; from a patient perspective, they would appear to fall under the HFEA regime, yet they do not. In some cases, the quality of those services are covered by a third party agreement with an HFEA licensed clinic; in other cases they are not. To summarise, in different service settings, different elements of the patient journey is not directly regulated by the HFEA.

Questions

A. What further explanation would be useful of 'allied' fertility services?
B. What further examples would you add from a patient perspective that would demonstrate this?

Donor Anonymity

The HFEA consultation said:

The Act should be amended to provide parental and donor choice to opt for anonymity until age 18 (as now) or identifiable information on request after the birth of a child.

Under this scenario donors (when they donate) must decide whether they wish to remain within the existing legal framework (where anonymity is protected under the Act until the donor conceived individual becomes an adult), or whether they wish to be identifiable to parents by request via the HFEA. If a decision to opt for anonymity until 18 had been made, then the donor conceived adult would gain information access rights from the age of 18. Parents would need to decide at the point of treatment whether they would like to choose a donor who is identifiable before or after their future child turns 18.

11. While LRAG felt that a 'dual system' was a good idea when this was discussed in 2022 the consultation responses revealed a variety of positions. Some wanted to go further and have full identifiable information available for all children and parents from birth, others argued for retrospective identification for pre-2005 donors and others wanted the sibling registry to be opened so that donor conceived individuals could contact their genetic full/half siblings from their donor(s). Equally, there were also respondents who wanted to re-instate full anonymity for all children born from donor gametes.

12. Concerns were raised by some that donors who would be identifiable by birth would 'cost more' due to administrative charges from clinics and that a two-tier system may create conflict given that some children would know their donor from birth whereas others would not.
13. Under present arrangements, donor conceived individuals can decide whether to contact their donor at aged 18. In the suggested dual/double track system, the decision of whether to contact the donor (and when) would instead lie with the parents. Questions were raised as to whether the right of the donor conceived individual to decide when to apply information should remain with them.
14. All of these and other points were made against the widespread acknowledged backdrop that information can now be found from a wide range of sources (for example social media and DNA testing sites) well before donor conceived individuals turn 18. This reflects the HFEA concern that information provision at 18 may in future be largely obsolete.

Questions

A. Do LRAG members still support a dual/double track system?
B. Is there a better alternative?
C. Given that the 2005 changes are only coming to fruition in Autumn of 2023, should recommendations to Government suggest that the Act be amended to allow changes to donor information provision (whether to a dual track system or some other proposals) to take place via regulations at a point in the future when deemed appropriate?

Simplifying consent

The HFEA consultation said:

> The present system requires each participant to actively 'opt-in' to consent to each element of treatment or scenario. A different way to approach consent might be to follow a variant of the 'opt-out' approach which has been successfully adopted in some other areas of medicine. This could involve a consent regime built around a small number of common relationships. People would then be asked whether they wished to adopt this consent package or to actively 'opt-out' to make bespoke choices.
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> However attractive such a model might be, there is a risk that the potential variations in the circumstances of patients (such as a relationship breakdown, or death) might mean that consent could in some circumstances lack the degree of protection offered by the current consent regime.

15. There was broad consensus that consent is complex, however there was no consensus on *how* this complexity of consent could be resolved. Some supported the 'opt-in' model proposed in the consultation, provided patients fully understood what they were agreeing to, or that the model did not embed preference norms. Others appeared to misunderstand the proposal by raising concerns about the extent to which it could accommodate the full variety of family forms (NB. the proposal assumes that bespoke consent will always be necessary in some cases).
16. Assisted reproduction enables new family forms that are not adequately captured in the longstanding registration categories of 'father' and 'mother' and one way of simplifying consent would be to move to the use of 'parent' (echoing parental orders in surrogacy) or 'intention to be a parent'.
17. LRAG members were keen to support the idea of changes to the consent system – with some advocating for a separation between clinics taking medical consent and for legal parenthood to be dealt with elsewhere. However, separating consent in this way would likely involve additional costs to patients and risks making record keeping more complex.

Questions

A. Consent in fertility treatment will always be complex and any proposals for change will involve pros and cons, given the variety of responses to the consultation, where would LRAG prioritise reform?
B. Should consent simplification be primarily for the patient or the clinic?

Scientific developments

The HFEA consultation said:

That the Act is 'future proofed' This survey is not the place to resolve whether the current restrictions should change, but whether, given the pace of scientific development in the field, the Act should be 'future proofed' so that it could become more accommodating of potential new developments that offer patient benefit. Any change in the regulation of these advances would require wider public debate prior to parliamentary amendment.

18. The varied responses to this area ranged from those who would prefer there to be no changes to the Act or that embryo research should be restricted in some way or altogether; to others who reasoned that 'future proofing' the law was a priority to better support crucial research in the field. Of the latter, there were a variety of views as to the appropriate balance between primary (the HFE Act) or secondary legislation. Many who supported the idea of future proofing were attracted by the proposal in the consultation, which suggested using secondary legislation as a timelier means of responding to scientific developments – an approach similar to that used in the 2008 revision to the HFE Act regarding mitochondrial donation, where the definition of a permitted egg or embryo could be changed by subsequent regulations (which occurred in 2015).
19. There was less consensus on the merits of using primary legislation (the HFE Act) to set clear limits which could not be passed – e.g., even if it were decided that the current 14 day rule should be amenable to change by regulations, some thought the Act should still set a limit that subsequent regulations could not override. There was also a variety views about the extent to which significant changes (however defined) should only be introduced after meaningful public debate and engagement.

Questions

A. Are there areas of 'scientific developments' that LRAG would keep in primary legislation? For example, should any extension to the 14-day rule remain in primary legislation (and continue to specify a set number of days), or should the Act be amended to provide a flexible framework within which regulations may permit the extension of embryo research past 14 days in the future?
B. Do LRAG members have views about enshrining a requirement in legislation of the need for meaningful public engagement prior to any significant changes in the regulation of novel scientific developments? Any such proposal would need to note that there should not be a requirement of public consensus before legislative change.

Annex A – Consultation questions

1. To what extent do you agree or disagree that the HFEA should have greater freedom to vary its inspection regime?
2. To what extent do you agree or disagree that there should be more flexibility in the appointment of clinic leaders, for example introducing the option of a deputy PR, and broadening the criteria for the qualifications and experience required to be a PR?
3. To what extent do you agree or disagree that the HFEA should have a broader, more effective range of powers to tackle non-compliance?
4. To what extent do you agree or disagree that the HFEA should have a broader range of powers to impose financial penalties across the sector?
5. To what extent do you agree or disagree that there should be an explicit duty on the HFEA and clinics to act to promote patient care and protection?
6. To what extent do you agree or disagree that the HFEA should have a broader range of powers to tackle related fertility services not taking place in licensed clinics?
7. To what extent do you agree or disagree that the current appeals process should be changed?
8. To what extent do you agree or disagree that there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions?
9. To what extent do you agree or disagree that clinics should be required by law to inform donors and recipients of potential donor identification through DNA testing websites?
10. To what extent do you agree or disagree that the Act should be amended to provide parental and donor choice to opt for anonymity until age 18 or identifiable information after the birth of a child?
11. To what extent do you agree or disagree that the Act should require all donors and recipients to have implications counselling before starting treatment?
12. To what extent do you agree or disagree that the current consent regime could be simplified (for example to an ‘opt out’ model) in ways that continue to provide protection to patients?
13. To what extent do you agree or disagree that the sharing of fertility patient data in a non-fertility medical setting should be brought in line with the current regulations for the sharing of other patient/medical data between healthcare providers?
14. To what extent do you agree or disagree that consent for donating embryos should be extended to allow patients who wish to, to give consent to research embryo banking?
15. To what extent do you agree or disagree that the Act should explicitly give the HFEA greater discretion to support innovation in treatment?
16. To what extent do you agree or disagree that changes should be made to the Act to allow Regulations to be made (by secondary legislation or statutory instruments) to enable future amendments and extensions?