

# Legislative Reform Advisory Group (LRAG) Meeting notes

29 March 2022

Teleconference (Teams meeting)

Advisory Group	Present	David Archard, Adam Balen, Nina Barnsley, Gwenda Burns, Tim Child, Emily Jackson, Jackson Kirkson-Brown, Robin Lovell-Badge, Francesca Steyn. Peter Thompson (HFEA Chief Executive) Julia Chain (HFEA Chair, and Chair of LRAG meeting)
	Apologies	Raj Mathur
Members of the executive	Present	Clare Ettinghausen (Director of Strategy and Corporate Affairs) Catherine Drennan (Head of Legal) Laura Riley (Head of Policy- Scientific)

## 1. Welcome

- 1.1.** The Chair welcomed members to the first meeting of the Legislative Reform Advisory Group and thanked them for their involvement. The Human Fertilisation and Embryology Act is 30 years old. Much of it has stood the test of time, but it shows its age in places. While any decision on reopening the Act is for the Government, DHSC has agreed that the HFEA can undertake work with the aim of identifying where the Act needs updating, reporting back at the end of 2022. The individual expertise of the invited members on the Advisory Group will inform this iterative process.
- 1.2.** LRAG members are not being asked to speak as representatives of their organisations or their profession. The scope of LRAG meetings will be wide. Expertise of members is varied, and members don't need to have a view on every topic. No consensus position needs to be reached among the LRAG. Chatham House rules apply and a note of the meeting, together with all the papers would be published on the HFEA website.

## 2. Terms of Reference

- 2.1.** All present were content with the Terms of Reference, as circulated in advance of the meeting.
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### **3. Work Programme**

- 3.1.** The Chair noted that the outline work programme for LRAG, as circulated in advance, indicates areas of the Act that the HFEA feel need revision, but is not comprehensive. All present were content with the outlined work programme.
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### **4. Legislative reform: patient protection and licensing issues**

The Chief Executive introduced the paper, as circulated in advance, noting that the licensing side of the sector is 30 years old, and was largely unchanged in the 2008 amendments to the 1990 HFE Act, whereas the sector has changed very much in 30 years. In discussion, the LRAG raised the following issues:

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### **5. Patient protection**

- 5.1.** LRAG agreed that a principle explicitly stating a duty to protect the patient should be added to the Act.
- 5.2.** LRAG members raised that:
- While they agreed strongly with the important need to add in 'patient' protection, this should be drawn more widely than individuals in treatment, to include their existing children, or whole family as needed. Their partners, donors and other people whose interests are at stake should also be protected.
- 5.3.** In thinking about how 'patient' protection might be best achieved, the 2005 Mental Capacity Act and new Mental Health White Paper might provide a suitable model, involving some overarching principles, that then guide the rest of it. An updated HFE Act could provide such principles (for example around patient protection) and then state that the regulator should decide on how these principles should be applied in practice.
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### **6. Compliance and enforcement**

- 6.1.** LRAG agreed on the need for the HFEA to have a wider range of sanctions, both in the event of serious non-compliance and in general, to shape clinic conduct. An updated regulatory scheme, broadly in line with the Regulators' Code, should include powers to impose licence conditions, suspend all or part of a service for a defined period, issue fixed penalty warning notices, and impose financial penalties on clinics
- 6.2.** LRAG members raised that:
- HFEA could consider seeking new legislation for more appropriate powers to regulate and sanction, rather than seeking to add more detail on the face of the legislation.
  - Fines will be felt differently by clinics depending on their ability to pay.
  - Some clinics may push back on the proposal to introduce financial penalties. HFEA will need to give clear reassurance of checks and balances involved in any new financial powers.

- It was suggested that ‘straightforward’ IVF could be entirely removed from regulation in future. However, other members disagreed, replying that while medically some IVF may be straightforward, to all patients, their embryos are precious, valuable and significant. Anecdotally, one of the reasons that patients have said that they stayed in the UK for their IVF treatment, is that UK regulation involves an appropriately high standard of regulation.

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## 7. Length of the clinic licence

**7.1.** Most members of the LRAG agreed on the need for the HFEA to move to a more risk-based model where the HFEA regulates performance. This would see licensed clinics keeping their licence unless their performance suggests otherwise. Currently, fixed-term licensing periods are mandated regardless of performance. Removing periodic licensing would not remove periodic inspection.

**7.2.** LRAG members raised that:

- an indefinite license system should specify that the licensed clinic remains subject to the rules that are in force at that particular time, but if the HFE Act or HFEA Code of Practice changed and re-licensing was required, the process for this would need to be made clear.

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## 8. The role of the clinic PR

**8.1.** LRAG agreed on the need for a deputy PR role to be permitted by the Act. Job sharing jointly in the PR role and similar inclusive, flexible working arrangements should also be permitted. LRAG also agreed that the HFEA should require Persons Responsible to be revalidated when requirements on PRs change. The ‘suitability’ test for the PR should also be defined in the Act.

**8.2.** LRAG members raised that:

- This approach would allow HFEA to give more focused support to PRs. It would help to maintain communication and contact when there is a change of PR.
- The Act should permit one PR to be appointed for a group of linked clinics, especially if HFEA begins to license groups of clinics together in future, and a number of deputies at each clinic.
- PR role currently has a lot of responsibility but little explicit power in the Act to affect change. In practice, the influence of the PR depended on the circumstances of particular clinics.
- In some clinic models the PR role is peripheral to the running of the clinic. But even where the role is central, HFEA must maintain the current clinic licensing regime alongside requirements focusing just on the PR, in order to support patient safety and well-run clinics.
- Junior staff must always be able to raise concerns about PRs. The regulator needs to be able to see the clinics in the round, not just hear the PR’s account of it. Virtual inspections must build in ways for inspectors to make informal, free and private approaches to other staff, in the way that in-person inspections do.

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## 9. Role of the Clinic Licence Holder

**9.1.** LRAG agreed that the HFEA should propose that the clinic licence holder role is either made mandatory and more clearly defined in the Act, as distinct to the PR, including to determine who is “suitable” to be a LH and how this is assessed. Alternatively, that the LH role should be removed, and the deputy PR role introduced instead.

**9.2.** LRAG members raised that:

- in an updated Act, the LH could be the business or NHS Trust who was providing the service not the individual.
- Some clinics have a corporate entity and an individual as licence holder, but the role does not work well without a real personal sense of responsibility so this needs to be brought into the role.
- Some LH are currently uninvolved, so could not deputise for the PR because they don’t know much about the working of the clinic.
- By contrast, HFEA research licence holders, tend to be very directly involved in their project. This could be because in research, the project itself is licenced, rather than the institution it is based in.

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## **10.** Any other business

**10.1.** None raised.

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