Minutes of the Authority meeting on 17 July 2023

Members present	Julia Chain Jason Kasraie Tim Child Graham James Frances Flinter	Gudrun Moore Alex Kafetz Geeta Nargund Catharine Seddon Christine Watson Alison McTavish
Apologies	Jonathan Herring Alison Marsden Zeynep Gurtin	
Observers	Steve Pugh and Amy Parsons (DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Ana Hallgarten Angharad Thomas	Paula Robinson Alison Margrave

Members

There were 11 members at the meeting – 6 lay and 5 professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and Department of Health and Social Care (DHSC) colleagues present.

1.2. The Chair also welcomed staff who were present and observers online and stated that the meeting was audio recorded in line with previous meetings and for reasons of transparency the recording would be made available on our website to allow members of the public hear it.

1.3. Declarations of interest were made by:

- Jason Kasraie (PR at a licensed clinic)
- Tim Child (PR at a licensed clinic) and
- Geeta Nargund (Clinician at a licensed clinic).
- Alison McTavish (British Fertility Society Trustee and Progress Educational Trust Trustee)
- Frances Flinter (Progress Educational Trust Trustee)

1.4. Catharine Seddon also placed on record her recent appointments to the disciplinary committee of the Royal College of Veterinary Surgeons and as an Institute Director of the Chartered Insurance Institute. In that capacity she has also been appointed as a Board Director for the Personal Finance Society, which entailed also becoming a company director. The Chair congratulated her on these recent appointments.

2. Modernising Fertility Regulation - update

2.1. The Director of Strategy and Corporate Affairs introduced the report, which followed several Authority discussions and input from experts. This also included several meetings with the Legislative Reform Advisory Group and a targeted public consultation held earlier in 2023.

2.2. At its meeting in May, the Authority had discussed the initial quantitative results from the public consultation and heard that there had been widespread support for most of the proposals. However, the initial qualitative analysis showed that four of the draft proposals required further work either to clarify wording or identify a preferred way forward. The paper before the Authority today presented draft proposals, together with background information where further discussions had taken place since the May Authority meeting. The report included an outline of where further discussions were needed, the risks relating to this work, and the proposed next steps after today's discussion. A confidential draft proposal document for submission to the Department of Health and Social Care was circulated to Authority members only, prior to the meeting.

2.3. Members noted the report as a whole, and discussed the following points:

Annex A: Proposals

2.4. Members confirmed their agreement to proposals 1-13 set out in Annex A, which were as follows:

Patient safety and promoting good practice:

1. The HFEA should have greater freedom to decide the regularity and form of inspections.

2. 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. The HFEA should have a broader, more effective range of powers to tackle non-compliance.

4. The HFEA should have a broader range of powers to impose financial penalties across the sector.

5. There should be an explicit duty on the HFEA and clinics to act to promote patient care and protection.

6. The Act should be revised to accommodate developments in the provision of related fertility services in order to have a broader range of powers to tackle related fertility services not taking place in licensed clinics.

7. The Act should be amended to allow the HFEA to determine and set a more proportionate appeals process.

8. The HFEA should have the ability to make rules governing how standard licence conditions are made and revised, there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions.

Access to donor information:

9. Clinics should be required by law to inform donors and recipients of the potential for donor identity to be discovered through DNA testing websites.

10. The Act should require all donors and recipients to have access to information about the implications of their decision before starting treatment.

Consent:

11. 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.

12. Consent for donating embryos should be extended to allow patients who wish to, to give consent to research embryo banking.

Scientific developments:

13. The Act should explicitly give the HFEA greater discretion to support innovation in treatment.

Annexes B, C and D: Policy proposals in progress

2.5. It was agreed at the May 2023 Authority meeting that four areas required further examination following the consultation. These were:

- Ways in which to simplify the current consent process
- Potential changes in donor information provision
- The potential use of secondary legislation and other mechanisms for changes to the regulation of scientific developments
- Elements of the HFEA's regulatory powers, most notably the regulation of allied services – the issue here was in better explaining, rather than reviewing options for reform.

2.6. Further discussions on three of these proposals (donor information, scientific developments, consent) was outlined in Annexes B, C and D. The further description on regulation of allied services would be incorporated into the full response as the requirement was for better explanation, rather than for decision and as such did not require discussion at today's meeting.

Simplifying the consent process

2.7. Members noted the options set out in Annex B, namely:

1. Keep current system and make no recommendations for change
2. Recommend 'opt-out' model (proposed in the consultation)
3. Keep current system and make recommendations for changes that don't overhaul the whole system
4. Recommend a thorough overhaul of consent regime, possibly identifying areas where opt-out might be appropriate, but say we will work closely with DHSC and others to make detailed recommendations at a later stage
5. Recommend a change to legal parenthood as set out in a recent academic paper by Jackson/Horsey.

2.8. The Chief Executive noted the centrality to the legal framework of consent, and its complexity owing to the many possible scenarios patients might face. Both patients and clinic staff find the law complex, and the complexity can lead to the possibility of error. However, simplifying the consent regime is not straightforward.

2.9. A significant proportion of patients are couples in a formal relationship using their own gametes. The 'opt-out' model would enable a simpler regime for such patients. However, this proposal received mixed support in the consultation. The paper therefore looks at the five possible options set out above, one of which would be to retain the status quo. The other options represented other potential ways to address existing problems with the regime. Option 4, an overhaul of the regime, would take longer to achieve. Similarly, option 5 would require further work, after the submission of our recommendations to the DHSC.

2.10. Members questioned how prescriptive the Act needed to be in relation to consent, since the scenarios requiring consent do tend to evolve. It was felt that there was some flexibility in how the Act could be redrafted in future to allow for change over time.

2.11. Consent was acknowledged as a major issue for the sector. Safeguards are needed that cover the unlikely events that can happen from time to time, as well as common scenarios. Consent, or the lack thereof, has been at the root of many legal cases. Mistakes and oversights could have far-reaching consequences for people.

2.12. Members agreed that an overhaul of the regime (option 4 and/or 5) was the most appropriate response, while acknowledging that either option would require a lot of further work, preferably in collaboration with the sector. Option 5 would make legal parenthood more straightforward in the future and be more equitable for different family types. It was suggested that considerations raised about legal parenthood could perhaps be explored at a later stage, after further detailed work on option 4 had taken place.

2.13. It was noted that the sector is used to the current complexity of the regime, and that any change would carry risks and difficulties as well as advantages, but it was felt that this was the right thing to do. In relation to potentially defining legal parenthood in a different way, this might be the right thing to do in law, although it may not be supported by all the general public. It would be important to work with others on this to ensure as much consensus and understanding as possible.

2.14. The Authority agreed developing and proposing option 4 and further consideration of a link with option 5.

Donor information provision

2.15. The Director of Strategy and Corporate Affairs introduced the discussion. Members noted that the most challenging issues concern the proposals on access to donor information. Each of these proposals has a host of potential consequences which would raise numerous tricky policy questions.

2.16. Members were reminded of the range of options that were considered prior to the consultation:

1. Status quo plus – keep the current statutory position where all donors remain anonymous until the resulting child reaches the age of 18 after which the donor-conceived person may seek information about their identity from HFEA if they wish to.
2. Early identification by consent – introduce a voluntary system for donors to become identifiable earlier on, perhaps under agreed terms about the level of contact/localised arrangements (either from the outset or at any point before children born from their donation reach 18 with the consent of the parents, or consent varied by the child after a certain age).
3. Remove anonymity completely – amend the Act so that donors are identifiable to the recipients from the outset: whether from the time of considering all donors, so donor details are always identifiable, or after selecting a specific donor, or when treatment commences, or upon pregnancy, or birth.
4. Double track system – in which donors must choose between the status quo (i.e., donor identifiable information available when the child turns 18) and being identifiable from the outset (to be defined in new legislation). Under this option patients could choose between donors who wish to be identifiable and those who do not.

2.17. Members were reminded of current legal requirements in relation to information access for donors and donor-conceived people. Several further issues were raised by consultation respondents as outlined in the paper. The current system has also been overtaken by developments such as DNA websites and social media. Retrospective opening of the register was also proposed by some respondents, as was the removal of anonymity completely.

2.18. It was not yet possible to know what the public appetite would be for the full range of options, including the complete removal of anonymity and what any unintended consequences of the options were at this stage.

2.19. It was suggested that the status quo should perhaps be maintained while there is some investigation into the possibility of complete removal of anonymity in the future, which is a route some other countries have already gone down. Options 2 and 4 may be seen as too complex and result in a great increase in the need for implications counselling.

2.20. People have a right to know their genetic origins, and this could be important information in certain medical situations (including at a younger age than 18). It was noted that this may create a discrepancy between the rights of adopted children and donor-conceived individuals.

2.21. A question was raised about whether anyone from particular ethnic minority groups had expressed a distinct view on this issue. A breakdown of responses by ethnicity had not been carried out but broadly, there was no specific support from consultation respondents on any alternative proposal than the one that had been in the consultation, although there was some support for option 3.

2.22. In discussing the potential for a double-track system, option 4, it was acknowledged that while it had merit at the present time, it may not be the right option for the future, given that there is perhaps now more of a public appetite for the removal of anonymity and greater transparency. The Act in 1990 was grounded in the principle of the anonymity of the donor; however, most donors now realise (and accept) that their anonymity will not be guaranteed, and donor numbers are still rising. Given ongoing changes in the world, if a double track system, as a temporary measure, was not felt to be truly viable, option 3 should be chosen.

2.23. It was observed that option 3 would require a lot of further work and have a lot of implications, but that it may be the most appropriate option given wider developments, if it was agreed in principle that we should try to future-proof the legislation. Given how easily donor conceived individuals can access DNA databases and feasibly identify, by triangulation, their donor or someone closely related to them, it was agreed after discussion that the favoured option should be option 3, even if it takes some time to get there.

2.24. The proposal could be to change the law such that over the next 5-10 years, for example, anonymity would be removed, i.e., not with immediate effect. This would give more of a chance to obtain the views of the public, donors and donor-conceived individuals on this and consider possible unintended consequences. If the change of circumstances being brought about by DNA testing and social media means that anonymity effectively cannot be maintained, the law should reflect that. It was pointed out that not everyone would be able to use DNA testing sites or social media in this way, and that we should ensure that the approach adopted is socially fair. With regard to social inequality, this may apply more to some groups, and this would require an eventual equality impact assessment.

2.25. The immediate removal of anonymity would be a huge change compared to current practice, and we do not currently know what the public would think about that. It was also pointed out that not all donors are UK-based, and that those in the UK may have a different view to overseas donors. Therefore, a stepping stone approach, over time, may be appropriate.

2.26. It was acknowledged that extra work would be needed as a result of recommending option 3 when any change in the law occurred. This would require close working with our stakeholders and providing clear information for clinics and support for donors.

2.27. We should also bear in mind the effect on those who are considering using donated gametes, some of whom might seek treatment abroad in the event of complete removal of anonymity.

2.28. It was agreed that a fuller proposal would be produced for the September Authority meeting.. There could also be a step involved that would reduce the age of 18 for accessing identifiable information within the present system to a lower age, although we have not consulted on that.

2.29. In summary, since donors are likely to be found in any case, through other information routes, it was agreed that option 3 was the right option, with consideration given as to how best it might be introduced. The proposal would therefore indicate the stages that may be needed so as to reach this point and consider a potential timetable for ultimate removal of anonymity.

Regulation of scientific developments

2.30. Members considered whether to make a recommendation on the need to 'future-proof' the Act so that it could better accommodate novel scientific developments as they occur (as proposed in our consultation); or whether to go further (as some of the responses to our consultation suggested), and make recommendations that certain specific advances, as laid out in further detail in the report, should be considered in any revision of the Act. This might include several particularly pressing issues - new categories of cells, the 14-day rule for the use of embryos in research, and heritable nuclear germline genome editing.

2.31. The Public Policy Manager presented this part of the report. Greater discretion to support innovation in treatment received positive feedback in the consultation. Annex D of the report set out ways in which the Act could be future-proofed. There were questions and reservations from some respondents about what this would mean in practice and what safeguards would be put in place.

2.32. In relation to the broad question of future-proofing, members felt the HFEA needed to be more nimble since we operate in a fast-moving area of science. Such advances occur frequently and would be very difficult for Parliament to respond to in a timely way. Therefore, this could be better addressed by the HFEA having more discretion. Aspects that are likely to be more controversial, such as the 14-day rule, might be reserved to Parliament itself. In relation to new categories of cells, which are not currently regulated at all, the question was should they be regulated, and if so, how. They do not fall under the current definition of a 'permitted' embryo in the Act. They could potentially be referenced separately, although this would require further work to resolve – this would be a challenging area, with many ethical and philosophical issues. Regardless of the system ultimately chosen, there remains a necessity for us to be able to be responsive to new developments as and when they arrive.

2.33. Although no recommendation specifically looking at the 14-day rule was proposed in our consultation, members raised the following points in relation to the general area as this is a live topic of discussion for some researchers. . Were the Government to decide to look at this area in the future then consideration would need to be given to: the possibility of having a scientifically derived limitation rather than specifying the number of days; and a proposed number of days that was both appropriate and acceptable to the wider public. Fourteen days was considered to be the point of pre-sentience when it was first agreed, and this should be borne in mind. It would also be

important to explain to the public the reason, and the importance, of any future extension to the 14-day rule, and to explain the stages of embryo development over time. It was also acknowledged that any Parliamentary discussion would likely include voices who would argue for the 14-day limit to be reduced, rather than extended, since some do not agree with embryo research at all. The views of scientific researchers' are not the only important ones and ethical arguments should form part of any additional future work. These considerations were not for the current HFEA work on law reform.

2.34. More work might also be needed on new types of cells.

2.35. There was a general view that heritable nuclear germline genome editing was not so developed that there was a case to depart from the current status quo, it was noted that it may be judged to be safe and effective at some time in the future. Therefore, further work may also be required on this at some stage, and we should perhaps set out some principles for the DHSC in relation to this and other potential future developments that will arise. Broadly, consideration should be given to the governance framework around any future decision-making, including the use of expert advisory groups.

2.36. Inevitably, any review of the Act would be subject to much Parliamentary scrutiny and public discussion, so incorporating the 14-day rule and new cell types could be part of that public process, if that is what a future Government decided.

2.37. It was noted that scientific advances are always likely to outstrip the particulars of any legislation if it is not future-proofed (or made more resilient) in some way. Even so, dealing with particular scientific developments directly within legislation will always be difficult to achieve and new wording could be overtaken by events even while it was still being discussed by Parliament.

2.38. It would be important to express in our proposals how an appropriate balance would be maintained so that the HFEA was not seen to be 'writing its own rules' on a range of matters.

Decision

2.39. Members approved the proposals for change to the Human Fertilisation and Embryology Act 1990 (as amended) as set out in 1-13 in Annex A noting that minor drafting changes may occur in wording on these proposals over the summer.

2.40. Members also agreed the following in relation to consent, release of donor information and scientific developments (set out in Annexes B, C and D):

2.41. **Consent:** Option 4 (overhaul of the regime), with the possibility of further work in the future on option 5 (legal parenthood), was agreed as the best approach.

2.42. **Release of donor information:** It was agreed that option 3 (removal of anonymity) was the right option, with consideration given to how this could be best implemented over time.

2.43. **Scientific developments:** It was agreed broadly that some level of resilience was needed in the Act, in order to address fast-changing areas of science. Given the speed of developments, the 14-day rule and new types of cells, might require further work in the not-too-distant future.

Next steps

2.44. It would be important to engage with the DHSC and agree a plan with them in respect of how best to deal with areas where there are unresolved questions and where further work would be necessary in the future.

2.45. A report on the consultation will also be published, setting out the overall quantitative and qualitative responses. The final HFEA proposals will be published with full communications support, in due course.

2.46. A further paper would be brought to the Authority's September meeting. It was agreed that some sections could usefully be shared with members, for their expertise, in the intervening period.

3. Any other business

3.1. No further items of business were raised.

Chair's signature

I confirm this is a true and accurate record of the meeting.

Signature

Chair: Julia Chain

Date: 13 September 2023