Human Fertilisation & Embryology Authority

Authority meeting

Date: 17 July 2023 – 2pm to 4pm

Venue: Via Teleconference

Agenda item	Time
1. Welcome, apologies and declarations of interest	2.00pm
2. Modernising Fertility Law - recommendations For decision	2.05pm
3. Any Other Business	3.50pm
4. Close	4.00pm

Modernising Fertility Regulation - proposals

Details about this paper

Area(s) of strategy this paper relates to:	Shaping the future
Meeting:	Authority
Agenda item:	2
Meeting date:	17 July 2023
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs Ana Hallgarten, Public Policy Manager

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to discuss and approve the proposals to be submitted to the Department of Health and Social Care or request further consideration of proposals where needed.
Resource implications:	Staff resources as planned in the current business plan
Implementation date:	Ongoing
Communication(s):	As outlined in the paper – through regular public and stakeholder updates
Organisational risk:	Medium

1. Introduction

1.1. The HFEA has been developing proposals for changes to the Human Fertilisation and Embryology Act 1990 (as amended).

1.2. There have been several Authority discussions and input from experts, a Legislative Reform Advisory Group and a public consultation earlier in 2023.

1.3. Previous updates to the Authority in February 2022, May 2022, July 2022, September 2022, March 2023, and May 2023 have noted the background to this work and developments to date.

1.4. At the last Authority meeting in May, we presented the top-level quantitative results of the public consultation. To recap, there was widespread support for most of the proposals we consulted on (as measured by combining those who indicated that they 'strongly agreed' and 'agreed' with any proposal). However, we also noted that when detailed written submissions were looked at it, was clear that four of the draft proposals required further work to clarify wording or identify a preferred way forward.

1.5. This paper provides draft proposals for Authority decision and background where further discussions have taken place since the Authority meeting in May 2023. Section 2 introduces the draft proposal document for the Department of Health and Social Care. Section 3 outlines where further discussions are needed; section 4 outlines the risks relating to this work and then the paper goes on to outline next steps.

2. The proposals for change

2.1. The proposals for change are as set out in Annex A and further detailed in a separate confidential paper. This paper will, in time, form the basis of our submission to the Department (see section 5 below). Most of the proposals are based on agreed policy positions established through discussions with the Authority and received clear support from the consultation respondents. We therefore assume that these proposals (numbered 1-13 will not require significant further discussion (though we may decide to fine tune the drafting).

2.2. Annexes B, C and D are policy developments in process and are subject to review and change.

2.3. There will be a full HFEA report to set out the issues, the case for change and the proposals. We will also publish a report on the consultation setting out the overall quantitative and qualitative responses. The final HFEA proposals will be published with full communications support.

3. Further proposal examination

3.1. As noted above, it was established at the May 2023 Authority meeting that four key areas required further examination following the consultation; these were (in no particular order):

- Potential changes in donor information provision
- The potential use of secondary legislation and other mechanisms for changes to the regulation of scientific developments
- Ways in which to simplify the current consent process

- Elements of our regulatory powers, most notably the regulation of allied services – the issue here was in better explaining rather than going back to review options for reform.

3.2. The further thinking on three of these proposals (donor information, scientific developments, consent) is outlined at Annexes B, C and D. The further description on regulation of allied services is set out in draft in the confidential full draft report. Note that this is draft text subject to change.

4. Risks

4.1. The risks outlined in the **May 2022 Authority meeting** are ongoing and include:

- The short time available to complete the work
- Criticism of the presented issues or focus
- A lack of consensus
- Wider challenges for or against the idea of regulation itself.

4.2. We know from the consultation responses that the risks outlined above were reflected in some of the responses we received.

4.3. The proposals have always been intended to be high level, rather than detailed drafting, and we recognise that should the government agree to make changes to reopen the HFE Act, there will need to be further policy work in some areas before the proposals are ready for legislative drafting.

4.4. It is also important to note that some of our proposals support one direction, going too far for some and not far enough for others. The Authority will therefore need to be content with a level of criticism from those that would hope for a different proposal or outcome.

4.5. Lastly, the consultation itself brought some criticism in terms of the HFEA and our remit. Our proposals are aimed at better supporting both clinics and patients (in the widest sense of the term which we use as an umbrella term to mean all those affected by fertility treatment) and it is our strong belief that advocating for these changes will help the HFEA to be a modern up-to-date regulator that can best address the challenges from the changing fertility sector.

5. Next steps

5.1. Following agreement from Authority on the proposals for change, we will then prepare a submission for to the Government via the relevant Minister in the Department for Health and Social Care.

5.2. We will then publicise the HFEA's views on change in a report, together with a short report on the consultation and will have a communications plan in place for this.

5.3. We know there is widespread interest in this area from the media, clinic staff, stakeholders and the wider public. Any publicity of these issues is likely to also attract criticism from those who do not agree with either the direction of travel, the wider remit of the HFEA or the specific proposals recommended.

5.4. Any change to the law is likely to take place in the years to come and the HFEA will continue to advocate for these changes.

5.5. In the meantime, the HFEA will continue to be an effective regulator within the statutory framework that currently exists.

6. For decision

6.1. Authority is asked to:

- Discuss and approve the proposals for change to the Human Fertilisation and Embryology Act 1990 (as amended) as set out in 1-13 in Annex A
- Discuss the options set out in Annexes B, C and D on the issues below and make recommendations for proposals on:
    - Consent
    - Release of donor information
    - Scientific developments

Annex A: Draft Proposals

The proposals below use the text from the public consultation. This text maybe revised in the coming weeks.

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.

The proposals below were included in the consultation but are subject to further discussion by the Authority.

Consultation wording:

14. 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.
15. The current consent regime could be simplified (for example to an ‘opt out’ model) in ways that continue to provide protection to patients.
16. 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.

Human Fertilisation & Embryology Authority

Annex B

Consent – further discussion paper

1. Introduction

1.1. This paper sets out further options relating to consent. The summary below is taken from previous discussions with the Authority and Legislative Reform Advisory Group (LRAG) papers.

1.2. Consent is an area where there has been ongoing feedback that the way the current law is drafted leads to complexities which can increase the potential for mistakes in the consent process.

1.3. For clarity, the consents that the HFEA are concerned with are solely those that relate to the use of gametes and embryos as required by the HFE Act. Any consent taken by NHS or private clinics relating to medical consents to treatment are entirely separate.

1.4. The LRAG paper from May 2022 and the subsequent meeting note outline some of the issues with the current consent regime. Earlier discussions also considered separating legal parenthood, but it was felt at the time that there was no way to introduce this without it having negative consequences for patients, including greater financial costs and possible delays to treatment. Further discussions following on from LRAG meetings developed into proposals for an 'opt-out' model which was proposed in the public consultation.

1.5. The proposal to move to a type of 'opt out' model was an attempt to simplify consent for the largest single patient group (i.e., those patients in a relationship who wish to use their own gametes). Patients that were not in a legally recognised relationship or used donor gametes or a surrogate would still require more complex consent arrangements. The merits of consulting on such an 'opt out' model was that allowed the HFEA to see what sort of support there might be for it. It is of note that the consultation responses showed no agreement for any other model.

2. Issues to consider

2.1. Although some respondents to the consultation felt that an 'opt-out' model would be a good way to simplify aspects of the current complex system, others thought it would not in practice greatly simplify the process. Some respondents were concerned that it may increase the risk of people being coerced into consenting by their partners and that every measure that maximises opportunities for truly free individual consent should be retained.

2.2. Other respondents felt that the consent regime should be extended to new areas, for example, that there should be separate consents for treatment add-ons. Some patients reported that having to fill forms in repeatedly after unsuccessful treatment cycles was difficult and that the forms themselves were hard to understand. Others commented that filling in forms with a member of clinic staff where their questions could be answered was better than doing it through an online platform where it is harder to ask questions.

2.3. In earlier discussions with Authority members, we had floated the idea of separating out legal parenthood into an alternative part of law, but this idea was rejected at the time as it was not felt

that this would improve the situation for patients. However, a recent article in Modern Law Review by Emily Jackson and Kirsty Horsey argues that the legal parenthood provisions in the 1990 and 2008 Act are out of date now given modern family and relationship types.[1] They ask whether the requirement to consent to parenthood could be removed entirely from the HFE Act given that for many families, the law and terminology on parenthood following fertility treatment does not match the reality of people's lives. More radical reforms might better reflect diverse families prioritising "the intention to become a parent as the defining feature of parenthood".

> *"That way, whenever people become parents through assisted conception, the people who intend to parent the child would be recognised as the child's legal parents (and be under a legal obligation to register the birth), and more than two parents could be accommodated, if that is what is intended. Using 'intention to be a child's legal parent' as the defining feature of legal parenthood would also simplify the current parentage provisions, which differ according to whether the mother is married/civilly partnered, and whether the second legal parent is a man or a woman. In practical terms, these unnecessarily complicated rules are confusing for patients, and, because they result in patients having to fill in different forms depending upon their family circumstances, they increase the likelihood that the wrong form will be filled in."*

From a patient's perspective, they argue that there is confusion between the consent to medical treatment and the intention to be a legal parent and separating these might avoid confusion and mistakes.

2.4. Although this argument is a newer one, it may not make things simpler than they are. The prospect of a separate modernisation of the law relating to birth registration is unlikely and practical reform would therefore depend on finding a solution within the terms of the HFE Act.

3. Options

3.1. The following options are for discussion:

	Options	Advantages	Disadvantages	Risk
1	Keep current system and make no recommendations for change	Known system, with its complexities. Understood by HFEA and sector	Complex and hard to understand for both clinic staff and patients	HFEA would not be seen to be hearing the voices of those asking for change
2	Recommend 'opt-out' model	Clearer and easier for majority of patients, less complex	Could only be used by some patients to the exclusion of others. May be seen to reduce choice and some may not feel their decision was fully informed, leading	Lack of majority support and may mean new regime is as contested as the existing one.

[1] Horsey, Kirsty, Jackson, Emily. The Human Fertilisation and Embryology Act 1990 and non-traditional families. *The Modern Law Review*. 2023; 00- 00. https://doi.org/10.1111/1468-2230.12818

			to confusion over time where some patients may dispute what it is they have consented to.	
3	Keep current system and make recommendations for changes that don't overhaul the whole system – see these in Table A **here.**	Less controversial and more achievable	Less likely to bring about big changes to the consent regime that some want	Would need to consider how we 'sell' not going for a big overhaul.
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	Keeps big changes in scope without any specific detail but could establish a series of principles identifying where opt out was appropriate and separate out consents e.g. research consent, legal parenthood etc	Suggests significant reform but doesn't provide any detail	Overarching recommendation to include a series of principles without some detail might be open to criticism.
5	Recommend a change to legal parenthood as set out by Jackson/Horsey.	Sets up HFE Act for modern families and removes and potential confusion about parenthood provisions. May be administratively simpler	Requires complete overhaul of parenthood provisions and (possibly) establishing in another area of the law.	Work with others to develop this further but leads to criticism that it may not be achievable.

4. Recommendation

4.1. The Authority is asked to discuss the options above and make recommendations for which proposal they prefer or would like further analysis carried out.

Annex C

Access to donor information – further discussion paper

1. Introduction

1.1. This paper sets out further options relating to information access and donor anonymity. The summary below is taken from previous discussions with the Authority and Legislative Reform Advisory Group (LRAG) papers.

1.2. In particular, the **LRAG paper** from May 2022 goes into some detail as to why these issues are high priority and what led to the options in the public consultation. A summary of the discussion of that paper can be found on the **HFEA website**.

1.3. Three separate proposals were set out in the consultation. Respondents were generally in favour of the proposal for a requirement to inform donors and recipients of potential identification in advance of formal applications to the HFEA, with a majority of patients and professionals agreeing or strongly agreeing with the proposal. The proposed dual track system drew a more mixed response, with about half of patients agreeing or strongly agreeing and just over a third of professionals. On the proposal for a legal requirement for implications counselling before treatment, there was overwhelming support with well over half of patients and professionals agreeing/strongly agreeing with the proposal.

1.4. This paper sets out further issues to consider in respect of access to donor information that were raised during the consultation (section 2) and reviews the options for Authority in the light of this (section 3).

2. Issues to consider

2.1. Several issues were raised by respondents to the consultation. It was generally recognised that the current system – disclosure of information at 18 on request – may be overtaken by other means (e.g. DNA consumer tests, social media) accessible to parents and DCIs at an earlier age.

2.2. In terms of broad principles there were questions raised about changing the relationship from one where - at present - it is the donor conceived person who holds the right to access information from the HFEA, to one where the parents may have that right to information – and potential relationship with a donor – from an early age. This would be a significant policy shift, although there is arguably no option that could resolve those competing rights. While this leads to a complex discussion on rights, the proposal for a 'dual track' continues to offer the option of 'anonymity until 18'; and many parents are already accessing information about their donor through a combination of DNA testing, social media and other online methods, thereby making the decision for their child in any case. Any change to the current system would transfer the *right* to access that information away from the DCI who is the only person that can formally access identifiable information at present.

2.3. Other responses ranged from those who think there should be retrospective 'opening of the register' for pre-2005 donors, to those who want access to the donor sibling link to be widened to include children of donors and parents of donor conceived children wanting to access the

donor sibling registry at an early age so their children can (potentially) grow up knowing their donor conceived sibling.

2.4. The question is how to balance what is in the law with what is taking place at present and to recognise that any change to the current law may create other consequences, some of which may not be more advantageous than the system we have at present.

2.5. In effect, the ability for people to trace their donors through a combination of DNA testing and social media means that at *present an informal dual track system already* exists, albeit outside of the formal legal framework.

2.6. It may therefore be the case that the choice is more stark than set out in the consultation – keep the law as is, or opt for a system where there is no 'anonymous until 18' donation. However, we have not assessed the public appetite nor consequences of a wholly non-anonymous system. A significant piece of further work would need to take place with key stakeholders and professionals to better establish views of a wholly non-anonymous system.

2.7. An appraisal of the advantages and disadvantages of this and any possible unintended consequences has not been carried out.

2.8. The current system upholds the principles that we believe should be upheld:

- That there remains a need for an official 'record of truth' and that the HFEA should continue to collect data about children born from a donor
- That consent is properly obtained, and donors and recipients are fully informed about the potential challenges to anonymity from DNA testing and matching services
- That parents should not be legally required to disclose to their children that they are donor-conceived. But patients should continue to be encouraged by clinics to be open with their children about how they were conceived.

3. Options

3.1. The most difficult issue concerns the proposals on access to donor information. Each of these proposals has a host of potential consequences which would raise numerous tricky policy questions.

3.2. Although we consulted on one option, it may be helpful to stand back and look again at the range of options that were considered prior to consultation:

A. 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.

- Ensure that the Act is amended to include a statutory responsibility on clinics to inform donors and recipients of the likelihood of identification outside of the statutory scheme.
- There would remain the high likelihood of information coming to light outside of the consented process and the need for amendment to the Act to provide for a statutory duty to inform donors and recipients about the high likelihood of early identification outside of the HFEA information.
- Seeks to protect donor anonymity until the donor-conceived child is 18 years old, but there is always a risk of information being revealed informally, whether the donor-conceived person is younger or older than 18 years.
- Retains the right to information formally with the DCI.
- May effectively be out of date because of DNA testing/social media.

B. **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).

- Risks adding more consent options on top of already complex consent requirements, which could be burdensome for some patients and clinics.
- Would be resource intensive for clinics and the HFEA and could result in increased mistakes being made.
- Donor-conceived people may find it difficult that their parents actively made a concealing choice - whereas where parents have no choice there can't be blame.
- This would move the right of information access to parents.
- Could create inequalities between those who have the information and those who don't, including between donor conceived siblings.
- May initially result in a fall in donors.

C. **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.

- Already in place in some countries – e.g. in New Zealand donors are identifiable from birth – and system can be made to work.
- Some people are already going online to find their donor in childhood. Questions raised as to why 16 and 18 are the right ages to reveal information.
- Not everyone will want to know about their biological or genetic origins, even when identifiable information is available.
- This would move the right of information access to parents.
- Resource heavy at least at the outset.
- Culture and openness: is the UK ready to have this option?
- Likely to raise even more concern over pre-2005 DCIs retrospectively opening the register.

D. **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. This could provide more autonomy to donors and patients in deciding the type of information/contact they want. However, where patients opt for the status quo, donor-conceived people still might wish to find out details about their donor earlier than 18. This option has the advantage of choice for the patients but the disadvantage of not permitting a uniform set of options for all donor-conceived people.

- Provides choice: protection for those who need them, with earlier openness for those who want that.
- Better reflects the reality of a world in which donor information is available by other means and provides parents and donors with options as to how they deal with that new reality.

- This option still contains the current strong advice that anonymity in childhood can't be guaranteed, but may encourage more people who want to have earlier access to donor information to have treatment in regulated UK clinics it could allow as many people as possible to have regulated UK clinic treatment rather than going overseas for donor treatment or going online informally in the UK.
- It doesn't give all donor-conceived children equal rights and would create a 'two-tier' system between those who opt for anonymity until 18 and those who don't.
- This option would be resource heavy for both the HFEA and clinics.
- Clinics might end up charging different amounts for donors who have consented to be identifiable from birth, and those who have not.
- This option would need careful discussion with patients before treatment, when they may be having to take in a lot of other information already.
- May initially result in a fall in donors.

4. Recommendation

4.1. The Authority is asked to discuss the options above and make recommendations for which proposal they prefer or would like further analysis carried out.

Human Fertilisation & Embryology Authority

Annex D

Scientific developments – further discussion paper

1. Introduction

1.1. This paper sets out further options relating to scientific developments. The summary below is taken from previous discussions with the Authority and Legislative Reform Advisory Group (LRAG) papers.

1.2. In particular, the **LRAG papers** from June 2022 on scientific developments part 1 and 2 go into some detail as to why these issues are high priority and what led to the options in the public consultation. A summary of the discussion of that paper can be found on the HFEA website.

1.3. The following are considered key issues:

- The regulation of certain scientific advances in the Act means that our rules can be slow to adapt to the detriment of patients.
- Scientific advances are creating new 'categories' of cells such as in vitro-derived gametes, embryo-like entities, and stem-cell based embryo models which are outside the regulatory categories of the Act.
- The Act places limits on the use of human or admixed embryos in research which are now being challenged by scientific developments.
- The Act does not permit interventions in the nuclear DNA of gametes or embryos for use in reproduction.

2. The 'future proofing' of the Act

2.1. Making the HFE Act more 'future proof' received considerable support from patients and patient and professional respondents, with over 40% agreeing or strongly agreeing with the proposal. This was further supported by those responding in a professional capacity, with over 45% agreeing or strongly agreeing.

2.2. Some professional and organisational responses noted the benefits of future proofing the Act in order to ensure that scientific developments would be better addressed:

2.3. There was also clear agreement regarding the need for appropriate oversight and scrutiny for any changes in this area.

2.4. Additionally, there was opposition from a large number of respondents who were against embryo research more broadly.

2.5. The method used in the case of mitochondrial donation is one way in which this could be achieved, where the HFE Act was revised in 2008 to allow for change via subsequent secondary legislation. In this case, the work to review the science and develop the regulatory policy issues was extensive and publicly available, so that by the time regulations to allow mitochondrial donation were passed in 2015 there had been a very wide-ranging discussion of the issues involved. That said, secondary legislation is subject to less parliamentary scrutiny than primary legislation and some will argue (and some did during the consultation) that future

proofing by such means risks reducing the democratic legitimacy of a particular technology. Nonetheless, as the case of mitochondrial donation demonstrates there are ways of ensuring that the merits of a new technology is properly considered before a decision in Parliament, which could also include a report by the relevant Commons/Lords committee. With the right checks and balances this can be an appropriate means of providing a degree of future proofing specific elements of the primary legislation.

2.6. Any change in the regulation of these advances would require wider public debate and engagement prior to parliamentary amendment. Organisational responses noted the importance of public and parliamentary input at all stages of the process when considering the regulation of novel scientific developments. Broad and meaningful public engagement should therefore take place prior to legal change.

2.7. We did not seek specific views on the merits of the developments in the 14-day rule, new categories of cells, or the advance of heritable germline genome editing. Given the controversial nature of all three it is for the Authority to decide whether it would wish to recommend (or not) that they be adopted into a revised HFE Act at this time, without further consideration. Given the time it will inevitably take to have a revised Act ready for Parliamentary consideration, the Authority may wish to recommend that serious work be begun in the interim on any or all of these technologies.

2.8. Developments in these three topics are considered below, however there is a longer list of considerations that will need to be made in any 'future proofing' of the Act including, for example, ectogenesis and embryo selection based on polygenic risk scores.

2.9. It was noted that in the case of particular scientific developments that raise more significant ethical issues, that it may be beneficial to conduct in-depth and targeted consultations. In addition to engagement with the public and key stakeholders, some organisations and professionals noted the benefits of collaboration with other regulators, professional bodies, and academic experts.

2.10. Authority must therefore consider:

- Whether to make a recommendation to the DHSC on the need to 'future-proof' the Act as novel scientific developments occur
- Whether the Authority wants to go further, and make recommendations that certain specific advances, as laid out in further detail in sections 3, 4, and 5 below, should be considered in any revision of the Act.

3. Future regulation of new categories of cells

3.1. The Act currently specifies that research involving gametes and embryos is regulated by the HFEA. At present the Act governs human embryos and gametes and sets out prohibitions on human admixed embryos. The legislation in the UK prohibits the use of in vitro-derived gametes in treatment (s. 3ZA requires that eggs or sperm permitted for treatment are "produced by or extracted from the ovaries of a woman/testes of a man").

3.2. Despite their biological similarity to in vivo-derived gametes or embryos, these new categories of cells including in vitro derived gametes, embryo like entities, and stem cell-based embryo models are not currently regulated by the Act. These entities are becoming increasingly similar

to bona fide human gametes and embryos, and research on these could offer significant benefits.

3.3. As part of this consideration, it may be necessary to address whether the Act needs to be revised to include these entities, or whether these biological cells should fall under the remit of other regulators. Without a flexible regime, the potential future use of any such developments for patient benefit (including, for example, disease modelling and drug testing) could be limited, even when the advances in the field establish that their use is ethical and safe.

Options to consider:

3.4. **Status quo –** recommend to the DHSC that at this point no new categories of cells (including but not limited to embryo like entities, in-vitro derived gametes, stem cell-based embryo models) should be brought under the Act.

- This option would allow for flexibility for scientists, but would maintain the current lack of regulatory safety nets and scrutiny in this field of research. Other options would include that such regulation should instead fall under the HTA, or continue to fall outside of regulation.
- As regards stem cell-based embryo models, if an embryo model contains human cells, the Act and the guidelines prohibit any attempt to use it to establish a pregnancy and is therefore already prohibited for this purpose.

3.5. **Further research** – recommend to the DHSC that further work should be undertaken into whether new categories of cells (including but not limited to embryo like entities, in-vitro derived gametes, stem-cell base embryo models) should be brought under the Act, and if so, how. Given the advances made in different new categories of cells, the Authority may wish to recommend that the DHSC conduct further research into the benefits of bringing all (or some) of these new categories of cells under the Act.

- Bringing these new categories of cells under the Act would provide structure and regulation for research.
- This could take place through regulations, but these cells may need to be regulated differently and distinctly from ‘real’ embryos or gametes.
- Questions arise including as to whether in-vitro derived gametes may at some point be considered appropriate for use in treatment.
- Additional considerations include that as stem-cell based embryos quickly and clearly start to demonstrate development potential similar to ‘real’ human embryos, there is a strong argument that Act should cover them. Furthermore, would the development of stem-cell based embryo models bring into question whether the use of ‘real’ embryos for research is acceptable, if stem-cell based embryo models mimic human embryos so closely?

4. The 14-day rule

4.1. At present the Act limits the use of human or admixed embryos in research to 14 days or the appearance of a primitive streak (if earlier). It is now increasingly possible for researchers to keep embryos alive beyond 14 days. If this were permitted in the UK for research purposes, it would lead to improved understanding of early embryo development and the possibility of new

or improved treatments. There is a window of very early pregnancy between 14 – 28 days of embryo development which is not currently well understood by any existing permissible route. Increasing the 14-day rule would allow scientists a valuable insight into embryonic development and the study of disease processes, such as miscarriage and the development of congenital abnormalities. Extending this limit has been proposed by some international organisations. For example, the International Society for Stem Cell Research recently proposed **guidelines** to remove the 14-day limit on embryo research, and replace this with strict case-by-case oversight of any research past 14 days where justified, and after extensive public engagement.

4.2. Of the scientific development technologies considered in this consultation question, respondents suggested that the debate on the merits of the 14-day rule is most pressing; research is advancing quickly and it is clear that science would be able to move beyond this limit, with potential significant benefits to our understanding of early embryo development. However, given the importance of putting some limit on embryo research a consensus on any new limit would need to be reached and we need a mechanism for doing that. The Authority will wish to consider whether it is still important that any possible amendment of the Act should continue to have a clear limit of days for embryo research set within primary legislation.

4.3. If there were a view that it would be appropriate to seek to amend the 14-day rule to ensure that such a change could be dealt with in a timely, and flexible, manner a new mechanism could be put into law to allow for parliamentary consideration of the 14-day rule in the future, outside of reopening the HFE Act. This could be similar to the regulation making power written into the HFE Act in 2008 that required positive approval of the resulting **statutory instrument** of the **Mitochondrial Regulations of 2015**.

Options to consider:

4.4. **Status quo** – recommend to the DHSC that at this point the current restrictions should be kept in place.

- This option would be less ethically contentious and in line with *most* international positions.
- Science continues to push against this 14-day limit, and therefore the current legislation will limit some research from taking place in the increasingly near future.
- There is demand from (some) researchers to reconsider the 14-day rule.
- Not examining the current restrictions at this stage could unduly delay embryo research as it may be decades before the Act is re-examined and re-opened again, this is therefore a unique opportunity.

4.5. **Further research** – recommend that the DHSC that further work should be undertaken into possible changes to the 14-day rule.

- Given the advances made in embryo research since the Act was last amended in 2008, and considerable changes in the views of key research bodies regarding the 14-day rule, this is arguably an appropriate time to consider conducting independent research into the suitability of the 14-day rule.
- The Authority may want to recommend the DHSC that as a particularly pressing issue, specific changes to the 14-day limit should be examined in addition to the overarching recommendation to ‘future proof’ the Act.
- Changes to the 14-day rule would be welcomed by (some) scientists given the increased research possibilities in the area that it would provide.

- Extensive research would be needed given the ethical issues raised by extension of the current research limit.
- Two possible mechanisms could be examined as part of further work commissioned by the DHSC:
    - Option 1: Extending the 14-day rule in primary legislation
        - A new clear limit (e.g., 21 or 28 days) would be needed
    - Option 2:
        - Extending embryo research in primary legislation with a specific limit, with regulations used to modify permitted time incrementally
        - This would allow the limit on embryo research to remain at 14-days in the first instance, with slow incremental changes
        - A clear limit (e.g., 21 or 28 days) would be needed

5. Heritable Nuclear Germline Genome Editing

5.1. The Act does not permit interventions in the nuclear DNA of gametes or zygotes/germline genome editing, regardless of whether at some point in future it were shown to be safe and effective, as set out in 3ZA of the Act (as amended 2008). In theory, this is the only technique that some patients would be able to use for avoiding passing on a heritable condition, since PGT-M cannot be used in certain circumstances, such as when, for example, one parent is homozygous for a dominantly-acting disease gene variant. It is possible that genome germline editing technology combined with PGT-M may eventually be more efficient than use of PGT-M alone. At present there are significant safety, efficacy, and ethical issues raised by the application of nuclear germline genome editing in treatment.

5.2. Work on heritable nuclear germline genome editing is least advanced at present and our consultation revealed little support for changing the Act to permit its use at this time. Research rarely proceeds in a linear fashion and there may be a significant breakthrough which might mean that nuclear germline genome editing becomes a realistic prospect but given the important issues involved at this point, we do not recommend that the Act is revised to permit its use in assisted reproduction at this time.

5.3. In thinking about future options, we have not set out detailed steps about the possible mechanisms by which to consider the use of heritable nuclear germline genome editing alongside assisted reproduction. The recommendation to the DHSC should be that that current restrictions should remain in place.

6. Recommendation

6.1. The Authority is asked to discuss the options above at paragraphs 3.4, 3.5, 4.4, 4.5, and 5.3 and make recommendations for which proposal they prefer or would like further analysis carried out.