Embryos and liminal entities: rethinking questions of status and protection in shifting scientific, legal and ethical landscapes

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Workshop report

Contents

1. Background to the workshop and this report

This workshop

The emergence of new reproductive technologies, including stem cell-based embryo models (SCBEMs) and in vitro gametogenesis (IVG), poses challenges to existing legal frameworks regulating how human embryos can be used in both research and treatment, not least because they threaten to undermine the definitions on which these frameworks have been premised. Given the importance of the implications for research and treatment, for legal parenthood, and indeed for the morally acceptable boundaries of reproductive science, this workshop was convened to explore the underlying question of whether all human embryos and embryo models merit the same protections in law, and to help define the parameters and challenges that an expanded regulatory framework would need to address. It builds on a number of strands of work conducted under the umbrella of the Future of Human Reproduction project (funded by Wellcome), including the report published in July 2025, in partnership with the Nuffield Council on Bioethics, that called for scientists, ethicists, policymakers and regulators to work together to consider carefully the implications of IVG and its possible applications, before it is considered for use in the clinic.[1]

Key questions to address

Current legal approaches in the UK, in particular the Human Fertilisation and Embryology Act 1990, as amended (the HFE Act), are underpinned by the idea that reproductive medicine is 'special': morally distinct from other areas of clinical research and treatment because of the special status of the embryo.[2] In seeking to explore whether novel approaches in reproductive research merit the same regulatory protections, key questions include:

- Is it helpful to look at *equivalence*, asking whether SCBEMs and embryos produced from in vitro derived gametes (IVD gametes) using IVG, are, or are not, the *same* as the entities governed by the HFE Act and equivalent

[1] Nuffield Council on Bioethics, *In vitro gametogenesis: A review of ethical and policy questions* (2025).
[2] See, for example, M. Brazier, 'Regulating the reproduction business?' (1999) 7 *Medical Law Review* 166.

legislation in other jurisdictions? And if so, could they and should they be brought within these definitions?

- Alternatively, is it more useful to consider, feature by feature, ways in which they are *similar*, that might justify parallel but different regulatory approaches?
- Alongside these approaches, is it also necessary to think about how they relate to the creation of *organoids*, such as neural organoids, that do not come within this 'reproductive exceptionalism' but potentially raise similar ethical and regulatory issues?
- And finally, is there a need to 'lean in' to the inherent ethical tensions involved, recognising that scientific value is precisely found where the model is as similar as possible to what it is modelling, but, in the case of the treatment of embryos, ethical comfort comes from emphasising the differences?

This report

This report provides an overview of themes explored during the workshop, drawing on input from presentations and plenary discussion, including follow-up comments shared afterwards. It does not attempt to offer a comprehensive account of the scientific, legal and ethical presentations shared, but to highlight those elements that emerged during the workshop as being most significant in informing future policy directions. It should not be assumed that any participant agreed with any specific point made. All participants are listed in Annex 1, and included scientists, academic lawyers and ethicists, policy makers and regulators.

This report was drafted by Katharine Wright, with input from all attendees. The workshop was organised by Professor Sara Fovargue and Dr Laura O'Donovan from the School of Law, University of Sheffield. It was funded by a University of Sheffield ESRC-IAA award and by the Future of Human Reproduction project.

2. Introduction to developments in reproductive science

Stem cell-based embryo models

'Stem cell-based embryo models' (SCBEMs) is an umbrella term for 3D, organised structures made from human stem cells that aim to model the embryo at different stages of its development. Possible research benefits that could derive from reliable SCBEMs include optimising reagents and methods used in reproductive medicine; improving understanding of the implications of genetic and epigenetic changes on embryogenesis; investigating experimental factors on a scale incompatible with donated embryos; and improving understanding of drug or toxin exposure during pregnancy (currently not permitted on embryos donated for research under the HFE Act).

Although some SCBEMs are getting closer to replicating elements of integrated early embryonic development, most do not attempt to model the whole embryo; rather, they focus on particular aspects of embryo development, such as the heart. These new models collectively provide opportunities to study events in human development that are otherwise currently inaccessible to science because of the '14-day rule' that governs embryo research in the UK (see section 4). Aspects of models identified as being in particular need of further development include their modelling of extraembryonic tissues – those tissues, external to the embryo itself, on which it depends for support while in the process of development.

There was clear consensus among participants that, at least in their current form, SCBEMs *cannot* be considered to be the 'same' as human embryos. Important distinctions identified between SCBEMs and embryos included:

- their cellular origin (stem cell vs fertlised gametes);
- differences in some of the early processes through which they develop;
- substantial molecular differences;
- the partial nature of many models, i.e. containing some, but not all, cell types;
- uncertainty about the ability of SCBEMs to undergo integrated development beyond implantation, given the limited development to date of non-human SCBEMs following transfer to a non-human animal host.

It was suggested that current SCBEMs might be better understood as proxies for embryonic or extraembryonic tissues, with possible useful comparison to ‘organoids’ – 3D stem cell-based structures being developed of individual organs, such as neural organoids modelling elements of brain development. The closer such proxies become to the entity they are modelling, the more desirable this would be from a scientific point of view. It was argued, however, that if SCBEMs could ever be developed to be ‘as good as’ a human embryo, they would need to be subject to comparable regulatory requirements (see section 4).

In vitro gametogenesis (IVG) and in vitro-derived gametes (IVD gametes)

The aim of IVG is to create viable eggs and sperm (gametes) outside the body, by growing them either from embryonic stem cells or from induced pluripotent stem cells (iPSCs), such as those derived from skin cells. Much like embryo models, IVG may help us to understand human development, such as how gametes develop, as well as how genetics and environmental cues can contribute to infertility. However, IVG may also have distinct, additional future clinical applications, with a long-term aim being to create viable embryos from IVD gametes, leading to live births as part of reproductive healthcare.

If IVG reached the stage of being sufficiently safe and effective for clinical use, it could offer an alternative to the use of donated eggs and sperm for reproductive treatment for people who have undergone childhood chemotherapy, developmentally infertile couples, and single or same sex prospective parents, for whom traditional assisted reproductive therapies are insufficient or not acceptable. It might thus be a possible response to current challenges associated with donor conception, including inadequate donor recruitment, limited availability of information about the donor (depending on jurisdiction) and diversity. Importantly, it could also reduce the risks and harms people are exposed to during the egg retrieval process. IVG could lead to a potentially transformative approach for human reproduction, for same-sex couples and for mixed sex couples where one is infertile, enabling them to have a child who is genetically related to both parents. In addition, as many jurisdictions currently do not allow the donation of eggs for research purposes, IVG might help to fill this

particular need, assuming that the same regulatory prohibitions were not held to apply to this use of IVG.

Caution was expressed, however, as to the speed with which these developments might translate into sufficiently safe and effective therapies – in particular, in relation to recent reports of 'mitomeiosis' (the creation of gametes directly from skin cells, without the need first to create iPSCs).[3] It was noted that this technique, as reported, involved substantial risks of chromosomal abnormalities *and* guaranteed imprinting abnormalities, and thus could not be considered a safe method for creating a human embryo. The idea that IVG could be used to facilitate 'solo' reproduction (with both gametes derived from the genetic material of the same person) was also strongly criticised. It was noted that this would be very unsafe in terms of the high risk of any resulting child inheriting one or more serious genetically recessive conditions.

[3] N. Marti Gutierrez et al., 'Induction of experimental cell division to generate cells with reduced chromosome ploidy' (2025) 16 *Nature Communications* 8340.

3. Ethical considerations: the 'special status' of the human embryo and its applicability to these developments

In seeking to understand the extent to which new reproductive technologies might share the special status that human embryos are granted under current regulations, it is important to recognise that there is unlikely ever to be consensus on *why* embryos have such a status (or, indeed, on whether such status can be justified at all). In the field of reproductive medicine, regulation functions as a compromise in the light of widespread, deep and persistent ethical disagreement.

Such disagreement arises first in connection with the justifications proposed for assigning (or not assigning) moral status to the embryo. Grounds commonly proposed as relevant to the moral status of an entity include possession of a soul; possession of significant cognitive abilities; potential to develop those abilities; species membership (i.e. being human); sentience; and being alive. An embryo would clearly meet some, but not all, of these grounds (and nor would newborn babies meet all of them). Disagreement also arises in connection with whether moral status should be understood as a threshold concept (which would entail that an entity either has, or does not have, moral status), or whether it admits of degrees (e.g. 'emerging' moral status or partial moral status).

Defining features of an embryo identified by participants included those of being:

- a living, human, self-organising system;
- a transient structure (leading to the suggestion that it should be understood not so much as a 'thing' but as a process');
- akin to a 'machine' that needs to function *while* being built – hence is reliant on extraembryonic tissues for nutrient and oxygen supply before birth.

Building on these characteristics, it was considered by many that the key *morally* relevant property of an embryo is to be found in its *developmental potential* (see also the House of Lords decision discussed in section 4). This would imply that a SCBEM could, at some future date, have equivalent moral status *if* it were to achieve the same developmental potential, i.e. if such an entity were to be capable of being

transferred into a uterus and being born alive. However, a number of significant challenges were raised in connection with the possibility of making such a judgement:

- How could the developmental potential of a human SCBEM, or of a human embryo created from IVD gametes, be tested? In the absence of actions by rogue actors, this could only be inferred by proxy; for example, through research with non-human primates *in vivo*.
- And how could a comparison be made with equivalent development in a human embryo, given that this is a period of human development about which very little is currently known *because of* the current limitations on research on embryos beyond 14 days? It was suggested that this challenge highlights the importance of further research developing *in vitro* implantation platforms to learn more.
- How 'potential' is to be understood is also crucial; in particular, whether 'potentiality' is to be judged specific to the entity (*this* embryo model or *this* embryo created from IVD gametes) or to the *category* of all such embryos/models? It was argued that developmental potential must be intrinsic – that it is not possible to have more or less of it – and hence must be applicable to the category. It was also noted that, aside from biological considerations, any regulatory provisions that prevent the transfer of a SCBEM into a uterus would also create a normative and constitutive restriction on developmental capacity.

Furthermore, while the recognition that an entity has moral status entails particular duties (it cannot, for example, be used purely instrumentally and is capable of being wronged), entities that do not have moral status may still be given consideration for other reasons. In the context of embryos, this could include their relative scarcity (and hence their value in being made available for research of potential human benefit). It could also include the fact that they are valued by others who *do* have moral status – as illustrated in the attachment felt by some people undergoing infertility treatment to their stored embryos.

Such forms of ‘indirect’ moral status are relevant to the potential uses of SCBEMs or embryos created from IVD gametes for research. For those who regard any ‘specialness’ of embryos as deriving from their scarcity, or human attachment, these biotechnologies would offer an ethically preferable solution to the use of donated ‘surplus’ embryos. On the other hand, those who hold the view that *all* embryos have inherent moral status will not find any form of research with embryos acceptable – and they would manage reproductive services differently to ensure that no ‘surplus’ embryos were created.

4. The current regulatory environment and its applicability to novel technologies

Existing regulation of embryos in the UK under the HFE Act[4]

The HFE Act regulates how human embryos may be created and used, whether as part of medical treatment or for research purposes. In brief, embryos cannot lawfully be created without a licence from the Human Fertilisation and Embryology Authority (HFEA); only 'permitted' eggs, sperm and embryos may be placed in a woman; and no licence can permit cultivating an embryo for more than 14 days, not including time during which it is cryopreserved. The implications of this regulatory framework for new reproductive technologies clearly depend substantially on how 'embryos' are defined.

The definition of 'embryo' set out in the original HFE Act 1990 was the subject of judicial scrutiny in 2003, in the light of developments in cell nuclear replacement technologies after the successful birth of Dolly the cloned sheep.[5] The House of Lords concluded that human embryos created through cell nuclear replacement *did* fall within the provisions of the HFE Act and thus the regulatory remit of the HFEA. Their reasoning is of wider relevance to other new reproductive technologies as it was said that the purpose of the statutory definition was:

> *not to define the word "embryo" but rather to limit it to an embryo which is (i) live and (ii) human. These are the essential characteristics which an embryo must possess if it is to be given statutory protection. The important point is that these characteristics are concerned with what an embryo is, not how it is produced.* (para 45)

The House of Lords emphasised that embryos created by cell nuclear replacement and embryos created by fertilisation 'are essentially identical as far as structure is concerned, and each is capable of developing into a full grown example of the relevant species' (para 34). They concluded that:

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[4] See Nuffield Council on Bioethics, *In vitro gametogenesis: A review of ethical and policy questions* (2025) for a fuller account and detailed references.
[5] *R(on the application of Quintavalle) v Secretary of State for Health* [2003] UKHL 13.

> *So far as the human embryo is concerned it is this capacity to develop into a human being that is the significant factor and it is one that is shared by both types of embryo*. (para 34)

Notably, it was held that:

> *a regulatory regime that excludes from its ambit embryos created by cell nuclear replacement is contrary to the intention of Parliament in introducing the Act. The prospect of such a regime is both startling and alarming.* (para 42)

While the revised definitions of 'egg', 'sperm' and 'embryo' in the subsequent 2008 amendments to the HFE Act remain circular ('embryo means a live human embryo and does not include a human admixed embryo'), the House of Lords judgment in *Quintavalle* makes clear that:

- capacity to develop into a human being should be determinative in deciding what 'counts' as an embryo for the purposes of the Act; while
- the manner in which the embryo has been produced is *not* significant.

There are now provisions in the amended HFE Act giving the Secretary of State the power to make Regulations amending the definitions of 'embryo', 'egg' and 'sperm'. There is thus flexibility to respond, as thought necessary, to further technological developments without the need to rely on the courts for further judicial interpretation of the meaning of these terms.

In their present state of development, SCBEMs do not fall within the definitions of 'embryo' in the HFE Act and so research on such models is not currently subject to governance through the HFEA licensing regime. Similarly, while only a 'permitted' embryo can legally be transferred into a woman's uterus, the effect this provision would have on preventing a SCBEM from being transferred is unclear.[6] It was noted,

[6] E. Jackson, 'Regulating embryo models in the UK' (2024) 11 Journal of Law and Biosciences https://doi.org/10.1093/jlb/lsae016.

though, that any such attempt would be covered by other provisions, such as professional codes governing the conduct of health professionals.

By contrast, if embryos were to be successfully created from IVD gametes, they would appear to fall within the definition of 'live human embryo' in the HFE Act and so any research using them *would* require a licence from the HFEA. However, as the Act only permits medical treatment with the use of 'permitted' eggs, sperm and embryos, and IVD gametes or embryos created from them do not fall within the current definitions of what is 'permitted', it would not be lawful to use them in treatment without amending the current definitions.

Approaches in other European jurisdictions and in the European Court of Human Rights

The regulatory approach in the UK reflects one approach to compromise between differing attitudes and beliefs regarding the status of the embryo (see section 3): one that sets limits on how embryos can be used for research or treatment and permits both research and treatment within these limits. While similar approaches are found in other European countries, such as Sweden, others take a very different stance, with Germany, for example, prohibiting any kind of embryo research and exercising strong controls over stem-cell research. This lack of European consensus has led, perhaps inevitably, to considerable ambiguity within the Council of Europe's Oviedo Convention,[7] and within the case law of the European Court of Human Rights (ECtHR). While there is broad consensus within Council of Europe institutions on the need to 'protect' the embryo, questions as to its status and what 'protection' should entail are left unresolved. In particular, it was noted that:

- It is ambiguous whether the embryo or fetus are included in definitions of 'everyone' and 'human being' in Article 1 of the Oviedo Convention (which sets out the overarching duties of signatory states to protect people's dignity, rights and fundamental freedoms).

[7] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, 1997.

- In ECtHR case law, it has similarly been left open whether Article 2 of the European Convention on Human Rights (right to life to be protected by law) is applicable to embryos.[8] It was suggested that leaving this determination to the margin of appreciation enjoyed by national law cannot be sustainable, as assigning Article 2 rights to an embryo would logically imply that an embryo has the right to be transferred to a woman's uterus against her will.
- Alongside emphasising the margin of appreciation, the case law highlights the expectation of consistency within a jurisdiction's approach. For example, it has been held that embryos cannot be granted greater levels of protection than fetuses, so where termination of a pregnancy for fetal abnormality is permitted, it cannot be justifiable to prevent the use of preimplantation genetic testing for an embryo.[9]
- Some statements within the case law fail to distinguish between the need to protect the embryo and granting *rights* to the embryo; for example, assuming that protection of the embryo automatically entails that it is covered by Article 2 rights.[10] However, it was noted that rights constitute only one of the possible mechanisms for achieving appropriate protection. Other mechanisms, for example, include the imposition of controls on *how* an embryo could be used – as indicated below with respect to commercialisation in patent law, for example.

It was argued that these ambiguities – which could be characterised as a reluctance to face difficult questions – result in a failure to address and protect important interests other than those of the embryo. These include the interests of people who wish to reproduce and require medical assistance to do so, and, more broadly, the public interest in benefits that might have accrued if it were not for lost opportunities to conduct valuable research.

[8] e.g. *Vo v France* [2004] ECHR 326 (53924/00).
[9] *Costa and Pavan v Italy* [2013] ECHR (54270/10).
[10] Examples of both making, and not making, this distinction are found in the majority decision in *Vo v France* and in the Separate Opinion of Judge Costa.

Relevance of patent law

Article 6(2) of the Biotechnology Directive 98/44/EC (which is applicable to all EU countries and has also been incorporated within national legislation within the UK) sets out four specific applications for which a patent cannot be granted. These include the use of human embryos for industrial or commercial processes and processes for modifying the germ line genetic identity of human beings. The latter is of particular relevance in the context of IVG, when it is likely to be one of the first situations where the advances in technology – unimagined when the Directive was first drafted – mean that this exception or prohibition will be applied.

In relation to uses of human embryos for industrial or commercial purposes, the absence of definitions in the Directive means that subsequent case law has explored both the definition of 'embryo' and what should constitute 'use'. Emerging guidance from the case law includes that:

- The aim should be to protect human dignity – encouraging a broad and inclusive approach to what might be considered an embryo. The entity must possess 'inherent capacity' to develop into a human being in order to come within the definition, thus not capturing SCBEMs in their present state of development.
- 'Use' of embryos includes destruction; hence, if the invention necessarily involves the destruction of an embryo, a patent will not be granted.[11]

In relation to modification of the germ line genetic identity of human beings, it will be necessary to explore, for example, (i) what is a human germline modification and when/if it arises, and (ii) whether all work on IVG, given its potential for clinical use, would be covered by this prohibition. It may be important to consider the impact of this prohibition going forward. Refusal of patent grant is a blunt tool and does not constrain the use of the technology, although it may affect funding and commercial potential. Any prohibition on patenting has the potential to stifle or prevent research on IVG in countries where the Biotechnology Directive applies, as compared to the

[11] WARF/Use of embryos G2/06 [2009] OJEPO 206; Case C-34/10 Oliver Brüstle v Greenpeace e.V. ECLI:EU:C:2011:669; Case C-364/13 International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks ECLI:EU:C:2014:2451.

more liberal approach in other parts of the world. Moreover, where patents are not permitted there is an increased risk of research being kept secret for commercial reasons, which can reduce public scrutiny of the ethical and moral concerns. With regard to whether there needs to be a change to the legal regime for patents in this area, this issue will become more pressing if there is a desire to maintain interest and progress in this field.

It was highlighted that while patent law alone is not a suitable vehicle for addressing ethical questions around the commercial exploitation of reproductive technologies, it is important to be alert to how commercial behaviour can influence the interpretation of patent law and recognise the importance of ensuring that wider regulation takes such commercial drivers into account. It was suggested that patent offices are reliant on input and guidance from experts, such as those contributing to this workshop, to help define the borderlines of what is acceptable; this is not their own area of expertise.

A comparator: regulation of neural organoids

The development of neural organoids raises many of the same ethical and regulatory challenges discussed in this report in the context of new reproductive technologies, particularly where they interconnect with other organoids to create neural assembloids. Neural organoids do not fall within the remit of the Human Tissue Act 2004 (HT Act) or Human Tissue (Scotland) Act 2006 (HT(S) Act) and are not currently subject to any other regulatory regime in the UK. It was argued that there is a clear need for some kind of equivalent to the 14 day rule for such organoids, linked, for example, to the capacity to feel pain or the existence of consciousness. As a minimum, there is a need for monitoring and oversight. It was also argued that thought should be given to how a joined-up approach could be achieved, recognising similarities between neural organoids, embryo models and other stem cell-derived models, rather than, for example, creating multiple separate new regulatory bodies.

Implications for donor consent

Consent is a cornerstone for the donation of bodily material used for research in the UK under the HFE Act, the HT Act or HT(S) Act. Concern was expressed that more needed to be done to enable people considering donating tissue that might become an iPSC line to understand the ever-developing uses to which their donated tissues could be put. At present, for example, most donors would probably not envisage that their donated tissue could be used to create an embryo that would then be destroyed. Similar issues arise in connection with the donation of 'surplus' embryos for research. In addition to noting the scope for re-approaching donors for consent for specified uses that might not have been envisaged at the time of donation, caution was expressed about the risk of putting too much 'moral weight' on consent – consent alone cannot be sufficient to guarantee an ethical approach.

5. Regulatory challenges and requirements: what considerations should guide new regulation?

A number of considerations emerged repeatedly throughout the discussions that were thought important in helping to shape future regulation.

- It is crucial to determine what purpose regulation would serve – to identify what any future regulation should be attempting to achieve. Making distinctions between embryos and other forms of entity does not mean that the latter are morally neutral or do not need regulation; rather, it highlights the need to account for their different purposes and different needs. It is also important to be alert to how the purposes of research and possible future treatment applications need to be considered separately.

- It is about regulatory choices. It could be argued that while, at the moment, there are important differences between embryos and entities created through new reproductive technologies, these may lessen in time – and in any case similar oversight is required. Or, it could be argued that that they are two quite different things – one derived from eggs and sperm and one stem-cell created, and therefore they need regulating in different ways.

- Timing is crucial. There is a need to be responsive to the speed of development and to the risk of regulation being out of date before it is even in force. This speaks to the importance of drawing on capacity-based approaches to regulation: asking, for example ‘does this model have the capacity to give rise to a viable fetus’, rather than ‘does it meet specific criteria?’ which may then go out of date. It also highlights the need for agility and flexibility of approach; for example, through the use of a trusted regulator rather than the imposition of hard and fast rules.

  There are, however, challenges associated with timely regulation:

    - Progress is not linear and speed of progress is unpredictable, which makes the ‘right’ time to regulate difficult to identify. If regulation is left too late, trust in science will be damaged, but if it is too early, in response to concerns that may prove exaggerated, the result may be over-regulation.
    - In practice, a degree of anticipatory regulation will be required because the potential of a new embryo model cannot be fully known before it has been created. Moreover, as discussed earlier (see section 3), there are serious challenges to our ability to make a judgement as to the developmental capacity of an SCBEM or an embryo created from IVD gametes.

- Clear boundaries are essential and, on the whole, are welcomed by scientists. They provide a basis for public trust because they establish ‘red lines’ that scientists will not cross. They enable research to go ahead without the imposition of stifling bureaucracy, and they actively support development, in the light of the difficulties in securing investment without a degree of regulatory certainty.

- The commercial aspects of research in this field must be kept in view, with increasing involvement by the private sector in multiple jurisdictions, in addition to traditional public funding to academia. This means that different kinds of incentives and sanctions are required. For example, while concerns about obtaining future funding might be an important constraining factor on the actions of a publicly funded researcher, they might not necessarily be equally applicable in the private sector. The mentality of ‘move fast and break things’ that is prevalent in some parts of the private sector, is very different from the traditional publicly funded research environment.

- Lack of political appetite and parliamentary time can be limiting factors in achieving regulatory change (as has been the case for proposals in the UK and Sweden as discussed in section 6). One way to challenge this is through linking the economic importance of the life-science sector with the need for

regulation, given the facilitative role of a clear regulatory framework in supporting investment. It is also about finding effective ways of ‘telling the story’ as to what research is trying to achieve in ways that are meaningful; for example, IVG is about enabling people who want genetically related children to have them.

- The form that regulation should take is crucial: not only with respect to determining ‘what goes where’ (between primary and secondary legislation, codes of practice and guidance, for example), but also through the choice of regulatory approach. Principle-based regulation, for example, involves the expression of fundamental obligations to guide actions and decision-making – drawing on principles defined at a high level rather than setting prescriptive rules. Such an approach requires boundary-setting legislation, a skilled, agile, legitimate, accountable regulator, and ongoing dialogue with those being regulated. In addition to effective horizon scanning, such an approach also requires:

    - normalising stakeholder expectations and acceptance of the need for regulation;
    - real commitment on the part of regulators and policy makers to public engagement involving both outward-facing dialogue with the public and a willingness to take public views seriously;
    - a recognition of the tensions that arise at times between such a commitment and agility.

6. Developments: what is happening already and where are the gaps?

Participants provided updates on a range of ongoing 'soft-law' approaches to regulation that are being developed 'bottom-up' to help fill the current regulatory gaps, as well as specific proposals in the UK and Sweden to update the current legal frameworks. It was noted that such 'soft' approaches to governance often precede formal legal frameworks and can help to avoid the problem of legislating too early before a more accurate picture of what is required has had time to emerge.

Developments in regulating SCBEMs

The *SCBEM Code of Practice* was published in 2024 by Cambridge Reproduction and Progress Educational Trust, with the aim of drawing on good practice guidance from existing frameworks and tailoring them to research on SCBEMs, thereby helping build public trust. Aiming to be anticipatory, proportionate and revisable, the *Code* includes:

- mandatory specialist oversight, with all research subject to review by a dedicated process;
- no fixed temporal limits – i.e. no direct equivalent to the 14 day rule for embryo research, but a case-by-case limit to be justified by the purpose and nature of the model with an end-point agreed at the start;
- a red line that no SCBEM can be transferred into the uterus of a human or non-human animal, to provide assurance and to be in line with other international laws.

A national oversight committee, with a diverse membership (including scientists, legal, ethical and regulatory expertise, and public and patient voices) is proposed to provide proportionate review to research projects, maintain a research register, and advise researchers on ethics and compliance. The establishment of this committee depends on funding which is still pending.

The Nuffield Council on Bioethics' 2024 report, *Human stem cell-based embryo models: A review of ethical and governance questions*, sets out a road map for current and future governance of SCBEMs. It proposed that SCBEMs should be brought within the remit of the HFEA, while maintaining a clear distinction between embryos and embryo models. This could be achieved through a three-stage process:

- stage 1: soft law governance drawing on the 2024 *SCBEM Code of Practice*;
- stage 2: revision of the HFE Act, including a legislative ban on reproductive use in order to ensure public trust and establishing a regulatory 'sandbox' to test different approaches to governance;
- stage 3: in the light of the sandbox results, implementation of the chosen form of proportionate regulatory oversight.

The *EMERGE network* is a newly-formed interdisciplinary network, aiming to support better governance conditions through anticipatory thinking. Members share three broad orientations:

- the need to distinguish SCBEMs from embryos ('holding the tension');
- support for responsible science – resisting both complacency and over-reaction;
- a focus on urgent priorities (across multiple jurisdictions) including the need for registration, transparency, ethics review, and determining 'stop/pause points', thus helping to identify any future red lines.

The Swedish National Council on Medical Ethics made recommendations on embryos and embryo models to the Swedish Government in 2024, proposing:

- consideration of the extension of the existing 14 day rule for embryos to allow improved understanding of an important period of embryo development that is, as yet, little understood;
- a new regulatory regime governing SCBEMs that would provide oversight and require ethical review of all research, accompanied by developmental limits for models.

The proposed approach aimed to be technologically neutral, based on the developmental capacity of the entity rather than the manner of its production, and precautionary in approach, applying stricter protections where developmental capacity could not be ruled out. It has not, as yet, been acted upon by the Swedish government.

Developments in regulating IVG and IVD gametes

In 2023, the HFEA proposed 'future-proofing' the UK regulatory system, with recommendations echoing elements of principle-based regulation. Proposals included granting the Authority more discretion to enable it to adapt its approach appropriately in response to innovation, and future-proofing the HFE Act so that it was better able to accommodate future scientific developments and new technologies without requiring repeated specific legislative change. These recommendations have not, as yet, been adopted.

At the HFEA's Board meeting in January 2025, embryos created from IVD gametes were specifically considered and it was concluding that if they were capable of being transferred into a woman, these embryos would be the equivalent of any other embryo. However, they would warrant a distinct regulatory framework because of the unusual and experimental process by which they had come into being. Safety and public trust should be seen as non-negotiable. While much of the routine approach to regulation (such as licencing, competence requirements, oversight etc) would be the same as for other embryos, suggested differences for embryos created from IVD gametes included moving away from the binary model of either approving or rejecting specific techniques and towards a more dynamic, conditional approach to regulation. This could allow for a lower 'barrier to entry' for permitting the initial use of novel technologies, albeit one accompanied by greater ongoing engagement with the regulator, more post-approval control, use of real world evidence, and scope for de-authorisation if not deemed safe. These proposals have not, as yet, been acted upon by the UK government.

The Regulatory Horizons Council (RHC), which is hosted by the Department of Science, Innovation and Trade with the remit of advising the UK government on how to regulate emerging technologies, is currently working on a report on the regulation of IVG and modernising the HFE Act. Emerging themes include greater discretion for the HFEA; amending the HFE Act to allow it to evolve as technology develops; and allowing for outcomes-based collaborative regulation (in contrast, for example, to the way in which mitochondrial donation was permitted through Regulations that only allowed for two specific techniques, which, with hindsight, was unnecessarily limiting). It was noted that this approach would require more trust, communication and data sharing between the regulator and those subject to regulation. The RHC intends its work on IVG to act as a case study and be applicable to other areas of innovation, including, for example, fertility preservation for young girls with cancer using primordial ovarian follicles. It was noted that in both of these cases, clinical trials would be needed but it was difficult to envisage what form such a trial should take given concerns about the language of ‘experimental treatment’ or ‘clinical trials’ where the aim could be characterised as ‘creating’ rather than ‘treating’ a person.

7. Concluding remarks

The workshop concluded with group and plenary discussion of three matters:

- identifying the current most pressing ethical and regulatory questions arising out of new reproductive technologies (see Annex 2 for all those put forward);
- the importance of regulatory boundaries;
- opinions on how any future regulation should connect with existing regulatory frameworks.

The importance of regulatory boundaries

There was overwhelming consensus among the participants that regulatory boundaries ('red lines'), such as the prohibition of solo reproduction or of the transfer of a SCBEM to a woman's uterus, were required. Such boundaries were seen as a necessary part of a properly regulated field, of demonstrating that researchers hold themselves to a high standard, and of reassuring the public. It was, however, noted that red lines are not necessarily eternal – changing evidence or changing social attitudes may, over time, lead to their being drawn in a different place.

Should governance models relate to existing frameworks?

There was some doubt as to whether it would be appropriate for the HFEA or the Human Tissue Authority (the regulator created under the HT Act) to incorporate regulation of new reproductive technologies within their existing remits. It was argued that the HFEA's remit should be limited to the use of eggs, sperm or embryos outside the human body, and that bringing SCBEMs and IVG within its remit might over-burden or unbalance it with respect to its central functions. Similar concerns were expressed about the role of the HTA. Given increasing developments in organoids, it was suggested that it would be more appropriate to think more holistically about how all entities derived from stem cells, with increasing degrees of capability, should be regulated.

Annex 1: Participants' list

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Heidi Mertes, Ghent University
Sarah Norcross, Progress Educational Trust
Laura O'Donovan, University of Sheffield
Peter Rugg-Gunn, Babraham Institute, Cambridge
Nora Schulz, German Ethics Council
Rosamond Scott, King's College London
Sandy Starr, Progress Educational Trust
Roger Sturmey, University of Hull
Peter Thompson, HFEA
Stephen Wilkinson, Lancaster University
Nicola Williams, Lancaster University
Katharine Wright, freelance ethics consultant (rapporteur)

Annex 2: Pressing regulatory and ethical issues identified by break-out groups

The following responses came from group breakout discussions on ‘What are the most pressing regulatory and ethical issues raised by these developments (SCBEMs and IVG) and why?’

- Why do we think it is so important to protect embryos and how do we rationalise our current approach?
- *Are* there any pressing ethical issues?
- Do we need to settle questions about moral status etc *before* dealing with embryo models and IVG?
- How do we ensure public trust and oversight in this fast-moving area of science?
- How do we translate a novel or provisionally permitted reproductive technology into the clinic? If it is not a clinical trial (because no-one is being treated), how do we capture the process and recognise that outcomes are inherently unknowable?
- How do we avoid overregulation and unnecessary documentation, and if there is to be a registry, what should be included/required?
- If SCBEMs are different from embryos, how should we deal with the stem cells that contribute to the models? How do we deal with stem cells that become embryo models, and then become close to being embryos?
- The importance of recognising that there might be a pendulum between facilitating useful research and preventing poor outcomes and/or behaviours.
- The importance of considering the international landscape, while recognising that legislation is jurisdiction specific.
- While there may not be any pressing ethical issues, it is a good idea to get regulation in place.
- There is a need to learn from good practice in regulation and cooperation *across* regulators.
- The need for a greater variety of sanctions and/or enforcement activity for the HFEA.

- As there are many different areas informing each other, an institutional way of responding to new developments which ‘burst out’ and pull on many different threads in developmental biology is required.
- Being flexible about the research taking place requires the ability to recognise when you are stepping into an area that needs much closer examination.
- Moving away from the yes/no approach to regulation requires more effort and may require more of researchers.
- With respect to SCBEMs, it is important to get ‘everything up and running’ and the voluntary 2024 Code of Practice implemented – especially if there is international momentum. Otherwise, there is a risk of creating a media backlash.
- If SCBEMs are not embryos but they are connected, there is a tension which should be engaged with and there is a need to ‘square the circle’ with SCBEMs being understood as being ‘like’ embryos.
- The three steps recommended in the Nuffield Council on Bioethics report on SCBEMs should be implemented.