Nuffield Council on Bioethics

future of human reproduction

INTERDISCIPLINARY RESEARCH

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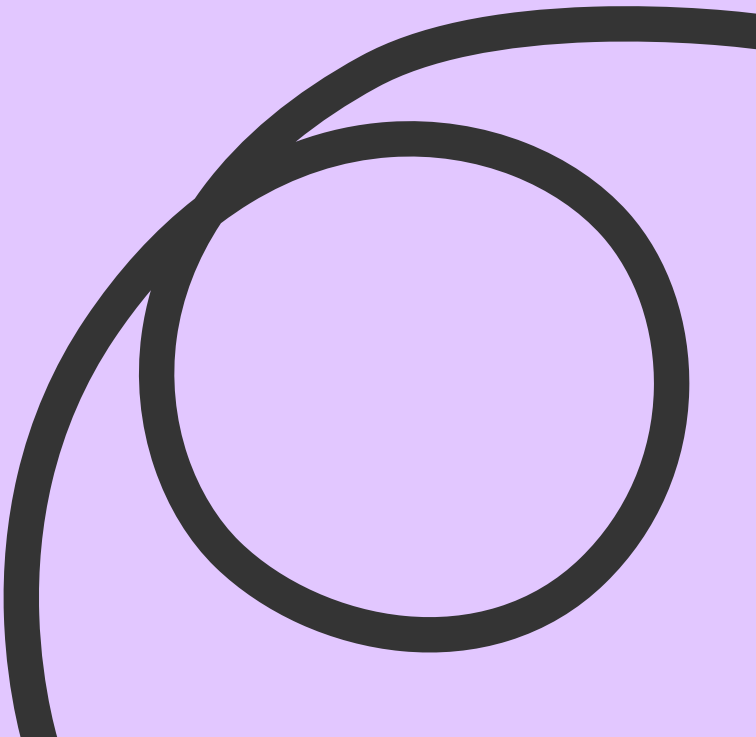
In vitro gametogenesis

A review of ethical and policy questions



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Preface

This report was produced as part of a two-year collaboration between the Wellcome-funded **Future of Human Reproduction Project** (222858/Z/21/Z) and the **Nuffield Council on Bioethics** (NCOB). The collaboration explored ethical and policy considerations raised by possible future uses of in vitro derived gametes in human reproduction. It has been informed, in particular, by discussions at two events: a workshop focussed on the UK context in London, July 2023, and an international symposium held in Leiden, the Netherlands, in June 2024.[1] These events were attended by UK and international experts and provided rich insights from areas including science and innovation, ethics and philosophy, policy and regulation. Both events were supported with funding from the Lancaster University Policy Support Fund. We would like to extend our sincere thanks to everyone who contributed to these events, as well as to those who have reviewed and provided feedback on this report at earlier stages of drafting.

The report is a joint publication of the Future of Human Reproduction (FoHR) and the Nuffield Council on Bioethics. It was researched and co-drafted by Sara Fovargue and Laura O'Donovan (both FoHR and School of Law, University of Sheffield), Stephen Wilkinson and Nicola Williams (both FoHR and School of Global Affairs, Lancaster University) and Ranveig Svenning Berg (NCOB).

1 More information about these events is available at: IVG Network – Lancaster University.

1 Introduction

Gametogenesis is the process by which eggs and sperm (gametes) develop, from their origin as early embryonic stem cells, into mature gametes capable of fertilisation. In vitro gametogenesis (IVG) aims to replicate this process *outside* the human body to produce in vitro derived gametes (IVD gametes).

While IVG technology is still in the early stages of clinical development, notable progress has been made in non-human animal studies, with (for example) the birth of mice with two biological fathers being widely publicised in 2023,[2] and in 2025 with some scientists predicting that the creation of viable human sex cells is 'about seven years away'.[3]

IVG in principle has the potential to provide new treatment options for people struggling with infertility and to create new types of biological family, such as offspring with two male or two female parents. Before direct application to human reproduction can be considered, however, there is a need for public engagement and a thorough consideration of the ethical and legal issues raised by this biotechnology, besides further research and testing to ensure safety and efficacy. While not the main focus of this report, we note that significant ethical questions are raised by IVG research using non-human animal models , and in the context of clinical translation and potential first-in-human trials.

This report outlines the key scientific, ethical, and legal issues raised by potential future uses of IVG, with a particular focus on its potential uses in human reproduction. Its primary aim is to help policymakers and other stakeholders to think through the questions that IVG raises. More generally it aims to support informed debate about those issues and potential ways forward, including future-proofing regulation to take into account developments in IVG. By this we mean regulation that is flexible and adaptable to scientific advances and societal responses to those advances. This could, for example, be in the form of review clauses in legislation, or providing relevant regulatory bodies or the Government with the power to respond to such changes without the need for primary legislation.

2 H. Devlin, 'Scientists create mice with two fathers after making eggs from male cells' 8 March 2023 *The Guardian*; H. Ledford and M Kozlov, 'The mice with two dads: scientists create eggs from male cells' (2023) 615 *Nature* 379.

3 H. Devlin, 'Lab-grown sperm and eggs just a few years away, scientists say' 5 July 2025 *The Guardian*.

In what follows we do not assume that IVG will or should inevitably one day become part of human reproduction. It is currently too soon to make this assumption and whether it does will depend not only on scientific developments, but on the social and ethical acceptability of the practices that it may make technically possible. However, since some commentators and those working in the field have made bold predictions about its feasibility in human reproduction, even within a decade, it is prudent to consider now the questions IVG raises.[4]

4 H.Devlin, 'Lab-grown sperm and eggs just a few years away, scientists say' 5 July 2025, *The Guardian*.

2 Scientific background

Key points

- Advances in stem cell research have enabled the process of gamete development to be partially replicated in the laboratory, using stem cells taken from early embryos or from adult cells as a starting point.
- Mouse gametes that can be fertilised and produce offspring have been created in the laboratory. This has not, however, yet been achieved in other non-human animals nor in humans.
- The development of gametes within the human body is a complex process which is yet to be fully understood, and a number of challenges need to be overcome before human in vitro derived gametes could be created and considered for use in human reproduction. These relate both to the process of development and to how safety and quality might be assessed.

The process of gametogenesis involves a complex interplay between the germ cells and the supporting cells within the ovaries and testes. The implications of replicating this process outside the body, including for the quality and/or safety of IVD gametes and any embryos created from them, are not yet known. While research is developing at a rapid pace, there is no consensus on the likelihood of achieving successful IVG in human reproduction or on how soon this might occur.

2.1 Gametogenesis

Embryonic stem cells, which develop in early embryos from about four days after fertilisation, are 'pluripotent'. This means that they have the potential to develop into any cell of the body. As the embryo develops into a fetus, its cells become more specialised. The process of human gamete development begins around the third week of gestation with the formation of germ cells, specialised cells which can only develop into eggs or sperm. These cells gather in a region of the embryo where gonadal cells (which will go on to form either ovaries or testes) are developing. At around week six, germ and gonadal cells either specialise further into female germ cells and supporting ovarian cells or into male germ cells and supporting testicular cells.[5]

5 R. Rey *et al.*, 'Sexual Differentiation' in K.R. Feingold *et al.*, *Endotext* (MDText.com, 2020); V. Lorenzi *et al.*, 'Human gonadal development, cell by cell' (2022) 12 *Clin Transl Med.* e1123.

From this point onwards, eggs and sperm follow different development pathways, but with some common features. Both undergo *meiosis*, the process which involves cells dividing twice to produce cells with half the amount of genetic material. Early on, female germ cells are encapsulated within a type of ovarian tissue called *follicles,* where they begin the first stage of meiosis. The process then pauses until puberty when hormonal cues trigger some follicles to mature and grow in the follicular phase of every menstrual cycle. Meiosis is completed during ovulation and, finally, fertilisation. Male germ cells proceed through a number of transitions during embryonic and fetal development until they pause development at 8-12 weeks after birth, resuming upon puberty to generate mature sperm cells. These cells undergo meiosis within the testes and can re-generate continuously.

2.2 Recapitulating gamete development outside the body: key scientific developments

Key steps to enable research IVG research include the development, in 1998, of a method to derive pluripotent stem cells from embryos in vitro (outside of the body),[6] followed, in 2007, by a method to reprogramme somatic cells (cells from the adult body that do not have reproductive potential, such as skin cells) to a state of pluripotency, producing induced pluripotent stem cells (iPSCs).[7] The process of directing these cells to specialise into germ cells and then into mature eggs and sperm has, so far, been most successful in mice, using both embryonic stem cells and iPSCs.[8] The resulting gametes have been fertilised, resulting in the birth of apparently healthy and fertile offspring, although in low numbers.[9]

In 2023, a study reported conversion of a small number of male mouse somatic cells into female cells and the subsequent development of mature eggs. The eggs were fertilised, resulting in the birth of healthy and fertile offspring, although only just over 1 per cent of the embryos created gave rise to pups.[10] While mouse pups born through IVG appeared healthy and fertile, the effects on further generations born from mice conceived in this way have not yet been examined. Recently, an alternative approach to IVG was reported using somatic cell nuclear transfer, a technique involving the insertion of genetic material from a somatic cell into an egg which has had its genetic material removed.[11]

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6 J.A. Thompson *et al.*, 'Embryonic stem cell lines derived from human blastocysts' (1998) 282 *Science* 1827.

7 K. Takahashi *et al.*, 'Induction of pluripotent stem cells from adult human fibroblasts by defined factors' (2007) 131 *Cell* 861.

8 Z-K. Li *et al.*, 'Generation of Bimaternal and Bipaternal Mice from Hypomethylated Haploid ESCs with Imprinting Region Deletions' (2018) 23 *Cell Stem Cell* 665.e4; M.V. Romualdez-Tan, 'Modelling in vitro gametogenesis using induced pluripotent stem cells: a review' (2023) 12 *Cell Regen* 33.

9 M. Saitou and K. Hayashi, 'Mammalian in vitro gametogenesis' (2021) 374 *Science* 2021 374.

10 K. Murakami *et al.*, 'Generation of functional oocytes from male mice in vitro' (2023) 615 *Nature* 900.

11 This approach is not the main focus of this report. It differs from others described here because it relies on the use of a donor egg: see A. Mikhalchenko *et al.*, 'Induction of somatic cell haploidy by premature cell division' (2024) 10 *Science Advances* DOI: 10.1126/sciadv.adk9001.

In human and non-human primate research, significant challenges remain but methods have been established for creating cells that closely resemble germ cells at an early stage of development.[12] By growing these in a culture containing supporting cells taken from mouse or human fetal tissue, researchers have produced cells with some key characteristics of early human eggs and sperm. Current research (in human and non-human animals) is focussed on several key challenges, including:

- **Improving understanding of how gametes develop within the body and their interactions with surrounding tissue**. Mapping out the characteristics of healthy gametes at different stages of development might enable more accurate evaluation of IVD gametes.[13]
- **Replicating particularly complex stages of development.** This includes meiosis, which is key to ensuring that heritable genetic information is correctly passed on.
- **Creating optimal culture conditions for different stages of development.** This is likely to involve creating cells and structures that mimic and serve the function of testicular and ovarian cells that support gamete development. A potential alternative approach, one that has been investigated in non-human animal studies, is to transplant partially developed IVD gametes into adult ovaries or testes to complete their maturation process within the body.[14] Research is also needed on the role and importance of timing, because gamete development occurs over different time periods in different species.
- **Understanding and mitigating the effects of using somatic cells as starting material to derive gametes.** Somatic cells are more prone to genetic mutations than embryonic stem cells or germ cells. The consequences of deriving gametes from somatic cells will thus need to be understood, including the impact on the viability of the gametes themselves and on any resulting embryos, and the potential health impacts on any future people born from these gametes (if this were ever to be used for human reproduction). There may be other (better) tools for selecting healthy gametes and/or techniques, such as genome editing, that might be used to mitigate or correct such errors, but these approaches have not yet been tested.

12 Y. Murase *et al.*, 'In vitro reconstitution of epigenetic reprogramming in the human germ line' (2024) 631 *Nature* 170; S.M. Czukiewska *et al.*, 'Human and non-human primate female in vitro gametogenesis toward meiotic entry: a systematic review' (2025) 124 *Fertility and Sterility* 6.

13 National Academies of Sciences, Engineering, and Medicine, *In Vitro–Derived Human Gametes as a Reproductive Technology: Scientific, Ethical, and Regulatory Implications: Proceedings of a Workshop* (The National Academies Press, 2023).

14 Ibid.

- **Developing approaches and tools for testing the quality of IVD gametes**. As well as a more detailed understanding of 'normal' gamete development, this might involve the development of new testing or screening techniques and continued research involving non-human animals. Ultimately, it might involve the creation and screening of human embryos and, if ever deemed ethically acceptable in future, clinical trials.[15]

15 National Academies of Sciences, Engineering, and Medicine, *In Vitro–Derived Human Gametes as a Reproductive Technology: Scientific, Ethical, and Regulatory Implications: Proceedings of a Workshop* (The National Academies Press, 2023).

3 Potential uses and benefits

Key points

- If IVG research is successful, IVD gametes could be used in numerous ways within human reproduction and beyond, e.g. for research purposes.
- In human reproduction, IVD gametes may be used for three major purposes:
  - To increase opportunity and choice and enable genetic parenthood for those currently unable to produce viable gametes.
  - To provide an alternative source of gametes for reproduction that reduces the risks and challenges associated with current gamete retrieval practices.
  - To expand selective reproductive practices such as pre-implantation genetic testing.
- The reproductive possibilities created by IVG raise ethical and legal issues that require careful consideration.

If IVG research develops and technical challenges are overcome, several possible reproductive applications could emerge.

3.1 Reproductive opportunity and choice

An estimated 30% of fertility patients are unable to produce viable gametes for various reasons (e.g. congenital disease, age, or injury).[16] IVG could be used in these situations where current reproductive options are limited to gamete or embryo donation and adoption,[17] and when patients have a preference for a genetic link with their children.[18] Similarly, IVD gametes could help those undergoing procedures that threaten fertility (e.g. radiotherapy and chemotherapy for cancer, or gender

16 J. Kashir *et al.*, 'Viability assessment for artificial gametes: The need for biomarkers of functional competency' (2012) 87 *Biology of Reproduction* 1.

17 A.R. Chapman, 'Do pluripotent stem cells offer a new path to reproduction?' (2022) 48 *American Journal of Law and Medicine* 256.

18 J. Kashir *et al.*, 'Viability assessment for artificial gametes: The need for biomarkers of functional competency' (2012) 87 *Biology of Reproduction* 1.

affirmation therapy and surgery), by offering an alternative to existing fertility preservation treatments such as egg, sperm or embryo freezing.[19] Ethical concerns associated with fertility preservation for pre-pubertal children and adolescents might be alleviated too.[20] Patients (and parents) might thus be reassured by the existence of this option, as it will reduce the need to make difficult decisions about fertility preservation, for example, in the context of serious and aggressive disease.

IVG could also be used for posthumous reproduction where, for example, a surviving member of a couple might seek to create IVD gametes from their deceased partner's skin cells where no gametes have been stored prior to death (see **Section 3.4**).

IVG may also enable people of any sex to produce both sperm and eggs for reproductive purposes.[21] In theory, this could mean that:

- Both members of same-sex couples could be their child's genetic parents.[22]
- Transgender people could contribute gametes to the creation of a child in a manner that aligns with their gender identity (trans women could contribute eggs and trans men sperm for reproduction).[23]
- An individual could create both eggs and sperm for 'solo reproduction' (although this would involve a high risk of genetic conditions being inherited by the offspring, see **Section 5**).[24]
- A child could be genetically linked to three or more individuals – so called 'multiplex parenting' (a method which would involve multiple stages, using IVGs to create embryos and then deriving gametes from these embryos for reproductive use) .[25] This potential use of IVG raises distinct ethical and social considerations which merit careful public discussion to determine whether it should be permitted.

19 A. Agarwal *et al.*, 'Contemporary and future insights into fertility preservation in male cancer patients' (2014) 3 *Translational Andrology and Urology* 27.

20 See, for example, P. Patrizio and A.L. Caplan, 'Ethical issues surrounding fertility preservation in cancer patients' (2010) 53 *Clinical Obstetrics and Gynaecology* 717; R.J. McDougall *et al.*, 'Ethics of fertility preservation for prepubertal children: should clinicians offer procedures where efficacy is largely unproven?' (2018) 44 *Journal of Medical Ethics* 27.

21 For a recent study exploring the views of LGBTQ+ individuals on the prospect of IVG see: A. Le Goff *et al.*, 'Anticipating in vitro gametogenesis: Hopes and concerns for IVG among diverse stakeholders' (2024) 19 *Stem Cell Reports* 933.

22 L. Notini *et al.*, 'Drawing the line on in vitro gametogenesis' (2020) 34 *Bioethics* 123. It is, however, important to note that a female same sex couple would only be able to create genetically female offspring (XX embryos), due to only their having X chromosomes. This does not preclude the creation of embryos with XX linked intersex variations.

23 N. Mattawanon *et al.*, 'Fertility preservation options in transgender people: A review' (2018) 19 *Reviews in Endocrine and Metabolic Disorders* 231.

24 L. Notini *et al.*, 'Drawing the line on in vitro gametogenesis' (2020) 34 *Bioethics* 123.

25 C. Palacios-González *et al.*, 'Multiplex parenting: IVG and the generations to come' (2014) 40 *Journal of Medical Ethics* 752, 75.

3.2 Transforming gamete procurement practices

In fertility treatment, IVG could reduce the demand for donated gametes by enabling clinics to create gametes from patients' own cells, instead of relying on donors.[26] Nevertheless, cases may remain where people prefer to rely on donor gametes, for example to avoid passing on a genetic condition.

Sperm donation is normally quick and painless, but obtaining eggs is not. Far fewer eggs can be retrieved from each donation cycle, and the process is time-consuming (three to four weeks), and burdensome (requiring daily injections, abstention from sexual intercourse, involving repeated trips to the fertility clinic for ultrasounds and blood tests, and surgical intervention) as well as short- and long-term health risks, such as abdominal pain, bloating, mood swings, and the risk of ovarian hyperstimulation syndrome.[27]

Births using donor gametes have more than tripled since the early 2000s, but the supply of donor gametes from within the UK, particularly sperm, does not match the demand.[28] As a result, in 2022, over 50% of new sperm donors registered in the UK were from outside this jurisdiction.[29] Notably, donor gamete shortages are more acute for those who seek donors with black, mixed, and 'other' ethnicities,[30] and for these communities' import rates are between 60% and 76%.[31]

If a UK licensed clinic imports gametes, the Human Fertilisation and Embryology Authority (HFEA), the regulatory body that oversees assisted reproduction and embryo research in the UK, requires them to have been donated under the same conditions as those applicable in the UK (e.g. regarding consent). There are, however, rules governing donation in the UK that differ from other jurisdictions. For example, many countries limit the number of offspring created from one donor,[32] whereas the HFEA limit applies to the number of *families* created from one donor (10). In determining the number of families, the HFEA only counts those created through donation in UK licensed clinics.[33]

26 A. J. Newson and A.C. Smajdor, 'Artificial Gametes: New paths to parenthood?' (2005) 31 *Journal of Medical Ethics* 184.

27 S. Carter Walshaw, 'In vitro gametogenesis: The end of egg donation?' (2018) 33 *Bioethics* 60.

28 Whittington Health NHS Trust, *Why Become A Sperm Donor?*.

29 Human Fertilisation and Embryology Authority (HFEA), *Fertility Treatment 2022: Preliminary Trends and Figures* (HFEA, 2024).

30 Human Fertilisation and Embryology Authority (HFEA), *Fertility Treatment 2022: Preliminary Trends and Figures* (HFEA, 2024).

31 Human Fertilisation and Embryology Authority (HFEA), *Ethnic Diversity in Fertility Treatment 2018* (2021).

32 The European IVF-Monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE), 'Survey on ART and IUI: legislation, regulation, funding, and registries in European countries—an update' (2024), 39 *Human Reproduction* 1909.

33 HFEA, 'Are there any limits on how many families can use the same donor?'.

This means that if the donor's gametes are used in the UK and in other countries, more than 10 families may be created from that donor across the world. Furthermore, it is possible for people to import gametes themselves, bypassing UK licensed clinics, which can cause problems, for example with respect to the attribution of legal parenthood (see **Section 6**).

3.3 Selective reproduction

If permitted, IVG technology has the potential to create a significantly higher number of eggs and (consequently) embryos than is currently possible for IVF treatment. This, combined with advances in genomics, could lead to expansion of the scope of preimplantation genetic testing (PGT), previously known as pre-implantation genetic diagnosis (PGD). However, it should be noted that PGT is currently regulated under the HFE Act 1990 (as amended), and overseen by the HFEA, and is only available in certain circumstances (see **Section 7.2**).

Using both IVG and PGT could, in principle, present prospective parents with a far greater number of embryos to choose from than is currently possible, allied with increasingly wide range of selection criteria.[34] Scientists may also be able to use IVD gametes to employ selection techniques over multiple 'generations' of embryos in a relatively short space of time, with the goal of selecting in/out desired/undesired traits in future generations.[35] These possibilities are discussed in **Section 7**.

3.4 Posthumous reproduction

Regarding the posthumous use of gametes, some people have sought permission from the court to extract sperm from an unconscious, dying patient without explicit or documented consent, for later use by their surviving partner.[36] One case involved parents seeking authorisation to extract sperm from their son who had suffered a catastrophic brain injury, and the judge recognised the nature of the sperm retrieval process as one which 'involves extracting sperm in circumstances that a conscious person would find invasive and some might find humiliating'.[37] Given cases of posthumous reproduction do occur (even if rare), it is plausible that an individual may seek to use IVG for this purpose. In that case, the creation of IVD gametes would eliminate the need for the process of sperm extraction and the specific objections to it, while still enabling the surviving partner and/or other relatives to fulfil their reproductive goals.

34 H. Bourne *et al.*, 'Procreative beneficence and in vitro gametogenesis' (2013) 30 *Monash Bioethics Review* 29; H. Greely, *The End of Sex and the Future of Human Reproduction* (Harvard University Press, 2016).

35 R. Sparrow, 'In vitro eugenics' (2014) 40 *Journal of Medical Ethics* 725.

36 *L v Human Fertilisation and Embryology Authority* [2008] EWHC 2149 (Fam); *R(AB) v HFEA* [2014] EWHC 1528 (Admin); *Y v A Healthcare NHS Trust* [2018] EWCOP 18.

37 *Re X (Catastrophic Injury: Collection and Storage of Sperm)* [2022] EWCOP 48 at [30], per Poole J.

However, this would not resolve any ethical and social concerns about posthumous reproduction itself, and using IVG in these circumstances may still raise issues of consent around the removal of skin cells, notwithstanding cases where English courts have dispensed with the requirement for consent in some gamete retrieval, gamete use, or embryo use cases.[38]

3.5 Gamete theft

The prospect of 'gamete theft' is another issue which must be considered. This would involve taking tissue samples without a person's consent which could then be used to create IVD gametes, potentially leading to the birth of a child and financial liability for child support. This might be a particular risk for certain people, such as the rich and famous. This is similar to the prospect of sperm theft, on which there are no reported cases in this jurisdiction to our knowledge. However, because IVD gametes can be created from skin cells (which we shed every day) the possibility of this form of gamete theft could be increased. While the chance of this happening in the UK may be low, this is an issue that the public may nevertheless be concerned about and wish to see reflected in public policy.[39] Policymakers should therefore consider how (if at all) the law should respond to this situation. It is a criminal offence to analyse DNA without consent in the UK.[40] However, whether this provision would extend to cover the non-consensual use of skin cells for reproductive purposes, would turn on whether a judge would be prepared to interpret the word 'analyse' as including the use of IVG to create gametes. Therefore, policymakers may wish to consider whether a specific criminal law sanction should be introduced, as discussed in **Section 6.3**.

38 Sperm – *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 WLR 806, CA; *L v Human Fertilisation and Embryology Authority* [2008] EWHC 2149 (Fam); *R(AB) v HFEA* [2014] EWHC 1528 (Admin); *Y v A Healthcare NHS Trust* [2018] EWCOP 18; *Re X (Catastrophic Injury: Collection and Storage of Sperm)* [2022] EWCOP 48; Eggs – *R (on the application of IM and MM) v Human Fertilisation and Embryology Authority* [2015] EWHC 1706 (Admin); *G v Human Fertilisation and Embryology Authority & Anor* [2024] EWHC 2453 (Fam). Embryos – *Evans v United Kingdom*, Application no. 6339/05 (2007), Grand Chamber; *Jennings v HFEA* [2022] EWHC 1619 (Fam).

39 *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984) Cmnd 9314 (Warnock Report), para 13.1.

40 Section 45 Human Tissue Act 2004.

3.6 Additional prospects and possibilities

Beyond the use of IVG for human reproductive purposes, research into IVG may increase knowledge and understanding in other related areas. The generation and study of IVD gametes could improve understanding of how human gametes develop, and understanding of infertility, by 'boost[ing] understanding of pathologies which particularly affect the germ cells'.[41] Studying IVD gametes which show imprinting anomalies could lead to an improved understanding of the processes involved in gene expression and enable the study and development of treatments for heritable genetic disorders. Finally, beyond the human context, IVG could, allied with other reproductive technologies, be a valuable tool for agriculture and livestock breeding programmes,[42] as well as de-extinction and conservation efforts, allowing scientists to create gametes from the cells of long extinct or critically endangered non-human animals.[43]

41 A. Smajdor and D. Cutas, *Background Paper: Artificial Gametes* (Nuffield Council on Bioethics, 2015).

42 See, for example, D.E. Goszczynski *et al.*, 'In vitro breeding: application of embryonic stem cells to animal production' (2019) 100 Biology of Reproduction 885.

43 See, for example, T.B. Hildebrandt *et al.*, 'The ART of bringing extinction to a freeze – History and future of species conservation, exemplified by rhinos' (2021) 169 *Theriogenology* 77.

4 The status of IVD gametes and IVG embryos

Key points

- Human eggs and sperm are not generally or currently seen as meriting the same protection and respect as human embryos.
- If IVD gametes were used to create human embryos with reproductive potential, this would raise the question of whether such embryos have the same moral and/or legal status as other embryos.
- While IVG is still at a relatively early stage of scientific development, a precautionary approach may require higher levels of scrutiny and restrictions on the creation and use of embryos created from one or more IVD gametes ('IVG embryos').
- The development of IVD gametes and IVG embryos could fall under the regulatory schemes in the Human Fertilisation and Embryology Act 1990 (as amended) and the Human Tissue Act 2004, with oversight by the HFEA and the Human Tissue Authority (HTA).
- A licence from the HTA may be required for the use of IVD gametes and IVG embryos.
- IVG for research purposes would be permitted by the current provisions in the Human Fertilisation and Embryology Act 1990.
- To assess questions of safety and viability, researchers might need to culture embryos created from IVD gametes beyond the existing 14-day limit set out in the Act. The development of IVG may therefore require extension of this limit.
- IVD eggs and sperm, and embryos created from IVD gametes, would not be 'permitted' eggs, sperm and embryos under the Human Fertilisation and Embryology Act 1990 and so could not be used in treatment without legislative change.

4.1 Status questions

The ethical, legal and administrative status of IVD gametes and IVG embryos requires attention because this affects what can and should be done with or to them. Questions to be considered include:

- Would (and should) IVD gametes have the same moral status as other gametes and merit the same levels of respect and protection?
- If IVD gametes are used to create IVG embryos would these embryos have the same moral status as embryos created from gametes produced 'naturally' within the human body (endogenously produced gametes) and merit the same levels of respect and protection?
- Would (and should) IVD gametes be subject to the same legal provisions as 'naturally' produced gametes?

The answers to these questions may necessitate consideration of changes to the current law to accommodate potential future uses of IVD gametes and any embryos created from them.

4.2 Moral status

To claim that a particular entity has moral status or moral standing is to claim that, in virtue of the properties that it possesses, it must be taken into account in moral decision-making for its own sake. For example, we may think that some non-human animals (e.g. primates, cats, or dogs) have moral status because they are conscious and can feel pain, or that the human fetus has moral status because of its potential to become a fully formed human person. While some consider human embryos to be intrinsically morally valuable, this is rarely the case with human gametes. Eggs and sperm are, instead, generally seen as (at most) instrumentally valuable – as means to an end, that end being the creation of embryos and ultimately children. While providers of fertility treatments need to ensure that gametes intended for reproductive purposes are not wasted (given their scarcity), nor damaged or defective, this is because of the possible effects on a future person or a family's ability to use them for reproductive purposes, not because of the intrinsic properties or special status of the gametes themselves.

From a moral status point of view, if IVG-created and other ('natural') embryos – (i) have, or could have, reproductive potential, (ii) are produced by fertilisation, and (iii) look and act similar as biological entities – it seems likely that they would be assigned the same status. While IVG techniques are still under development, there may, however, be important differences between IVG embryos and other embryos, including issues around safety, meaning that greater levels of scrutiny of the clinical uses of IVG embryos are (at least temporarily) justified, if clinical use does become technically, morally and legally permissible.

Defining the term 'embryo' is beyond the scope of this report, but how 'embryo' is defined may intersect with questions about future uses of IVG in some interesting and important ways. For example, one question is whether, for something to be deemed a human embryo it has to be created via fertilisation.[44] In England and Wales, the law states that 'embryo means live human embryo' which includes 'an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo'.[45] However, elsewhere, such as in Belgium and the Netherlands, the term 'embryo' includes cells with the potential to develop into a human being.[46] In Germany, there is an even more expansive legal definition of 'embryo', which includes 'any totipotent cell taken from an embryo, which is able to divide and become an individual'.[47]

Current and developing research on 'embryo models' (structures created from stem cells which resemble or replicate aspects of embryonic development) also raises questions about the moral status and intrinsic value (if any) of embryo-like structures. This has been considered elsewhere,[48] and the outcomes of that work may have implications for how IVG embryos are classified and understood in terms of their moral status.[49]

4.3 Legal status (UK)

In the UK, research and treatment involving gametes and embryos is regulated by the HFE Act 1990 and overseen by the HFEA.[50] The HFEA is responsible for granting licences for all research and treatment involving human embryos outside of the human body. The development and use of IVG may also involve the oversight of the HTA, an independent body which regulates the removal, storage, and use of human tissue for research, medical treatment, and education and training.[51] The HTA would become involved when skin cells were donated (and stored) to be manipulated into iPSCs. Once that process has started, cell lines and cells that have divided in culture are not categorised as 'relevant material' under the Human Tissue Act 2004.

44 If the term 'embryo' only refers to entities created via fertilisation, this would mean that 'Dolly the Sheep', for example, would not have been considered to have been an embryo because she was created via somatic cell nuclear transfer.

45 Section 1(1) HFE Act 1990.

46 Netherlands – Embryo Act (2002, revised 2007, 2008, 2011, 2013, 2018, 2019). Belgium – Act Regarding Research on Embryos In Vitro (2003) 2156 (2003).

47 Embryo Protection Act (1990, amended 2011) 2746 (1990); Stem Cell Act (2002, amended 2017) 2277 (2002).

48 Parliamentary Office of Science and Technology, 'Human Stem Cell Based Embryo Models – POSTnote 716' (28 February 2024).

49 In July 2024, a project led by Cambridge Reproduction, working in partnership with the Progress Educational Trust, produced a SCBEM Code of Practice. In November 2024, the Nuffield Council on Bioethics concluded a rapid review of SCBEMs, and published a report and policy briefing.

50 HFEA, 'About Us' (24 August 2023).

51 The Human Tissue Authority (HTA) was established by the Human Tissue Act 2004. See HTA, 'Who are the HTA?'.

At this point, other regulations relating to human tissue would apply,[52] and this may mean that, depending on the interpretation of these provisions, a licence from the HTA was required.[53]

Human gametes produced inside the body have no specific legal status in the UK, including as property,[54] unless they are stored outside the body for reproductive or research purposes.[55] This is because under English common law, the human body (whole, separated, or parts of it) is not treated as property, meaning that a person does not 'own' their body, organs or tissues.[56] The question of whether the human body should be seen as property raises important legal, ethical and social issues. This has been noted by the courts and there have been limited circumstances in which property rights in gametes have been recognised.[57] By contrast, human embryos created, used and stored outside the human body do have specific legal protection, though not as property, under the provisions of the HFE Act 1990.[58] Presumably, the existing legal provisions similarly apply to IVD gametes and IVG embryos, meaning that both have specific status where created, stored and used outside the human body.

Legal definitions

Except in relation to treatment (where alternative definitions are set out),[59] eggs are defined as 'live human eggs, *including* cells of the female germ line at any stage of maturity',[60] sperm as 'live human sperm, *including* cells of the male germ line at any stage of maturity',[61]and the embryo as 'a live human embryo' (which does not include a human admixed embryo.[62] Cells of the female and male germ line are those cells that differentiate into specialised cells – eggs and sperm – for reproduction.

52 Human Tissue (Quality and Safety for Human Application) Regulations 2007.

53 Regulation 7(1) states that 'no person shall store tissue or cells intended for human application otherwise than under the authority of a licence under Schedule 1'. Whether a licence from the HTA is required will depend on what is meant by 'intended for human application' and whether this includes the transformation of cell lines into IVD gametes for use at a later stage or if this is the creation of human embryos from IVD gametes.

54 See *R v Kelly* [1998] EWCA Crim 1578.

55 Schedule 2, HFE Act 1990.

56 *R v Kelly* [1998] (n54); *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37.

57 For example, in *Yearworth v North Bristol NHS Trust* [2009] (n56) it was held that for the purposes of their claim in tort, stored sperm that had been negligently destroyed could be viewed as the property of the male claimants.

58 See, for example, Sections 3, 4, 14, 14A and Schedules 3 and 3A of the HFE Act 1990 Act.

59 Section 3ZA HFE Act 1990.

60 Section 1(4)(a) HFE Act 1990.

61 Section 1(4)(b) HFE Act 1990.

62 Section 1(1)(a) HFE Act 1990, emphasis added. A 'human admixed embryo' is one that contains both human and (non-human) animal DNA.

As outlined in **Section 2** above, IVD gametes are created from the reprogramming of iPSCs (such as skin cells) or embryonic stem cells and not cells of the female or male germ line. However, as IVD eggs and sperm and any embryo created from them will be 'live' in the biological sense and 'human' because they are cells of the species Homo sapiens,[63] the definition of eggs, sperm and embryo set out under the 1990 Act could be interpreted to include them.[64] The HFEA has recently stated that as research involving IVD gametes and embryos created from them *could* be interpreted to fall within the definition of gametes and embryo in the 1990 Act, IVG research would be permitted, but any use of IVG in clinical treatment would be prohibited.[65]

4.3.1 Consent to the creation of IVD gametes and IVG embryos

If IVG were used in humans, it would be necessary to consider what type of consent was appropriate and required (e.g. general or specific, revocable or irrevocable) and for what purposes. For example, should people who provide tissue for IVG (for research or human reproduction) be treated in the same way that egg, sperm or embryo donors are treated, or should a different model of consent be used? This includes whether they should be treated as gamete donors for the purpose of information disclosure, given their genetic link to resulting children, meaning that their donation would not be anonymous (see **Section 5** for a discussion of children's rights to know their origins).

Consent is one of the key pillars of the regulatory framework set out in the UK's Human Fertilisation and Embryology Act 1990 (HFE Act 1990).[66] Written consent is required for all activities licensed by the HFE Act 1990 that involve the storage and use of gametes and embryos, including for posthumous reproduction or research. Consent to legal parenthood is also required.

Obtaining consent for any one of these activities can be complex because fertility treatment typically involves more than one person. There is a range of scenarios that patients are required to consider (including what should happen to gametes or embryos in storage in the event of the patient's death or mental incapacity) before they consent.

63 The word 'including' in Section 1(4)(a)-(b) of the HFE Act 1990 gives an example as to what might constitute 'live human eggs' and 'live human sperm' but does not exclude other things from also constituting those entities.

64 See HFEA, *Modernising Fertility Law: Recommendations from the Human Fertilisation and Embryology Authority (HFEA) for changes to the Human Fertilisation and Embryology Act 1990 (as amended)* (HFEA, 2023) – IVD gametes or embryos created from them not regulated by the HFE Act 1990; HFEA, 'In Vitro Derived Gametes – Scientific and Clinical Advances Advisory Committee Meeting' (8 June 2020), para 1.3 – could be used in research but not treatment. It may also be the case that cells of the female- or male- 'germline at any stage of maturity' could be interpreted as covering or applying to IVD eggs and sperm, given that gametes are germ line cells.

65 HFEA, *Authority Meeting 22 January 2025*.

66 Schedule 3, Human Fertilisation and Embryology Act 1990, as amended (HFE Act 1990).

The consent process is further complicated by the use of multiple consent forms by clinics. This has been recognised by the HFEA, which has recommended that the consent process should be simplified.[67] Developments such as IVG may add weight to calls for reform to the consent process, because it might present an additional element requiring consent. IVG might also involve additional parties (e.g. intended parents and tissue donors). If the law governing consent in assisted reproduction is reformed, it will be important to consider carefully whether it should be future-proofed to allow for specific consent requirements, e.g. mandatory counselling for using IVG in reproductive treatments.

4.3.2 Research involving IVD gametes

IVG involves research on gametes, and, under the HFE Act 1990, a licence is not required for this. However, if researchers intend to store any gametes created via IVG then a storage licence from the HFEA will likely be required.[68]

4.3.3 Research involving IVG embryos

Under the HFE Act 1990, if embryos are created from IVD gametes to be stored for the purpose of research then both a storage licence[69] and a research licence[70] will be required. Research on such embryos would be subject to the strict legal framework under the Act. This includes the 14-day rule which stipulates that a licence from the HFEA cannot permit keeping or using a human embryo outside of the human body after the appearance of the primitive streak.[71] Legally, this is taken to have 'appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began'.[72]

The 14-day rule may be relevant to IVG because it is not yet known if IVD gametes could be safe and effective for use in assisted reproduction in humans, and/or to create embryos.[73] Scientists have not yet established whether IVD gametes could be biologically equivalent to those produced in vivo, or whether they can produce healthy human fetuses.[74] Establishing this would likely require the permission and

67 HFEA, *Modernising Fertility Law: Recommendations from the Human Fertilisation and Embryology Authority (HFEA) for changes to the Human Fertilisation and Embryology Act 1990 (as amended)* (HFEA, 2023).

68 Section 11(1)(b) and Paragraph 2 of Schedule 2 HFE Act 1990.

69 Section 11(1)(b) and Paragraph 2 of Schedule 2 HFE Act 1990.

70 Section 11(1)(c) and Paragraph 3 of Schedule 2 HFE Act 1990.

71 This is the precursor of the development of a nervous system: see Nuffield Council on Bioethics, 'Human Embryo Culture – Discussions Concerning the Statutory Time Limit for Maintaining Human Embryos in Culture in the light of Some Recent Scientific Developments' (August 2017).

72 Sections 3(3) and 3(4) HFE Act 1990, as amended.

73 HFEA, *Modernising Fertility Law: Recommendations from the Human Fertilisation and Embryology Authority (HFEA) for changes to the Human Fertilisation and Embryology Act 1990 (as amended)* (HFEA, 2023).

74 V.G. Wesevich *et al.*, 'In vitro gametogenesis in oncofertility: A review of Its potential use and present-day challenges in moving toward fertility preservation and restoration' (2023) 19 *J Clin Med* 3305.

capability to culture embryos created from IVD gametes and assess their development past the 14-day limit. Whether the 14-day rule should be amended is currently a matter of debate.[75]

4.3.4 Using IVG in reproductive treatment

In the UK, there is a clear prohibition on the use of IVD gametes and embryos created from them in reproductive treatment. This is because only 'permitted' eggs, sperm or embryos can be transferred to the uterus of a woman.[76] These terms are defined in the HFE Act 1990:

- a 'permitted egg' is one '(a) which has been produced by or extracted from the ovaries of a woman, and (b) whose nuclear or mitochondrial DNA has not been altered' (since amended to permit certain alterations for the purpose of preventing the transmission of serious mitochondrial disease).
- 'permitted sperm' are sperm '(a) which have been produced by or extracted from the testes of a man, and (b) whose nuclear or mitochondrial DNA has not been altered'.
- a 'permitted embryo' '(a) … has been created by the fertilisation of a permitted egg by permitted sperm, (b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and (c) no cell has been added to it other than by division of the embryo's own cells'.[77]

This means that a licence to provide artificial insemination services would not cover IVD sperm and a licence to provide IVF treatment would not extend to IVG embryos. Noting the complexity of the law in this particular area, at a recent HFEA meeting, the Authority agreed that 'there should be a clear statement that "IVGs are not permitted gametes" to avoid any confusion about current legislation'.[78]

75 Nuffield Council on Bioethics (NCoB), 'Nuffield Council on Bioethics begin major review of the 14-day rule for research on human embryos' (NCoB, 2025).

76 Section 3(2) HFE Act 1990.

77 Section 3ZA HFE Act 1990.

78 HFEA, 'Minutes of the Authority Meeting on 22 January 2025' (HFEA, 2025), para 9.16.

4.3.5 Ways forward

The HFEA has recommended that 'IVGs are subject to some form of statutory regulation in time'.[79] This would align with the broader recommendations proposed by the HFEA to 'future proof' the HFE Act 1990 so that it is 'better able to accommodate future scientific developments and new technologies'.[80]

For IVG to be used to create gametes or IVG embryos for research and ultimately for their potential use in treatment, amendments to the HFE Act 1990 would be required. This could involve:

- amending the law governing consent in assisted reproduction to allow for specific consent requirements, e.g. mandatory counselling for using IVG in reproductive treatments;
- extending the 14-day rule to facilitate research on IVG embryos to enable scientists to validate their safety and viability as a first step; and
- as a second step either
  - amending the definitions of 'permitted' eggs, sperm and embryos in the primary legislation (the HFE Act 1990) to permit the use of IVD gametes and IVG embryos in clinical treatment; or
  - introducing a power to make regulations (secondary legislation) specifying changes to definitions contained within the HFE Act 1990, as occurred in response to mitochondrial donation treatment.[81] This option has also recently been suggested as a potential means of regulating the use of IVG by the HFEA.[82]

79 HFEA, 'Minutes of the Authority Meeting on 22 January 2025' (HFEA, 2025), para 9.16.

80 HFEA, *Modernising Fertility Law: Recommendations from the Human Fertilisation and Embryology Authority (HFEA) for changes to the Human Fertilisation and Embryology Act 1990 (as amended)* (HFEA, 2023).

81 See, for example, Section 3ZA(5) HFE Act 1990; The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

82 HFEA, 'Minutes of the Authority Meeting on 22 January 2025' (HFEA, 2025), para 9.16.

5 Safety and the welfare of children created through IVG

Key points

- The potential of IVG being used for reproductive purposes raises questions about the safety and wellbeing of any children created, particularly the risk of physical and/or psychological harm.
- Risks may arise as a direct result of using IVG or indirectly as a result of legal and social responses to the technology.
- It is important to consider acceptable levels of risk, and how risks should be weighed against the potential benefits of IVG.
- If the HFE Act 1990 was amended to permit the use of IVD gametes and IVG embryos in treatment, the existing welfare of the child provision (Section 13 (5)) would apply to treatment involving IVG.
- Fertility clinics with experience of providing services to those seeking IVF and other fertility treatments may be best placed to deal with any child welfare questions raised by the novel family types rendered possible by IVG.

5.1 Child welfare: safety and long-term impacts on children

Any proposal to use IVD gametes for reproductive purposes will raise questions about safety and the wellbeing of any children created – considerations that are raised by all new reproductive technologies. These may arise as a direct result of the use of IVG itself, or indirectly as a result of legal and social responses to it. Direct risks include the possibility of physical harm from genetic changes and mutations arising from the methods by which IVD gametes are created. These risks may differ depending on the ways in which IVD gametes are used. For example, to take what is perhaps the most extreme case, using IVG to derive both gametes from the same person is likely to involve a very high risk of autosomal recessive conditions occurring in the offspring because of the high risk of both gametes carrying the same potentially

harmful genetic mutations. Every individual carries several mutations in autosomal recessive genes. If both gametes are derived from the same individual, there is a high chance that both the egg and sperm used to create an embryo could carry the same mutation, causing autosomal recessive disease in the offspring. These conditions might vary in severity and any risks might, to some extent, be mitigated by using PGT. Nevertheless, the level of risk, or at least uncertainty, may well be considered unacceptable.[83] Indeed, in a meeting in January 2025, members of the HFEA agreed that 'the biologically dangerous and socially distasteful use of IVGs like "solo parenting" [referring to the use of IVG to create both eggs and sperm from the cells of one person] should not be permitted'.[84]

As in other contexts involving medically assisted reproduction concerns may also be raised regarding a child experiencing psychological harms, including distress resulting from discrimination and excessive scientific or media interest in their birth. The manner of the conception itself, and the implications of this for the child's concept of self and family relationships, might be thought to have the potential to cause harm too.[85] Many of these concerns, however, are not unique to IVG and have been raised in debates about other advances in medically assisted reproduction.[86] In contexts such as gestational surrogacy and egg donation it should also be noted that studies exploring psychosocial outcomes for children have generally found little evidence to support such concerns.[87] However, it should nevertheless be noted that as IVG might be used to enable post-menopausal, solo, multiplex, or posthumous reproduction, it has been suggested that children born in these 'novel' situations could experience confusion and distress, for example regarding kinship relations.[88]

While this would require a significant shift in regulation and practice, IVG may enable trait selection in offspring to a greater extent than is currently possible (see **Section 3.3**). If this happened, any resulting children could experience increased pressure to fulfil parental expectations given the lengths taken to ensure that they

83 For discussions about the acceptability of risk with respect to solo parenting through IVD gametes, see D. Cutas and A. Smajdor, '"I am your mother and your father! L. Notini *et al.*, 'Drawing the line on in vitro gametogenesis' (2020) 34 *Bioethics* 123.

84 HFEA, *Minutes of Authority Meeting on 22 January 2025* (12 March 2025).

85 For a recent example of this, see Nuffield Council on Bioethics, *Novel Techniques for the prevention of mitochondrial disorders: Ethical review* (2012), Sections 4.86-4.114, where similar concerns are identified and explored in the context of mitochondrial replacement therapy.

86 See, for example, G. Pennings *et al.*, 'ESHRE Task Force on Ethics and Law 11: Posthumous Assisted Reproduction' (2006) 21 *Human Reproduction* 3050, for discussion of possible psychological harms arising in children conceived posthumously; J.B. Appleby, 'The ethical challenges of the clinical introduction of mitochondrial replacement techniques.' (2015) 18 *Medicine, Healthcare and Philosophy*, 501 for discussion of such risks in the context of mitochondrial replacement techniques; and L. O'Donovan, 'Pushing the boundaries: Uterine transplantation and the limits of reproductive autonomy' (2018) 32 *Bioethics*, 489 for discussion of potential psychological harms in the context of uterus transplantation.

87 See, for example, V. Jadva *et al.*, 'Surrogacy families 10 years on: relationship with the surrogate, decisions over disclosure and children's understanding of their surrogacy origins' (2012) 27 *Human Reproduction* 3008; S. Golombok *et al.*, 'A longitudinal study of families formed through third-party assisted reproduction: Mother-child relationships and child adjustment from infancy to adulthood' (2023) 59 *Developmental Psychology* 1059.

88 S.M. Suter, 'In vitro gametogenesis: Just another way to have a baby?' (2016) 3 *Journal of Law and the Biosciences* 87.

possess specific traits.[89] While many of the physical risks of IVG may be addressed in preclinical research (in cells, non-human animals, and/or human embryos), some psychological risks may remain, e.g. as a result of discrimination or stigma.

Before any clinical uses of IVG are considered, an open discussion among stakeholders and publics and a transparent approach to decision-making regarding appropriate levels of risk in this area will be imperative to maintain public trust and ensure responsible, ethical innovation and accountability in this area of science.[90]

In addition to ethical considerations set out in other sections, important questions to be addressed are:

- How much risk (and risk of what) is acceptable in the use of IVD gametes in reproduction?
- How should we weigh concerns regarding the welfare of children conceived through IVG against the benefits that the use of IVD gametes for reproductive purposes may provide?

There is a range of different standards for determining acceptable risk levels, including the 'high risk of serious harm' or 'appropriate welfare' standard proposed by the European Society for Human Reproduction and Embryology (ESHRE). This requires that reproductive technology is used or trialled only if there is not a 'high risk' that it will result in the birth of children who 'lack the abilities and opportunities to realise those dimensions and goals that generally make human lives valuable'.[91] Another possibility could be adopting a more stringent standard which mirrors current HFEA criteria surrounding the welfare of the child in assisted reproduction; these limit access to assisted reproductive technologies in cases where there is a 'risk of significant harm' to the resulting child.[92] Under the HFEA criteria, this includes social and medical factors, such as where there is 'a significant risk' of 'serious physical or mental disability, a serious illness or any other serious medical condition'.[93] Alternatively, a focus on wider concerns, such as public health goals such as to reduce the overall burden of disease within a given society,[94] could favour imposing different limits than would be justified by an exclusive focus on individual child welfare. There is also debate about the basis for measures that are used in such

89 M.J. Sandel, *The Case Against Perfection – Ethics in The Age of Genetic Engineering* (Belknapp Press, 2007) 46. There is, though, no necessary link between desires to select the traits of one's offspring and 'pushy' parenting, and so such concerns may be criticised on these grounds. See, for example, S. Wilkinson, *Choosing Tomorrow's Children: the ethics of selective reproduction* (Oxford University Press, 2010) 21-56.

90 Similar prescriptions regarding trust, accountability and responsible innovation in the context of stem cell-based embryo models have been made in Cambridge Reproduction, 'Code of Practice for the Generation and Use of Human Stem Cell-Based Embryo Models' (2024).

91 ESHRE Task Force on Ethics and Law, 'The welfare of the child in medically assisted reproduction' (2007) 22 *Human Reproduction* 2585.

92 HFEA, Code of Practice, Version 9.4 (October 2023), s. 8.14.

93 Section 14 (4) HFE Act 1990.

94 L. Frith *et al.*, 'The long-term safety of medically assisted reproduction: Ethical aspects' in A. D'Angelo *et al.*, *The Long Term Safety of Assisted Reproduction* (CRC Press, 2022).

appraisals of risk, 'seriousness' and future well-being, and the extent to which these reflect the lived realities of people living with medical conditions.[95]

Whether IVG might be introduced as a treatment would likely be guided by a number of considerations including, for example, the results of clinical trials including long-term follow up studies with a limited number of children. While data on the health and wellbeing of those conceived using IVG will be crucial for demonstrating safety, such studies raise ethical questions themselves – although these are not unique to this context and arise for other longitudinal studies involving children.[96] Questions tend to focus on:

- ensuring appropriate consent from those with parental responsibility and eventually the children and young people themselves;
- children's ability to withdraw from participation once they have the capacity to make decisions, and the effects of this on the value of data collected;[97]
- how any such studies might be designed to ensure participation in any long-term follow-up studies is not unduly burdensome for children conceived through IVG.[98]

5.2 Assisted reproduction and the welfare of the child under UK law

If IVG for treatment purposes were to be permitted in law (and assuming that it became both sufficiently safe and effective for clinical translation and socially and ethically acceptable) it may be specified as an activity which can be authorised by a licence in the course of providing treatment services.[99] IVG would then be subject to the conditions of licences for treatment,[100] as is currently the case for IVF. This would include the duty to protect the welfare of any child who may be born as a result of treatment and the welfare of any existing child(ren) of the family.[101] To ensure this, treatment providers are required to undertake a welfare assessment to determine whether treatment should be provided at all.

95 For example, and in the context of prenatal screening, see F.K. Boardman and C.C. Clark, 'What is a 'serious' genetic condition? The perceptions of people living with genetic conditions' (2022) 30 *European Journal of Human Genetics* 160.

96 Nuffield Council on Bioethics ' Children and clinical research: ethical issues (2015), available at: Children and clinical research: ethical issues – Nuffield Council on Bioethics.

97 Ibid.

98 Ibid.

99 Schedule 2 HFE Act 1990.

100 These conditions are contained in Sections 12-14A HFE Act 1990.

101 Section 13(5) HFE Act 1990.

The HFEA frames the exercise of this legal requirement as a risk assessment activity,[102] which the vast majority of patients are likely to pass. Treatment should be refused where the centre considers that any child who may be born, or any existing child of the family, is likely to be at risk of significant harm or neglect, or where the centre cannot obtain sufficient information to conclude that there is no significant risk.[103] When undertaking welfare assessments, centres must ensure that patients are treated fairly, and, in particular, that they are not discriminated against on the basis of the protected characteristics under the Equality Act 2010.[104] This means that fertility providers must take care not to cross the boundary between the welfare assessment that they are required to undertake and moralising about alternative family forms.[105]

As noted in **Section 3.1** and **Section 6.2**, some uses of IVD gametes could disrupt current notions of parenthood and the family, and so may be seen to raise exceptional child welfare considerations in the context of this assessment. Some of these reproductive possibilities (solo and multiplex reproduction) are entirely new, but others while rare (post-menopausal and posthumous reproduction) are already possible using IVF. Therefore, treatment centres may be familiar with assessing welfare concerns in some of these contexts and so be well placed to identify any issues raised by the use of IVD gametes or embryos created from them.

A further issue related to welfare may be whether children created via IVG have a right to know their origin story. This argument has been raised in relation to existing donor-conceived people,[106] but a key difference is that in that situation not all the genetic material which creates the child comes from that child's parents. With IVG, the cells used to create the IVD gametes will most likely (see **Section 3.2**) come from one, if not both, of the intended parents. Nevertheless, there remain questions about whether a child born using IVG should be told that this is how they were created, and if so, when, how and by whom.

102 HFEA, Code of Practice, Version 9.4 (October 2023), 90.

103 HFEA, Code of Practice, Version 9.4 (October 2023), 93.

104 Age, disability, gender reassignment, marriage and civil partnership, race, religion, sex or sexual orientation.

105 L. O'Donovan, 'Why uterine transplantation requires us to rethink the role of the pre-conception welfare principle' (2022) 9 *Journal of Law and the Biosciences* 1. O'Donovan makes this point in relation to welfare assessments undertaken in the context of IVF treatment required for uterus transplantation, but it is one that applies broadly to a number of novel assisted reproductive treatments including IVG.

106 Discussed in, for example, I. Boone and M. Vonk (eds.), *The Right to Identity and Access to Information on Genetic Origin and Parentage* (Intersentia 2024). In the UK, all children born following gamete or embryo donations made after 1 April 2005 can access identifying information about their donor once they are 18, with non-identifying information becoming available at 16. Where the donation was made before that date, non-identifying information is available at 16 but the donor may choose to waive their anonymity: see HFEA, 'Donation'.

Similar discussions, and drawing parallels with donor-conceived people, were raised by the development of mitochondrial donation treatment.[107] With this treatment, in the UK it was decided that even though donation is involved, the egg donor will remain anonymous.[108] One reason for this is the minimal genetic contribution the egg donor makes to the resulting child.[109] In the case of multiplex parenting in particular, discussed further in **Section 6.3**, questions remain as to whether a child who is born with genetic material from more than two people, has the right to know this and/or who these contributors are, or if that contribution needs to reach a certain threshold before disclosure is required.

107 See, for example, J.B. Appleby, 'Should mitochondrial donation be anonymous?' (2018) 43 *The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine* 261; C. Mills, 'Nuclear families: Mitochondrial replacement techniques and the regulation of parenthood' (2020) 46 S*cience, Technology, and Human Values* 507.

108 HFEA, 'Does the mitochondrial donor have any rights over the child?'.

109 For an argument that a 'calculus of genes' approach is identifiable in public understanding of donor conception and mitochondrial replacement therapy in the UK, see I. Turkmendag, 'It is just a "battery": "Right" to know in mitochondrial replacement' (2018) 43 *Science, Technology, and Human Values* 56.

6 IVD gametes and novel family forms

Key points

- IVG has the potential to increase reproductive choices available for people who wish to have genetically-related children.
- Some uses of IVG may disrupt current notions of family and/or parenthood.
- An objection to using IVG in reproductive treatment is that it entrenches a view of the family that overemphasises the role of genetic relatedness.
- Using IVD gametes or IVG embryos (if permitted) would not affect who, in UK law, is the resulting child's legal mother, legal father, or other parent.
- IVG may challenge or complicate the attribution of legal parenthood in some reproductive scenarios, as well as social understandings of parenthood.
- The possibility of IVG facilitating 'gamete theft' requires careful consideration. For example, should a specific offence be introduced for situations where cells or tissues are taken without consent to create gametes in an attempt to create a child?

6.1 Expanding reproductive opportunities and creating novel family forms

As explained in **Section 3.1**, IVG has the potential to deliver benefits including increased reproductive choice for those who wish to have their own genetically related children, and enabling new and more diverse (biological) family forms. These possibilities however do raise important questions. Some of these are practical and relate to safety and the welfare of children (see **Section 5**). Others are ethical or social in character, such as whether the creation and use of IVD gametes and embryos created from them might disrupt established notions of family and parenthood in negative ways, or, conversely, that they may serve to further entrench existing overly biological or genetic understandings of family and parenthood.

6.2 Disrupting notions of the family and parenthood

Some uses of IVD gametes and embryos created from them may challenge existing ideas of family and parenthood. This could happen if, for example, eggs are created from the cells of a male human or sperm from the cells of a female human, or if older post-menopausal women use IVD gametes to create a genetically-related child, either becoming pregnant themselves or using a surrogate. More radically, there is the theoretical possibility of children with 3 or more progenitors.

Concerns about these possibilities fall into two main categories. First, there are those relating to the welfare of the children created and, more generally, safety and risk (addressed in **Section 5**). Second, there are questions about whether allowing a wider range of biological family forms might have unforeseen social effects.

There are also positive arguments for permitting IVD-driven social change. For example, in the case of post-menopausal genetic motherhood, there is an equalities argument for enabling older women to become biological parents just as older men can. Similarly, legal and social parenting by same-sex couples is permitted and accepted in the UK, and allowing IVG will enable same-sex couples equal opportunities to be genetically related to their children.[110] And, as noted above, IVG may contribute positively to reproductive diversity and choice.

It has been suggested that 'the most paradigm-shifting application' of IVD gametes and embryos created from them would be its use to enable three or more people to be a child's genetic parents.[111] For some, this might not be as ethically and legally radical as it appears. Arrangements in which three or more people have formal or informal parental roles for a child are not uncommon and, in some cultures, are the norm. As with same-sex families, using IVD gametes or embryos created from them in this way will provide a biological underpinning to such arrangements and allow these families the same opportunity to be genetically related as the (presently) more common two parent nuclear family. Having more than two genetic parents could also have advantages – perhaps akin to those said to be afforded by being part of a large extended family.[112]

110 C. Palacios-González *et al.*, 'Multiplex parenting: IVG and the generations to come' (2014) 40 *Journal of Medical Ethics* 752, 756. Similar arguments have also been made regarding uses of mitochondrial replacement therapy to allow for genetic relatedness between same sex-female couples and their offspring: G. Cavaliere and C. Palacios-González, 'Lesbian motherhood and mitochondrial replacement techniques: Reproductive freedom and genetic kinship' (2018) 44 *Journal of Medical Ethics* 835.

111 C. Palacios-González *et al.*, 'Multiplex parenting: IVG and the generations to come' (2014) 40 *Journal of Medical Ethics* 752. The expression 'three parent babies' has been used in the UK media to describe mitochondrial donation; see, for example: I. Sample, 'First UK baby with DNA from three people born after new IVF procedure' 9 May 2023 *The Guardian*; J. Hamzelou, 'Three-parent baby technique could create babies at risk of severe disease' 2 March 2023 *MIT Technology Review*. In fact, mitochondrial donation does not mean that the resulting child has three genetic parents – or at least not in the sense intended here. This is because the procedure involves replacing only the defective mitochondrial DNA, which comprises a tiny fraction of the total genetic material, and the nuclear DNA, which determines the vast majority of genetic traits, comes exclusively from the two primary parents.

112 E. Treleaven, 'The relationship between extended kin resources and children's healthcare utilization: An analysis of family networks' (2023) 321 *Social Science & Medicine* 115720.

For others, this may be a step too far and an unacceptable extension of the notion of the family and family forms. It is therefore important that a range of views on families is heard and considered when deciding which uses of IVG should be permitted.

More generally, an important objection to the use of IVD gametes, and embryos created from them, might be that doing so further entrenches an overly biological or genetic view of the family;[113] one in which being genetically related to a child is somehow 'better' than other arrangements, such as adoption. How strong this argument is in practice may depend on, amongst other things, the extent to which any introduction of IVG to human reproduction was accompanied by continued or strengthened recognition of and support for, other routes to parenthood, including adoption and gamete donation.

6.3 The legal regulation of parenthood in the UK

Legal parenthood provides official recognition of a parent's relationship with their child. The attribution of legal parenthood creates financial rights and responsibilities, including inheritance rights, and legal parenthood also determines the child's nationality.[114] It is therefore important to consider how the legal relationship between prospective children and the adults involved in treatment using IVD gametes or embryos created from them might be recognised.

In the UK, a child can have no more than two legal parents and, as well as having legal parents, a child will have at least one person who has parental responsibility (PR) for them. PR concerns 'all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and [their] property'.[115] PR primarily relates to matters involving the care of a child. It is possible for someone who is not a legal parent to have PR for a child (such as a grandparent) and, conversely, for a legal parent not to have PR for their child (some unmarried fathers, for example). There is no limit on the number of people who can acquire PR in relation to a particular child.[116] Only the legal mother of a child automatically has PR for their child, but there are a number of ways through which the legal father, other legal parent, or someone else can acquire PR for a child.[117]

The routes to legal parenthood in the UK may differ depending on whether the child has been born following medically assisted or unassisted reproduction. The parenthood provisions for assisted reproduction are set out in the Human Fertilisation and Embryology Act 2008 (the HFE Act 2008). The legal mother is the

113 See, for example, A. Petropanagos, 'Pronatalism, geneticism and ART' (2017) 10 *International Journal of Feminist Approaches to Bioethics* 119; T. Rulli, 'Preferring a genetically-related child' (2016) 13 *Journal of Moral Philosophy* 669.

114 NGA Law, 'Securing Parental Rights in Ways Other Than Adoption'.

115 Section 3(1) Children Act 1989 (CA 1989).

116 Section 2(5) CA 1989.

117 See Sections 2, 4, 4ZA, and 4A CA 1989.

person who gives birth to the child 'as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child'.[118] This provision applies regardless of whether the embryo or gametes were placed in that person when they were in the UK.

Determining who is the legal father or second parent of a child born through assisted reproduction is more complex:

- If the legal mother is married to or in a civil partnership with a man at the time of treatment and his sperm was not used to create the embryo, he will be treated as the father unless he did not consent to the embryo, sperm and eggs being placed in her, or to her artificial insemination.[119]
- If the legal mother is married to or in a civil partnership with a woman at the time of the treatment, that woman will be treated as a parent unless she did not consent to the embryo, sperm and eggs being placed in the woman, or to the woman's artificial insemination.[120]
- These provisions apply regardless of whether the embryo or gametes were placed in the woman when she was in the UK.

If no person is to be legally treated as the legal father or second parent following these provisions, then provided that:

- the embryo or gametes were placed in the woman or she was artificially inseminated in the UK in the course of treatment provided under a licence,
- the '*agreed fatherhood conditions*' or '*agreed female parenthood conditions*' were met when the embryo or gametes were placed in the woman, or the woman was artificially inseminated,
- the man or other woman was alive when the treatment was provided, and
- the embryo was not created using the man's sperm,

then that man will be treated as the legal father,[121] or the woman will be treated as the second parent of the child.[122]

118 Section 33 Human Fertilisation and Embryology Act 2008 (HFE Act 2008). This will also be the case in surrogacy where the surrogate will be the child's legal mother unless and until a parental order is granted transferring legal parenthood to the intended parent(s) – see Section 54 of the HFE Act 2008.

119 Section 35 HFE Act 2008.

120 Section 42 HFE Act 2008.

121 Section 36 HFE Act 2008.

122 Section 43 HFE Act 2008.

The '*agreed fatherhood conditions*'[123] and '*agreed female parenthood conditions*'[124] are that:

- the man or other woman has consented in writing and signed a notice stating that they agree to being the father or other parent of any child;
- the woman being treated has consented in writing and signed a notice stating that she agrees to the man or other woman being treated as the father or other parent of the child;
- those consents have not been withdrawn;
- the woman being treated has not given notice that she consents to another man being treated as the father of the child or to another woman being treated as a parent of the child; and
- the woman being treated and the man or other woman are not within the prohibited degrees of relationship.[125]

Any situation that falls outside the provisions relating to assisted reproduction and parenthood as set out in the HFE Act 1990 and HFE Act 2008, will be treated as 'natural' reproduction and the common law rules on legal motherhood and fatherhood will apply. This means that the legal mother is the person who gives birth,[126] and legal fatherhood is bestowed on the genetic father, or it will be presumed that if the person who gives birth is married or in a civil partnership, that their husband or civil partner is the father, or that the man named on the birth certificate is the legal father.[127]

Applying the current law to situations where IVD gametes are used to create an embryo, there will be **no** change as to who is the 'mother', as motherhood is determined solely by birth in the UK.[128] Similarly, using IVD gametes or embryos created from them will **not**, on the face of it, disrupt the legal provisions on fatherhood or other parenthood under the HFE Act 2008. The fictional scenarios below illustrate how IVG may make possible some reproductive scenarios that could challenge and raise questions about the current attribution of legal parenthood, as well as social understandings of motherhood and fatherhood:

123 Section 37 HFE Act 2008.

124 Section 44 HFE Act 2008.

125 The prohibited degrees of relationship are set out in Section 58(2) of the HFE Act 2008. Two persons are within prohibited degrees of relationship if one is the other's parent, grandparent, sister, brother, aunt or uncle, if they are full blood or half blood relations, or are current/former adoptive children/parents.

126 *Ampthill Peerage Case* [1977] AC 547. This will also be the case in surrogacy where the surrogate will be the child's legal mother unless and until a parental order is granted transferring legal parenthood to the intended parent(s) – see Section 54 of the HFE Act 2008.

127 See Weightmans, 'Who is a legal parent and who has parental responsibility?'. In cases of surrogacy, where the surrogate is married or in a civil partnership, the surrogate's spouse or civil partner will be the legal father or parent of any child born unless the parties were legally separated at the time of treatment or it can be shown that the spouse or civil partner did not consent to the surrogate's treatment. See HFEA, 'Code of Practice, version 9.4' (October 2023) 79-80.

128 Section 33 HFE Act 2008; *R (McConnell and YY) v Registrar General for England and Wales* [2020] EWCA Civ 559.

Scenario 1 Consent and legal parenthood

Anna and Beth are females in a same-sex couple who want to start a family. They are not married or in a civil partnership. They attend a clinic offering IVG and IVF services with the aim of having a child genetically-related to both of them. The clinic presents them with numerous consent forms. They sign all the forms consenting to IVG and IVF treatment but not any relating to parenthood.

At the clinic, Anna's eggs are collected and tissue samples are taken from Beth in order to produce IVD sperm. Embryos are created and one is transferred to Anna's uterus, resulting in the birth of a child, Charlotte.

A partner of a person undergoing fertility treatment at a licenced clinic in the UK is required to consent to being the legal parent, if the partner:

- is not married or in a civil partnership, **and**
- their partner is receiving treatment using donor sperm, or embryos created outside the body **using donor sperm**, **and**
- they wish to be the legal parent of any child born from their partner's treatment.

Who will be the legal parents?

As the person who gave birth, Anna is Charlotte's legal mother. Beth is Anna's partner and so **presumably** her IVD sperm **will not** be classed as 'donor sperm' meaning that Beth **will not** be Charlotte's legal parent.[129]

If, however, this situation was seen as more akin to a mixed-sex couple undergoing IVF and using the male partner's sperm to create the embryo, then the question is whether **genetics** would mean that Beth was Charlotte's other parent. Whether IVD sperm will be treated in this way under the common law is uncertain.

It is also important to note that the current law is framed around the idea that sperm is derived from a biological male and so it might be necessary to either read 'sperm' as gametes, or to amend the law to recognise this.

129 Section 41 HFE Act 2008.

Scenario 2 Multiplex parenthood[130]

Drew, Elliott, Farah and Gia are in a relationship together and want to parent a child and all be genetically related to that child.

Using IVG with IVF will enable two embryos to be created from either couple, using either 'natural' or IVD gametes. Drew and Elliot create embryo 1 and Farah and Gia create embryo 2. IVD eggs could then be derived from embryo 1 and IVD sperm could be derived from embryo 2 to be used to create embryo 3 – for transfer to Farah's womb.

Embryo 3 would be genetically related to all four prospective parents, who would be the child's genetic grandparents, with the 'genetic parents' being embryo 1 and embryo 2 – the IVD embryos – which will not be transferred to a womb and brought to birth. This means that the resulting child's genetic parents will never have been recognised as legal persons.[131]

Who will be the legal parents of any resulting child?

Farah will be the legal mother if she gives birth to the child. If she is married or in a civil partnership, then her spouse or civil partner will be the legal father or second parent. If she is not married or in a civil partnership, then the agreed fatherhood or female parenthood conditions might apply to determine who can be the legal father or second female parent. If this is not the case, the child might not have a legal father or second parent.

Not having a legal father or second parent named on the birth certificate is not an unusual situation, as many people only have their birth mother named on their birth certificate. However, in this scenario there are four people who want to be named as legal parents and under the present law, only two of them actually could be. Applying the law may though result in only Farah being named, if she gives birth to the child. However, if a surrogate is involved, then none of the four may end up being listed on the birth certificate – despite their intentions.

130 This example is drawn from C. Palacios González *et al.*, 'Multiplex parenting: IVG and the generations to come' (2024) 40 *Journal of Med Ethics* 752.

131 While legally this will not affect the parenthood provisions, described above, this may raise issues for the child's psychological adjustment and the risk of psychological harm.

Scenario 3 Gamete theft and legal parenthood

Helena attends a party at the house of Idris, a single wealthy businessman who does not wish to have children. Helena wants to start a family and thinks that a child with Idris' genetic traits is highly desirable. During the party, Helena surreptitiously obtains a sample of Idris' skin cells to take to a clinic offering IVG and IVF services.

IVD sperm is created from the sample and used, along with Helena's eggs, to create embryos. An embryo is later transferred to Helena's uterus resulting in the birth of a child, Jude. Helena is now pursuing Idris for child support.

Helena will be Jude's legal mother because she gives birth, but Idris has not consented to the use of his skin cells in this way. Will he, nevertheless, be Jude's legal father? It appears that as he is the genetic father, under current law he could be listed as the legal father and would then be liable to pay child support.

Beyond this matter of legal parenthood, as the current legal view is that there is no property in the body (see **Section 4.3**) it is not clear whether taking human cells or tissue without consent is currently a criminal offence. If it is not, as noted earlier, it is important to consider whether a specific offence should be introduced to deal with a situation where cells or tissues are taken without consent to create gametes to bring about the birth of a child.

These scenarios raise a number of questions specifically regarding the law governing parenthood, including whether the law should only recognise two legal parents, and whether the current law appropriately reflects who potential parents and wider society might think a child's legal parents are and should be. If it does not, the development and use of IVD gametes and embryos created from them might precipitate reform of the laws on legal parenthood in the UK in the context of assisted reproduction.

7 Selective reproduction

Key points

- IVG might make it easier to create larger numbers of embryos and so make the practice of selective reproduction (choosing between different embryos) technically easier.
- IVG may lead to germline genetic changes if a person who is brought into existence by IVG then themselves reproduces and passes on any alterations to their own children.
- At present, PGT can only be authorised in limited specified circumstances, meaning the advent of IVG is unlikely to lead directly to any changes in the way PGT is regulated in the UK.
- The HFEA has the power to grant a *research* licence permitting gene editing in human embryos, though gene editing is currently prohibited for use in *treatment,* except for prescribed treatments relating to serious mitochondrial disease.
- However, there may be calls to revisit this prohibition in the future to reduce the incidence of serious inherited genetic disease, for example.

It has been suggested that IVG could make it easier to intentionally alter the genetic composition of future generations. Ethical issues raised by these possibilities are considered here, as well as possible regulatory responses.

7.1 IVG and selective reproduction

As noted in **Section 3.3**, IVG could make it easier to create very large numbers of viable human embryos. This might, in turn, increase our ability to practice selective reproduction, which in this context means choosing between different embryos for implantation and so choosing which possible future people, or what characteristics of possible future people, are brought into existence.[132]

IVG might also lead to germline genetic changes to the population, with effects passed on through the generations indefinitely, in ways that are difficult to predict or

132 H. Greely, *The End of Sex and the Future of Human Reproduction* (Harvard University Press, 2016); R. Sparrow, 'In vitro eugenics' (2014) 40 *Journal of Medical Ethics* 725.

control. This would happen if people created from IVD gametes or embryos created using IVD gametes went on to have their own children using their own gametes, and their offspring did the same, and so on. Thus, discussions about selective reproduction need to consider potential long-term effects on humanity and societies as a whole, not just the interests of particular children and families.

Using IVG along with selective reproduction could, in theory, reduce the prevalence of heritable genetic diseases, improve population health, and reduce future healthcare costs by reducing the number of people born with particular health conditions. Giving prospective parents more choice may also be welcomed by some.

However, this application of IVG raises a number of questions including:

- whether IVG and selective technologies might be used for 'eugenic' purposes, and/or have negative effects on existing or future people with disabilities;
- whether IVG and selective technologies could be used to select traits other than those related to health (e.g. cosmetic features or enhancements);
- whether it will lead to more embryos being discarded and thus to concerns that insufficient respect is being shown towards embryos (see **Section 4**); and
- what the short and longer-term consequences of extensive embryo selection will be.

It is important to note that IVG need not be used for any of these purposes, and genetic selection is not an inevitable consequence of developing IVG. We could, for example, decide to restrict the kinds of selection permitted, as happens at present (see **Section 7.2**). In addition, some of these concerns (e.g. about eugenics and human enhancement) are not unique to IVG and have been debated extensively in relation to other reproductive practices.[133] What follows is, therefore, limited to a brief outline of two such key concerns.

7.1.1 Eugenics and effects on people with disabilities

Many people are worried that attempts to 'screen out of existence' certain genetic conditions and disabilities are like the kind of abhorrent eugenics programmes linked to some of the worst atrocities of the 20th century. These include the horrific actions of the Nazi regime in the 1930s and 1940s, as well as non-consensual sterilisation programmes in a number of other places including the USA, Japan,

133 We highlight only the most obvious concerns here. There is a vast array of literature on the ethics of genetic modification and selective reproduction, most of which is applicable to IVG. See, for example, A. Buchanan *et al.*, *From Choice to Chance: Genetics and Justice* (Cambridge University Press, 2000); J. Glover *Choosing Children: Genes, Disability, and Design* (Oxford University Press, 2006); J. Harris, *Enhancing Evolution: The Ethical Case for Making Better People* (Princeton University Press, 2010); S. Wilkinson, *Choosing Tomorrow's Children* (Oxford University Press, 2010); Nuffield Council on Bioethics, *Non-Invasive Prenatal Testing: Ethical Issues* (2017); Nuffield Council on Bioethics, *Genome Editing and Human Reproduction: Social and Ethical Issues* (2018); World Health Organization, *Human Genome Editing: A Framework for Governance* (2021).

and Scandinavia.[134] Others are concerned that 'screening out' certain conditions sends a negative message to and about people with those conditions – that the world would 'be better if they did not exist'.[135]

Whether these concerns constitute decisive objections to IVG will depend on a number of contextual factors. For example, is what is being 'selected out' a genuine health condition that causes serious pain and/or significant shortening of life, or is it more of a difference or diversity than a disease or pathology? Many examples are liable to be contested in this debate, and the distinction drawn here is not a sharp one. Cases of the latter (more difference or diversity than disease) might include deafness (Deaf culture) and some types of neurodivergence. By contrast, cases of the former (health conditions with intrinsically negative effects) could include congenital heart defects, anencephaly, and Tay Sachs Disease (for which PGT is currently permitted). Reducing the prevalence of serious pain or very premature death in future populations might be considered a laudable goal and so less likely to raise concern. However, different considerations may apply when the characteristic in question looks more like difference than disease. Views also differ on what might be considered, or experienced as, 'serious' genetic conditions .[136]

7.1.2 Enhancement and cosmetic features

Reproductive selection could, in principle, be used to target aesthetic traits, such as eye colour, hair colour and texture, skin tone, or facial features. It could be used with the intention of giving certain children advantages or 'enhancements', including enhancing physical traits (e.g. height/strength or disease resistance beyond the normal range) or even cognitive enhancement, although to what extent the latter is technically possible remains contested.[137]

These possibilities mean that it is important to consider the extent to which the use of IVGs and embryo selection to increase parental choice, e.g. over what future children look like, should ever be permitted. It might be argued that parents are making choices for their children throughout their lives, however it has been suggested that there is a moral difference between choosing for a child once they

134 A. Bashford and P. Levine (eds.), *The Oxford Handbook of the History of Eugenics* (Oxford University Press, 2010).

135 J. McMahan, 'The Morality of Screening for Disability' (2005) 10 *Reproductive Biomedicine Online* 129; M.J. Sandel, *The Case Against Perfection – Ethics in The Age of Genetic Engineering* (Belknapp Press, 2007); T. Shakespeare (2008) 'Debating disability' (2008) 34 *Journal of Medical Ethics* 11; S. Wilkinson, *Choosing Tomorrow's Children* (Oxford University Press, 2010).

136 See, for example, F.K. Boardman, C.C. Clark, 'What is a 'serious' genetic condition? The perceptions of people living with genetic conditions' (2022) 30 *European Journal of Human Genetics* 160.

137 H. Greely, *The End of Sex and the Future of Human Reproduction* (Harvard University Press, 2016).

are born (choices that are made in families in the context of their social circumstances) and choosing what they are like before they are born.[138]

The same view could be taken of embryo selection. Allowing extensive preimplantation selection could also exacerbate social inequalities, if, for example, it leads to a less diverse society, or further discrimination against disabled people confers benefits that only some people could afford.

These are complex issues, not specific to IVG, and it will be necessary to consider each type of selection or modification on its merits and in its specific context while considering wider societal issues.

7.2 The law on embryo testing and selection (UK)

PGT is a form of testing which screens embryos created via IVF for genetic or chromosomal abnormalities linked to specific genetic conditions. In the UK, two types of PGT for genetic conditions are available – pre-implantation genetic testing for monogenic disorders (PGT-M) and pre-implantation genetic testing for chromosomal structural rearrangements (PGT-SR).

Embryo testing via PGT can be authorised in two situations in the UK:

1. Where there is a particular risk that the embryo to be tested may have a genetic, mitochondrial, or chromosomal abnormality, and the HFEA is satisfied that a person with the abnormality will have or develop a serious disability, illness or medical condition.[139]
2. Where there is a particular risk that any resulting child will have or develop a sex-related serious disability, illness, or medical condition. A condition is sex-related if the HFEA is satisfied that it affects only one sex or affects one sex significantly more than the other.[140]

In (1), the test may be carried out to establish whether the embryo has the suspected abnormality. In (2), the test is carried out to establish the sex of the embryo. PGT can **only** be considered where 'there is a significant risk of a serious genetic condition being present in the embryo',[141] and the HFEA must agree that a condition is 'sufficiently serious' before clinics are permitted to test for it.[142]

138 D.S. Davis, 'Genetic dilemmas and the child's right to an open future' (1997) 27 *Hastings Center Report* 7; S. Wilkinson, '"Designer babies", instrumentalisation and the child's right to an open future' in N. Athanassoulis (ed.), *Philosophical Reflections on Medical Ethics* (Palgrave Macmillan, 2005); D. Archard, 'Genetic enhancement and procreative autonomy' (2007) 1 *Stud. Ethics L. & Tech* 1; J. Feinberg, 'The child's right to an open future' in D. Engster and T. Metz (eds.), *Justice, Politics, and the Family* (Routledge 2015).

139 Schedule 2, para 1ZA HFE Act 1990. HFEA (n87), 99-100.

140 HFEA (n93), 99-100.

141 HFEA (n93), 99-100.

142 HFEA (n93), 99-100.

Where testing has identified a gene, chromosomal or mitochondrial abnormality in an embryo, Section 13(9) of the HFE Act 1990 provides that such embryos must not be preferred to those that are not known to have such an abnormality.

The legal framework in the UK means that access to PGT is currently limited, with patients only able to use it in specific circumstances. Therefore, while concerns about the increased use of PGT following IVG may be acute in countries where the regulation of embryo screening technology is less stringent, the use of IVG in the treatment context should this be realised may not lead to any changes in the way that PGT is regulated in the UK. The current legal framework would mitigate the risk of a significant expansion to embryo selection.

8 Funding and access

Key points

- Commercialisation in IVG research raises questions about how to encourage innovation while ensuring fair access.
- It also raises questions about what governance and oversight arrangements will best ensure that such biotechnologies are developed responsibly and in the public interest, in line with societal values and priorities.
- Consideration may eventually need to be given to whether IVG merits public funding and, given inevitably limited resources, whose needs should be prioritised.

8.1 Funding and prioritisation

If IVG is used in human reproductive treatment, several allocation and access questions will need to be addressed, including:

- Under what circumstances, if any, would IVG be an appropriate object of public funding?
- Which potential recipients of these new services should be prioritised?
- How should prioritisation decisions be made and by whom?

Decisions on such matters will depend on the precise circumstances at the time, including the state of scientific development and knowledge about the costs, benefits, and risks of IVG. At a minimum, for mainstream NHS funding to be justified, IVG (or IVG used in particular ways) would need to meet the same safety, efficacy, and cost-effectiveness criteria as existing treatments in reproductive medicine.

For each particular application of IVG, it will be necessary to consider whether there are existing treatments or interventions that can deliver similar outcomes, and how IVG performs compared with those. For example, for cancer patients whose radiotherapy or surgery could threaten their reproductive capabilities, IVG could be an alternative to extracting and freezing gametes. In this case, the benefits and risks of the conventional treatment (gamete freezing) versus IVG could be considered, and a relatively straightforward cost-benefit analysis undertaken to show which is preferable.

More difficult questions arise when IVG is contrasted with egg and sperm donation, as it is less clear that like is being compared with like. If IVG is more expensive than, or carried more risk than, current gamete donation practices, that would be an argument for not providing it on the NHS. However, prospective parents may counter that the extra cost and risks are tolerable given that IVG (unlike donation) can provide a genetic link with the resulting child and avoids the need for third-party involvement (egg or sperm donors) in the family formation process, which is a concern for some. The questions then become what value (if any) should be placed on providing genetic (over and above social and legal) parenthood, and whether this is a proper object of public funding. These are familiar types of questions from other contexts (e.g. IVF funding and uterus transplantation),[143] but considering this in the context of IVG is necessary and may be challenging.

Similar issues arise where the rationale for using IVG is something other than the alleviation of medical infertility. Multiplex parenting would be an example, as the primary driver for using IVG here would be to create a different kind of biological family for personal reasons. This could be seen as a preference rather than a clinical infertility issue, and it could be argued that it is, therefore, of lower priority and not appropriate for public funding. But, on the other hand, it could be argued that the desire to have a genetically related child (or any child for that matter) is always a 'preference' rather than a medical need and that there is therefore no *fundamental* difference between this example and many other well-established infertility treatments (e.g. IVF)[144].

The same could, perhaps, be said of posthumous and same-sex genetic reproduction, although the issues here are more complex. With the former, should the death of a partner be seen as akin to medical infertility? It has the same reproductive effects on the family and, provided that appropriate consent is in place from the deceased person, it may seem unreasonable to deny this service to people who have been bereaved. Others, however, may argue that wanting this service is just a preference because the surviving person, unless medically infertile themselves, could have children with another partner or by using donor gametes.

With same-sex genetic parenthood, the need for IVG may also not be caused by medical infertility. There would, though, be an equalities argument for enabling same sex couples to have the same genetic relationship with their offspring as many mixed-sex families. If IVG were denied specifically to same-sex couples, that could lead to or constitute a systemic inequality, because they would be prevented from

143 In the context of public funding for IVF and uterus transplantation for example, see S. Wilkinson and N. J. Williams 'Should Uterus Transplants be Publicly Funded?' (2016) 42 *J Med Ethics* 559 and L. O'Donovan, N. J. Williams & S. Wilkinson, 'Ethical and policy issues raised by uterus transplants' (2019) 131 *British Medical Bulletin* 19-28.

144 S. Fovargue *et al*, 'In vitro gametogenesis, 'social infertility', and the legacy of the Warnock report' (2025) Human Fertility https://doi.org/10.1080/14647273.2025.2525895.

accessing a biotechnology that is available to other families, and one that may even be actively supported by the state for other families.[145]

A final, and important, point on the issue of funding and access is the backdrop of unequal public funding for reproductive services against which IVG may be introduced, if it is deemed to be sufficiently safe and effective. Despite a previous government pledge to 'work with NHS England to address the current geographical variation in access to NHS-funded fertility services across England',[146] the acknowledged 'postcode lottery' persists.[147] Given finite NHS resources, the introduction of an additional fertility service (such as IVG) may compound this issue. Justifiable and transparent decisions about commissioning and eligibility criteria are, therefore, vital.

8.2 Intellectual property, commercialisation, and access

The assisted reproduction technology landscape has changed since the development of IVF in the 1970s, when little attention was paid to commercialisation by scientists and clinicians.[148] The culture of scientific research has changed too, with even academic institutions becoming increasingly focussed on patenting and commercialising university-developed technology.[149] Furthermore, over recent years, 'venture capital funding has started flowing to a handful of companies aiming to bring IVG to the clinic'.[150] This raises concerns regarding potential conflicts of interest and how to protect the interests of patients as potentially vulnerable consumers, while also ensuring transparency in provision and equity of access in an increasingly commercialised arena.[151]

145 A parallel here can be drawn with the case of access to IVF by female same-sex couples. Currently, National Institute of Health and Care Excellence (NICE) guidelines state that women under the age of 40 should be offered three full cycles of IVF if they have been trying to get pregnant through regular unprotected sexual intercourse for two years or they have not become pregnant after 12 cycles of artificial insemination, six of which should have been intrauterine insemination: National Institute of Health and Care Excellence, 'Fertility Problems: Assessment and Treatment Clinical Guideline (CG156)' (National Institute of Health and Care Excellence 2017). The result of this policy is that prior to accessing IVF, female same-sex couples are faced with an additional financial burden that heterosexual couples are not subject to. This inequality of access was acknowledged in the 2022 Women's Health Strategy, where more equitable access to NHS-funded fertility services for female same-sex couples was outlined as part of one of the government's 10-year ambitions for fertility, contraception and pre-conception: Department of Health and Social Care (DHSC), *Women's Health Strategy for England* (Cm 736, 2022).

146 Department of Health and Social Care (DHSC), *Women's Health Strategy for England* (Cm 736, 2022), 68.

147 T. Campbell, 'NHS postcode lottery leaves couple with huge IVF bill while 'you get more chances minutes away'' 26 March 2024 *The Independent*. See also L. O'Donovan and S. Waxman, 'The public provision of ARTs in England: Old arguments new inequalities' 27 August 2020 *Journal of Medical Ethics Blog*.

148 D. Cyranoski *et al.*, 'Intellectual property and assisted reproductive technology' (2023) 41 *Nature Biotechnology* 14.

149 D. Cyranoski *et al.*, 'Intellectual property and assisted reproductive technology' (2023) 41 *Nature Biotechnology* 14.

150 D. Cyranoski *et al.*, 'Intellectual property and assisted reproductive technology' (2023) 41 *Nature Biotechnology* 14.

151 For a recent discussion of the increasing commercialisation of assisted reproductive medicine see: S.A. Attinger, E. Jackson, I. Karpin, I. Kerridge, A.J. Newson, C. Stewart, L. van de Wiel, & W. Lipworth, Addressing the consequences of the corporatization of reproductive medicine, (2024) 32(4) *Medical Law Review*, 444–467.

Regardless of whether IVG is deemed safe and effective for use in reproductive treatment, issues of patents and intellectual property rights may affect access to this biotechnology. This is because university and commercial laboratories holding patent rights over IVG technology may keep costs high, meaning that, as with many other biomedical developments, only those with the financial means to pay could access IVG, and/or that the technology would remain unaffordable within the public sector.

In 2023, 12 IVG-related patents across multiple jurisdictions including Japan, Europe and the United States were identified – five of which were granted.[152] Patents relating to iPSCs may also be relevant.[153] With more research institutions and private companies pursuing the development of IVG technology, the patent landscape is set to become complicated and overlapping, and/or broad blocking patents may be sought.[154] This might mean that patients are faced with substantially higher prices if or when IVG technology comes to market because of reduced market competition. It is difficult to anticipate the effect of this in practice, because IVG research is still in a relatively early stage of clinical development. Nevertheless, the potential impact of intellectual property rights on access should not be underestimated.

152 D. Cyranoski *et al.*, 'Intellectual property and assisted reproductive technology' (2023) 41 *Nature Biotechnology* 14.

153 D. Cyranoski *et al.*, 'Intellectual property and assisted reproductive technology' (2023) 41 *Nature Biotechnology* 14.

154 D. Cyranoski *et al.*, 'Intellectual property and assisted reproductive technology' (2023) 41 *Nature Biotechnology* 14

9 Concluding summary

While its use in human reproductive treatment does not appear to be imminent, IVG has the potential to deliver significant benefits as a research tool. In future it may also be a means of preserving or restoring fertility and of opening up new reproductive possibilities, such as same-sex genetic families and genetic parenthood for older women.

This report outlines the central issues and concerns raised by potential future uses of IVG, with a focus on the issues that will need to be addressed before IVG is ever used as an assisted reproduction treatment. Some of the key issues which need to be addressed, and questions requiring further consultation and discussion, are summarised below.

9.1 Consent and information

The reproductive possibilities created by IVG require careful consideration of requirements of valid consent and whether amendments are needed to existing legislative and regulatory frameworks to ensure protection against non-consensual creation of IVD gametes and embryos created from those gametes.

Questions that remain to be explored include:

- What constitutes valid consent to have IVD gametes created from a person's cells?
- Could IVG be incorporated into existing frameworks for gamete or tissue donation, and how can any regulatory gaps be addressed? Are new frameworks required?
- If IVG children are created using third-party tissue (from people other than their social parents), would/should their rights to know their origins be the same as other donor-conceived people, or are there important differences between IVG and traditional gamete donation?

9.2 Moral and legal status of IVD gametes and embryos created from them

Prior to any research and reproductive uses, decisions must be made regarding both the moral and legal status of IVD gametes and permitted uses of IVD gametes and any embryos created from them, for example with respect to the extent to which the HFE Act 1990 (as amended by the HFE Act 2008) should be amended to accommodate new reproductive technologies and possibilities.

Questions to be explored include:

- Would (and should) IVD gametes have the same moral status as other gametes and merit the same levels of respect and protection?
- If IVD gametes are used to create embryos, would those embryos have the same moral status as 'naturally produced' embryos and merit the same levels of respect and protection? How does this question intersect with other ongoing debates about 'embryo models'?
- Would (and should) IVD gametes have the same legal status as other gametes?
- Depending on the answer to these questions, are any changes required to the current law to accommodate potential future uses of IVD gametes?

9.3 Child welfare and safety

Balancing the potential benefits of reproductive uses of IVD gametes against short- and long-term risks for the welfare of children created requires careful consideration of the point at which IVG is 'safe enough' to begin human trials, the size of initial trials, and the possibility of long-term follow-up studies.

Questions that remain to be considered include:

- How much risk (and of what) is acceptable in this context?
- How should we weigh such risks against the benefits that the use of IVD gametes for reproductive purposes may provide?
- What level of evidence would we need before concluding that IVG was 'safe enough' for use in human reproduction? And what safeguards and follow-up studies would need to be in place?

9.4 Parenthood and family formation

In opening up possibilities for genetic parenthood for diverse people and groups, IVG may both challenge and reinforce social norms regarding the 'ideal' family structure and the importance of genetic relatedness within the family. In terms of regulation, these possibilities necessitate consideration of whether the current law would appropriately reflect who a child's legal parents are or should be. If not, the development of IVG may precipitate reform of the laws on legal parenthood in the UK.

Questions to be explored include:

- If IVG were used in human reproduction, would that necessitate changes in how we think of family and relatedness?
- Would there need to be changes to legal and social arrangements regarding parenthood, and who counts as a parent at birth?
- Is 'multiplex' reproduction (3 or more 'genetic parents') via IVG ethically acceptable and should it be permitted?
- Could using IVG further entrench an excessively biological and/or genetics-based view of families?

9.5 Selective reproduction

The development of IVG, in particular the possibility of its facilitating testing and selection of embryos at a scale unlike anything currently possible, may prompt a reconsideration of fundamental legal and ethical questions about selective reproduction, such as:

- What grounds for embryo selection are ethically acceptable or unacceptable, in this new possible context?
- Which types of, and grounds for, selection should be legally permitted?
- What does this mean for society as a whole as well as for individuals and families?

9.6 Funding and access

If IVG becomes available to patients, then familiar issues about funding and access will arise, such as provision on the publicly funded NHS. Policymakers must consider these challenges, and also how intellectual property rights may affect access to IVG. This heightens considerations of how to encourage innovation while ensuring fair access to IVG.

Specific questions to be considered include:

- Is IVG an appropriate treatment for public funding?
- If IVG were only available to patients who can afford to pay, what would be the long-term effects of this kind of inequality?
- IVG different from any other infertility treatment service, many of which are already in effect only available to those who pay?

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