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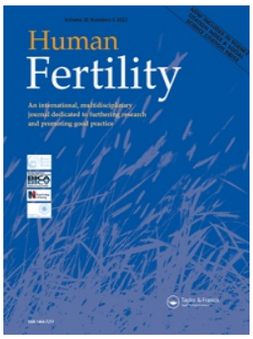

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RESEARCH ARTICLE

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In vitro gametogenesis, 'social infertility', and the legacy of the Warnock report

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ABSTRACT

In vitro gametogenesis (IVG) is a biotechnological development which aims to replicate the process of gametogenesis outside the human body. If proven safe and effective, IVG could disrupt various social and biological norms, and create new reproductive possibilities and opportunities for those who experience infertility as a result of both social and biomedical factors. In this article we argue that the new reproductive possibilities provided by IVG, much like earlier discussions of assisted reproductive technologies (ARTs) dating back to the Warnock Report, highlight the importance of exploring the distinctions often made in policy terms between 'medical' and 'social' understandings of infertility, and that any access and funding decisions made on this basis require careful and critical attention.

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In vitro gametogenesis; assisted reproduction; infertility; Warnock Report; bioethics; funding

Introduction

In vitro gametogenesis (IVG) is a biotechnological development with the potential to create many new reproductive possibilities and opportunities. It aims to replicate the process of gametogenesis *outside* the human body to produce in vitro derived gametes (IVD gametes). While currently at the early stages of scientific development, progress has been made in non-human animal studies, including the birth of mice with two 'biological fathers' in 2023 (Devlin, 2023; Murakami et al., 2023).

One interesting feature of IVG is that some of its more headline-grabbing potential uses relate to what might be called 'social' rather than 'medical' infertility. While this distinction is contested, *medical* infertility refers to an inability (or reduced ability) to conceive or maintain a pregnancy due to an underlying pathology, such as difficulties with sperm production, ovulation, or blocked fallopian tubes. In contrast, *social* infertility is a term often used to refer to an inability to have children resulting from social circumstances, not biological ones. Causes of infertility that may be deemed social include relationship status, sexuality, gender, or life choices (such as delaying reproduction).

In this article, we argue that the prospect of IVG, much like earlier discussions of assisted reproductive technologies (ARTs) dating back to the Warnock Report (Department of Health & Social Security, 1984), highlights the distinctions often made in policy terms between 'medical' and 'social' understandings of infertility—and reveals their limitations. To make this case, we first outline current research on IVG and the reproductive possibilities it could offer. We then examine how a distinction between different forms of infertility has been made in policy in England and Wales and the unequal access this creates, drawing on both discussions of infertility in the Warnock Report, and current NHS policies relating to the funding of infertility treatment. Finally, we explore how these policies could impact individuals seeking to use IVG for reproduction in the future, and question whether the distinction between different reasons for accessing ARTs is justified.

What is IVG?

IVG refers to the creation of gametes outside the body by reprogramming cells, such as embryonic stem cells or induced pluripotent stem cells (e.g. skin cells) to

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become functional egg and sperm cells – IVD gametes. It was reported in 2016 that the successful reconstitution of the entire process of oogenesis from pluripotent mouse cells had been achieved (Hikabe et al., 2016), and the first functional mouse IVD sperm cells were created in 2021 (Ishikura et al., 2021). These were successfully transplanted into the testes of infertile mice and live offspring were subsequently produced (Ishikura et al., 2021). In 2023, the successful creation of mice with two biological fathers was reported, by generating IVD egg cells from male mouse skin cells (Murakami et al., 2023). These IVD eggs were fertilised with endogenously produced mouse sperm, which resulted in the birth of seven mouse pups (from 600 embryos), and these mice went on to have offspring as adults (Devlin, 2023; Murakami et al., 2023; Devlin, 2025). An alternative approach to creating oocytes has also recently been reported which involves the insertion of nuclear DNA from somatic cells into a denucleated egg cell (Lee et al., 2022; Sample, 2024).

The reconstitution of germ cells *in vitro* is complex, and the consequences of replicating the process of gametogenesis outside of the body (e.g. in terms of safety and quality) are currently unknown. Indeed, while IVG research continues to progress there is currently no consensus on whether IVG can be successfully used for human reproduction or how long this might take.

Some of the potential uses of IVG

If IVG reached clinical application in humans, it could significantly expand reproductive choice for several groups (Le Goff et al., 2024; Merleau-Ponty & Le Goff, 2024; Smajdor & Cutas, 2015; Śmietana, 2023). These include those who can currently only achieve parenthood via gamete/embryo donation, or adoption, but who seek a genetic relationship with their offspring (Smajdor & Cutas, 2015), or those undergoing procedures that threaten fertility where existing fertility preservation options are confined to gamete/embryo cryopreservation (Wesevich et al., 2023). IVD gametes may also enable individuals of any sex to produce both sperm *and* eggs for reproductive purposes, enabling individuals to engage in 'solo' reproductive projects, though this is likely to involve a high risk of genetic mutations and genetic conditions (Notini et al., 2020).

IVG could, thus, increase reproductive choices for all regardless of the cause of infertility - disease, bodily malfunction, sexual orientation, relationship status, or gender identity. For example, IVG could, if desired, allow genetic parenthood for both members of same-sex couples, transgender women/men to contribute either eggs or sperm for reproduction (Le Goff et al., 2024; Śmietana, 2023), or for 'multiplex' parenting projects, whereby a child could have three or more direct genetic progenitors (Palacios-González et al., 2014). Beyond this, IVG could lead to changes in reproductive donation/procurement practices, and it has been suggested that it might result in an increase in the use of selective reproduction techniques (Greely, 2016).

While these possibilities may give hope to people that their reproductive options will be expanded, we suggest that both the current and historical landscape in England and Wales (and elsewhere) in relation to the funding and provision of ARTs, means that the *reason* for seeking to access ARTs, including IVG, may affect the options that are actually made available and/or funded. However, whether that should be the case is, as we demonstrate below, unclear.

The Warnock Report and the provision of ARTs in England

Against a backdrop of public excitement about the potential of ARTs, as well as unease and criticism of the ethical, legal and social issues raised, in 1982 the Committee of Inquiry into Human Fertilisation and Embryology was established to consider recent and potential developments in medicine and science related to human fertilisation and embryology. Chaired by Dame (later Baroness) Mary Warnock, in 1984 the Committee published its report (The Warnock Report) (Department of Health & Social Security, 1984) containing 64 recommendations on matters including the establishment of a licensing body and legal limits on research and fertility treatment (Department of Health & Social Security, 1984). This paved the way for a legal framework to regulate embryo research and fertility treatment.

It is useful to reflect on how people's *reasons* for seeking to access ARTs were viewed by the Committee. Was there, for example, a perceived difference between those who have 'medical' as opposed to 'social' reasons and, if so, is an explicit or implicit distinction made between these in current rules on accessing ARTs, particularly via the NHS? Arguments which were considered, at the time, to speak against the provision of fertility treatment generally were discussed in the Report, including worries about the environmental effects of fertility treatment, interference with nature, and the suggestion that infertility does not constitute a healthcare need, but a wish that should not have priority over 'genuine needs which

must be satisfied' for survival (Department of Health & Social Security, 1984, p.9).

The Committee responded to these concerns in turn, and in relation to the latter noted that 'medicine is no longer exclusively concerned with the preservation of human life but with remedying the malfunctions of the human body' (Department of Health & Social Security, 1984, p. 9), and that as 'an inability to have children is a malfunction', it should be 'considered in exactly the same way as any other' malfunction (Department of Health & Social Security, 1984, p. 9). Furthermore, it was noted that 'the psychological distress that may be caused by infertility … may precipitate a mental disorder warranting treatment' (Department of Health & Social Security, 1984, p. 10), and that it would be preferable 'to treat the primary cause of such distress' than to alleviate the symptoms (Department of Health & Social Security, 1984, p. 10). There was thus a clear commitment to take seriously the experiences of those with infertility and perhaps an aim to signal to NHS commissioners and future regulators that infertility is a condition meriting treatment, i.e. funding. The harms that an inability to bear children may have on someone's psychological welfare and life plans, and treatments aimed at alleviating these effects, were seemingly placed on a par with treatments for other medical conditions (Department of Health & Social Security, 1984, p. 8).

Having said that, while infertility resulting from 'malfunctions of the human body' was treated favourably within the Report, infertility as the result of choice or 'social' factors was not necessarily viewed as warranting assistance or as falling under the umbrella of 'infertility'. This can be seen, for example, in discussions of a scenario involving a woman who had previously been sterilised at her own request but now regretted her choice and sought infertility treatment. This was considered to be a difficult case to decide (Department of Health & Social Security, 1984, p. 10-11). The phrasing in this quote on the possibility of using ARTs to enable single women and women in same-sex couples the opportunity to reproduce is notable too:

> the various techniques for assisted reproduction offer *not only* a remedy for infertility, *but also* offer the fertile single woman or lesbian couple the chance of parenthood without the direct involvement of a male partner (Department of Health & Social Security, 1984, p. 11, emphasis added).

For, while the Committee was not wholly dismissive of the reproductive aspirations of single women or same-sex couples, a distinction clearly was made between infertility caused by 'bodily malfunction' and infertility caused by other ('social') reasons. Questions were asked about the appropriateness of providing treatment to such individuals, which were not asked where infertility was caused by 'bodily malfunction' (Department of Health & Social Security, 1984, p. 12).

Regulating access and funding for fertility treatment in England post-Warnock

In England, ARTs including IVF and intrauterine insemination (IUI), are funded at local level by statutory NHS organisations called Integrated Care Boards (ICBs). The current assisted conception commissioning policies of a number of ICBs demonstrate how the distinction between 'medical' and 'social' causes of infertility expounded in the Warnock Report has become entrenched in the funding and prioritisation decisions made by NHS commissioners. Consider, for example, the case of public funding for assisted conception services available to heterosexual couples compared to lesbian couples and single women.

Typically, ICBs require heterosexual couples with unexplained infertility to have undergone a period of expectant management (regular unprotected sexual intercourse) usually for two years before IVF will be considered (see e.g. Bedfordshire et al., 2022; Kent & Medway Integrated Care Board, 2024; Lancashire & South Cumbria Integrated Care Board, 2022; South West London Integrated Care Board, 2023; South Yorkshire Integrated Care Board, 2023). Same-sex couples and single women, however, are typically required to have undergone six to 12 cycles of IUI in order to demonstrate subfertility (see e.g. Bedfordshire et al., 2022; Kent & Medway Integrated Care Board, 2024; Lancashire & South Cumbria Integrated Care Board, 2022; South West London Integrated Care Board, 2023). While heterosexual couples may have to wait longer to be deemed eligible to access fertility treatment (due to the required period of expectant management), lesbian couples and single women are typically required to expend their own resources on numerous cycles of IUI, albeit over a shorter period. It should therefore be noted that for all categories of patient, criteria for eligibility for NHS funded fertility treatment is based upon evidence of 'medical' rather than 'social' infertility.

Does the medical/social distinction justify differential treatment?

As earlier sections have suggested, the distinction between 'medical' and 'social' infertility has had a role in debates about ARTs dating back at least to the

Warnock Report and is utilised today in certain NHS policies. It is also likely to have a central role in discussions of IVG in future.

Two main arguments may be forwarded for privileging medical over social infertility in policy or resource allocation. The first is that the primary function of medicine and healthcare systems is to promote or restore health, and alleviate the symptoms of diseases, *not* to support people's life projects (like creating their own biological families). A second is that social infertility sometimes results from choices made by the individuals concerned, e.g. if someone is single or asexual *by choice* then (it may be argued) they should not expect publicly funded health services to bear the costs of infertility treatments.

One response to the first argument is to advocate a broad definition of 'health', like the World Health Organization's; that health 'is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (World Health Organization, n.d.). If such a definition were adopted then interventions aimed at tackling 'social' infertility *would* count as health interventions, promoting 'complete physical, mental and social well-being'.

A second is to adopt a broad conception of the goals of medicine. Under a narrow conception, the focus is primarily on the prevention, diagnosis, and treatment of disease. A broad conception, on the other hand, views medicine as encompassing not only treating disease but also improving well-being and quality of life (Boorse, 2016; Brülde, 2001; Nordenfelt, 2001).

A third is to point out, as the Warnock Report does, that even if sometimes infertility is not, in and of itself, a disease or disorder, if left unalleviated, its harmful effects (e.g. on mental health) might nevertheless mean that it merits treatment (Department of Health & Social Security, 1984, p. 10).

Turning to the second argument, this states that social infertility sometimes results from individual's choices. If true, an inference might be drawn that these people's needs should have a lower priority as a result. On this view, some kinds of social infertility are like the case (considered in the Warnock Report) where a woman who was voluntarily sterilised later wishes to have children.

There are two main responses to this. One is that not all cases of social infertility are based on free choice. The leading examples discussed are same-sex couples, single people, and transgender people. In the case of single people, some of these may be involuntarily single and some voluntarily, and it would be infeasible to distinguish between them in clinical settings. In the case of same-sex couples or transgender people, we can note a similar problem. There is a significant body of work which supports the view that one's sexual and gender identity is not a choice but rather an intrinsic aspect of individual identity resulting from a complex interplay of biological and environmental factors (Bailey et al., 2016; Polderman et al., 2018). So, at the very least, the reliance on 'choice' here relies on a controversially voluntaristic view of gender and sexuality.

A second response is that is not obvious that someone whose health needs are caused by past choices should be deprioritised. If this were the case, then we would be routinely turning away patients whose health conditions have been caused or exacerbated by smoking, alcohol consumption, overeating, or participating in dangerous sports, such as skiing or mountain climbing (Buyx, 2008; Friesen, 2018; Sharkey & Gillam, 2010; Walker, 2010; Wilkinson, 1999). So again, at best, the argument once again rests on a contentious assumption: that people who have caused themselves to have additional healthcare needs through their own choices should not be treated, or should be assigned lower priority. With regard to health conditions caused by addiction, it could, of course, be replied that these are not wholly the result of free choice and that, as a result, it may be justifiable to deprioritise access to ARTs for the groups we have discussed, while continuing to prioritise treatment in such cases. Yet, as we have noted above, there are good reasons to believe that someone's sexual orientation, gender identity and/or relationship status will not be straightforwardly voluntary either.

Conclusion

The purported distinction between 'medical' and 'social' infertility has had a role in discussions of ARTs since the Warnock Report. The distinction seems also to underpin some aspects of current NHS policy, particularly around funding and the conditions of eligibility for infertility treatment services.

IVG has the potential to provide new reproductive options for those with both 'medical' and 'social' infertility. The medical/social distinction may therefore be invoked in future policy discussions of IVG with some seeking to privilege medical over social uses. This could arise in the context of regulation, or decisions about access and funding.

We have argued that the case for privileging medical over social infertility in these contexts seems weak or is at best based on contested premises. The

distinction, on its own, therefore looks like an unsound basis for policymaking, and careful and critical attention must be directed to any access and priority setting decisions made on such grounds.

Author contributions

CRediT: **Sara Fovargue**: Conceptualization, Writing – original draft, Writing – review & editing; **Laura O'Donovan**: Conceptualization, Writing – original draft, Writing – review & editing; **Stephen Wilkinson**: Conceptualization, Writing – original draft, Writing – review & editing; **Nicola Jane Williams**: Conceptualization, Writing – original draft, Writing – review & editing.

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Data availability statement

Data sharing is not applicable to this article as no new data were created or analysed in this study.

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