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Kaur, Amarpreet

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ARTICLE

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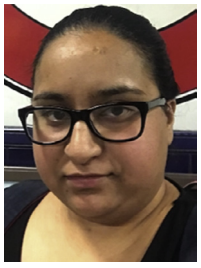

BIOGRAPHY

Amarpreet Kaur is a PhD student in the Department of Sociology at the University of Cambridge, UK. Her research focuses on attitudes towards human germline genome editing as a reproductive choice in the UK.

Amarpreet Kaur*

KEY MESSAGE

The Human Fertilisation and Embryology Act 1990 should be amended to avoid gender-based discrimination. Such amendments could also prevent the gender-based prohibitions within it potentially circumventing germline genome editing being used within the UK before the technology is considered safe enough to prevent disease in future generations.

ABSTRACT

Research question: What are the implications of the gender-based prohibitions relating to human germline genome editing (hGGE) in the Human Fertilisation and Embryology (HFE) Act 1990, as amended in 2008?

Design: A three-phase primary research design consisting of a mixed-methods online public survey of 521 UK citizens aged 16–82 years, 13 semi-structured interviews with experts and professionals involved in the future of hGGE, and structured interviews with 21 people affected by genetic conditions. The research was conducted between March 2018 and October 2019.

Results: Gender-based prohibitions in the HFE Act weaken its intent to prevent germline cells that have been altered from resulting in a pregnancy and the possible birth of people with edited genomes. This weakness could become increasingly problematic as genome editing technologies develop and social advances seek to eradicate gendered expectations and gendered binaries.

Conclusion: The HFE Act should be amended to avoid gender-based discrimination and the potential gender-based prohibitions have to circumvent germline genome editing being used before the technology is considered safe enough to prevent disease.

Department of Sociology, University of Cambridge, 16 Mill Lane, Cambridge CB2 1SB, UK

*Corresponding author. E-mail address: ak997@cam.ac.uk (A. Kaur). https://doi.org/10.1016/j.rbmo.2020.11.009
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KEYWORDS

Assisted reproductive technologies
Gender recognition certificates
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Legislation
Transgender
Uterine Transplants

INTRODUCTION

The term 'genome' refers to all the DNA in a cell. Genome editing is reference to techniques that can be used to make changes to a cell's DNA by adding new, deleting existing, or replacing DNA sequences (*Ormond et al., 2017*, p. 168). DNA consists of three components, one of which is called a base. There are four types of base, each of which is represented by a letter: A, C, G or T (*Komor et al., 2016*). The sequences of these bases form instructions for the various cells in our bodies and determine how they function. Cells that are heritable, i.e. egg, spermatozoa and embryo cells, are collectively referred to as germline cells (*Cavaliere, 2018*). The procurance, storage and use of such cells, outside of the human body, are largely regulated by the Human Fertilisation and Embryology Authority (HFEA).

The HFEA was established in 1990 under Section 5 of the Human Fertilisation and Embryology (HFE) Act, and is the UK's independent regulator of fertility treatment and research involving human gametes and embryos outside of the human body (*Birk, 2009*, p. 6). The HFEA is responsible for licensing, monitoring and inspecting fertility clinics and research centres to which they have granted treatment and/or research licences (*Parliament UK, 1990*, Schedule 2). Provisions relating to human germline genome editing (hGGE) in the HFE Act are detailed in relation to these two categories of licences.

Provisions in the HFE Act state that all activities involving human embryos outside of the body are only legally permissible if the HFEA grants a respective licence for them. The HFEA has a scope detailed in the HFE Act which outlines certain criteria for which it can permit licences; any activity outside of these prescribed criteria are outside of the HFEA's remit (*Parliament UK, 1990*, Sections 11–19). Currently, the HFE Act enables the HFEA to grant research licences that can include/involve hGGE. The HFEA has granted only one such licence to date; this licence is held by Professor Kathy Niakan at the Francis Crick Institute in London (*Human Fertilisation and Embryology Authority, 2018a*; *The Francis Crick Institute, 2016*).

The licence permits Professor Niakan's team to edit genes in human embryos. Any research involving human embryos has to be performed within the first 14 days of the embryo's development. After this time, any embryos used for research must not be kept or used (*Parliament UK, 1990*, Section 3(4)). The HFE Act as amended prohibits research activity from including edited embryos being transferred into a woman under a research licence. This gender-based prohibition is among those that pose judicial implications.

Treatment licences essentially encompass most activity involving assisted reproductive technologies (ART), including applications aimed at preventing the transmission of genetic disease. Mitochondrial transfer and preimplantation genetic testing (PGT) are examples of such applications. However, preventive interventions are not technically treatments – no medical care is given in such cases, nor does the future person exist prior to or independently of the interventions through which their being is brought about, so they cannot be 'treated' (*Mills, 2019*). This is relevant because hGGE should not be considered as a treatment either (*Nuffield Council on Bioethics, 2018*). Such terminology should also be considered if/when amendments to the HFE Act are made.

'Treatment' licences have several prohibitions; those which relate to hGGE are listed in relation to what can be placed inside a woman. Such terminology could not only be considered discriminatory, but means that the prohibitions do not apply to men; thus, they are referred to as gender-based prohibitions (GBP) in this article. The GBP have several implications, particularly because of how men and women are defined in relation to the prohibitions within the Act. The HFE Act defines women and men as respectively being a girl and a boy from birth (*Parliament UK, 1990*, Section 3ZA (6)(a)), i.e. cis people. While legislation in the UK provides no alternate definitions of men or women, the Gender Recognition Act 2004 was designed to enable trans people to be legally recognized by their 'acquired gender' if they hold a Gender Recognition Certificate (GRC) (*Parliament UK, 2004*).

The Gender Recognition Act states that '[w]here a full gender recognition certificate is issued to a person, the person's gender becomes for all purposes the acquired gender (so that, if the acquired gender is the male gender, the person's sex becomes that of a man and, if it is the female gender, the person's sex becomes that of a woman)' (*Parliament UK, 2004*, Section 9 (1)). This means that the HFE Act could also be considered to discriminate against trans people, especially if this definition negates/contradicts provisions under the Gender Recognition Act. Furthermore, in addition to seemingly negating peoples' legal gender identities, the GBP ignore people who want or choose to identify as non-binary. However, non-binary identities are yet to be recognized in UK legislation.

This article discusses the implications of the GBP in the HFE Act, in relation to hGGE, to relay why amending the HFE Act is perhaps no longer discretionary but necessary. hGGE as a reproductive choice in its own right is contentious. This is because heritable changes to DNA could potentially transcend generations (*Ormond et al., 2017*). In this context, ensuring that the technology cannot be used before it is considered safe for such application is within the best interests of society and why amending the GBP is paramount.

MATERIALS AND METHODS

The discussions presented in this article are based on triangulated findings from a three-phase, primary research design. The first phase of the research consisted of a mixed-methods online public survey of UK citizens aged 16 years or over, who were willing to respond to the survey voluntarily. The survey was designed using Qualtrics software, an online survey software with in-built data security (Qualtrics, London, UK), and was titled 'Understandings of Genetic Editing and its Potential Uses with Human Reproduction'. The survey was live for responses between 1 March 2018 and 31 May 2018.

The respondent sample was weighted on four demographic factors: gender, age, religion and whether the respondent is affected by a genetic condition. The latter two factors were deemed significant as people in these demographics are often anticipated to have strong views on genome editing (*MacGillivray and Livesey, 2018*).

The final sample consisted of 521 respondents, 52% of which self-identified as female, aged 16–82 years, (rounding the numbers) 37% of which self-identified as religious and 29% as being affected by a genetic condition.

Respondents were also asked to state their occupation, which to an extent could be indicative of their socioeconomic status and/or level of education. Respondents included professionals, skilled workers, some who were unemployed at the time of completing the survey and some who were retired. The majority of respondents had no direct expertise or professional interest in hGGE technologies and are therefore considered to be the wider public in the UK.

The survey included four sections; the first section was on knowledge and understanding of genome editing, the second was on hypothetical practical applications relating to factors of disease, the third was on regulation and ethics, and the final section captured the demographic information shared above. Findings from the survey were reached using mixed-method analysis via SPSS, a software largely used to analyse quantitative and statistical data (SPSS Statistics for Windows, Version 26 64-bit; IBM Corp., Armonk, NY, USA), and NVivo, a software used to find common themes in qualitative data (QSR International, Burlington, MA, USA). The findings were used to inform the semi-structured interviews with professionals/experts who could speak to the future of hGGE in the UK, and/or who could provide the most up-to-date information on hGGE. A total of 13 semi-structured interviews formed the second phase of the research and were conducted in two sets.

The first set of these interviews consisted of five interviews and linked directly to the third phase of the research; these were conducted between 29 April 2019 and 15 May 2019. Those interviews were largely focused on the science that underpins hGGE and potential access to the technology. The second set of these interviews consisted of eight interviews and were conducted between 20 September 2019 and 3 October 2019 as part of a Fellowship at the Parliamentary Office of Science and Technology (POST). The latter set of interviews heavily focused on the existing legislative parameters of hGGE in the UK and the foreseeable potential of how these parameters could evolve. The GBP in the HFE Act were unearthed as a result of, and discussed during, these latter interviews. Some of the data derived from these interviews also informed questions and activities for the 11 structured interviews that formed the third phase of the research.

The structured interviews consisted of a total of 21 people, of which 15 identified as female and six identified as male, aged 20–58 years, who were affected by a range of monogenic conditions. Some of these interviews were conducted in groups of 4–5 people, in pairs, or one-to-one depending on the health and availability of participants, either via Adobe Connect software or in accessible public meeting rooms. Adobe Connect is 'web conferencing' software which permits collaborative experiences that include video, audio, screen sharing, polls, chats, questions and answers, and document sharing, among other capabilities (https://www.adobe.com/products/adobeconnect.html). All the interviews were transcribed and imported to NVivo software for analysis. The analysis consisted of core themes being identified and then transformed into overarching categories for further exploration and/or consideration; such analysis is traditionally considered a mix between grounded theory and thematic analysis (*David and Sutton, 2004*; *Mason, 2017*).

All the primary research received ethical approval from the University of Cambridge's Department of Sociology's Ethics Committee prior to being conducted (approval for online survey granted 21 March 2018; approval for semi-structured interviews granted 19 March 2019; approval for third phase of research granted 29 April 2019), and conformed to the British Sociological Association's guidelines on conducting ethical research (*British Sociological Association, 2017*). All respondents to and participants in the research provided informed consent for the research they chose to be part of. Respondents to the survey could have withdrawn their data until a specified date by emailing their demographics to the researcher. In contrast, participants in the semi-structured and structured interviews were informed of their right to withdraw their participation in the research. However, due to the tight turnaround in analysing and triangulating the research data to produce findings, withdrawing data from a specific interview would have been a very complex and unfeasible process. In lieu, participants were asked whether they would want to review any data attributed to them. In this article, findings from the second set of interviews in the second phase of the research in particular, are discussed in conjunction with findings from the other phases of the research.

RESULTS

The research detailed in this article was designed under the common presumption that hGGE cannot legally be used in the UK to establish a pregnancy. As mentioned above, the GBP were realized towards the end of the research, after most of the research had been conducted, but catapulted recommendations to amend the HFE Act from being a luxury to a necessity. The following findings emphasize why the HFE Act needs to be amended in light of the GBP that relate to hGGE.

A question in the survey sought to ascertain whether the UK's public feel that hGGE should be a legal reproductive choice. This question was asked following questions that prompted respondents to consider the potential applications of the technology, namely for the prevention of disease, but also for any other uses if no restrictions were to be placed on the technology: 4.80% of respondents felt that hGGE should not be legalized in the UK, 39.54% felt that the technology should be legalized, and the remaining 55.66% answered that their answer depended on other factors. Of the factors cited by respondents, one of the most prominent was that robust regulation to prevent misuse of the technology would be needed. Misuse was considered to be any application of hGGE that is not intended to prevent genetic disease. Additionally, respondents felt that the technology should only be used once it is considered safe. This finding is derived from responses such as the following:

> Respondent 63: It [hGGE] has the potential to make a huge difference to the quality of life of so many people. However, it would need legislating really really carefully in order that it not be misused.(Female, 31, Midwife)

> Respondent 56: Needs to be very careful control of the process. Once it [hGGE] is tried and tested for preventing disease and illness where is the line drawn? Could make arguments for all sorts of 'improvements' and move towards some dystopian future.(Male, 22, Undergraduate Student)
>
> Respondent 323: If genetic editing works efficiently and safely, it should be available to all people who can benefit. If there are risks, these should be well understood and explained so that an informed choice can be made.(Male, 56, Computer Programmer)

These findings suggest that there is very little direct opposition for hGGE to be legalized as a reproductive choice in the UK, that the UK's public are largely in favour of its use for the prevention of disease, and that UK citizens may therefore be inclined to seek to use it. Due to the GBP, there are various categories of people that could circumvent the GBP to create, gestate and birth a child with an edited genome before the technology is widely considered to be safe and/or intentionally legally permissible.

The proportion of respondents who felt that hGGE should be allowed as reproductive choice depending on the severity of a given disease was 66.22–86.56%. The more impactful a disease is considered to be on a person's quality of life, the greater the support was for hGGE to be allowed for its prevention. Further to these findings, 65.64% of respondents felt that UK citizens should be allowed to travel abroad to access hGGE if the technology were not be legalized in the UK; 7.49% of respondents felt that UK citizens should not be allowed to access hGGE abroad if the technology is not legal as a reproductive choice in the UK. The remaining 26.87% felt that, among other factors, the intent for accessing hGGE abroad and the reasons why hGGE is not legal in the UK are factors to consider.

These findings indicate that a majority of the UK's public are not opposed to hGGE being added to ART in the UK as a reproductive choice for the prevention of disease, and are largely supported by participants in the third phase of the research, people who have genetic disease. The following quotations from those participants shows this support:

> Serena: I think it [hGGE] should be legalized so that we can use it in the most responsible way possible and if we make mistakes along the way you should learn from them and put more into those laws, but it shouldn't be prevented. [...] I can't think that anybody wouldn't want to use the technique. I would be desperate to use it. [...] I think that all conditions which result in a reduced quality of life – I think everybody should have the choice to not pass that on to the next generation.(Female, 53, has Huntington's Disease)
>
> Sally: Yes [hGGE should be legalized in the UK as a reproductive choice]. Because I think certainly, you know, if I'd known I had a syndrome before I got pregnant. and I thought that something could be done to ensure that my son wasn't born with it. And we don't know whether he is yet. But he certainly been born with a lot of issues. [...] If I'd known that I had this condition before, and I knew that there was a way of ensuring that my child didn't have it – God, yeah, I definitely would want to do that.(Female, 55, has Stickler Syndrome)

These quotes reiterate that there are people who are 'desperate' to use hGGE technologies to prevent genetic disease. Such views may not be limited to cis women, and people who could circumvent the current GBP in the HFE Act may be inclined to do so. The high levels of support for hGGE to be added to ART in the UK and the permissiveness of UK citizens accessing the technology abroad as a reproductive choice were it not to be legal in the UK are also important to consider. This is because the GBP mean that such application is not completely prohibited in the UK, so there is potential for applications of hGGE to culminate in a pregnancy and the potential birth of people with edited genomes to arise in the UK without committing any unlawful acts. However, this possibility is dependent on a person's gender, their reproductive capabilities and licensing from the HFEA.

Currently, the HFE Act states that only permitted embryos can be placed inside a woman (*Parliament UK, 1990*, Section 3(2)(a)). Permitted embryos include those that do not include cells that have had their 'nuclear or mitochondrial DNA' altered, i.e. which have not been genetically modified (*Parliament UK, 1990*, p. 3ZA(4)(b)). However, the prohibitions clearly only exist in relation to women. If a man were to obtain a uterine transplant, there are no limitations in terms of what can be placed inside him. Additionally, if 'acquired genders' are claimed to be recognized in the HFE Act, then what can be placed inside a (trans)man who has his own uterus is also unregulated.

The GBP were exposed upon analysis of the HFE Act 1990 as amended as part of research at the POST. These prohibitions seemingly highlight significant weaknesses in the Act in relation to regulating hGGE with ART as a reproductive possibility (*Kaur and Border, 2020*, p. 3). This is because such prohibitions are substantially problematic due to the social and judicial implications that could feasibly arise from them if the Act were not to be amended to address them accordingly.

Consultations with policy staff at the HFEA and the Department of Health and Social Care revealed that neither institution was able to clarify the implications that the weaknesses in the HFE Act present or how they relate to GRC. How the GBP relate to GRC is important to note, because although no particular relation would secure intents of the HFE Act, they could expose additional levels of discrimination within the it, i.e. not just discrimination against men, but the trans community as a whole. Furthermore, depending on the Act's relation to GRC, i.e. whether 'acquired genders' are acknowledged, the possibility of edited germline cells culminating in a birth in the UK could be easier to achieve. This is because a man who has his own uterus may be able to achieve a pregnancy with fewer interventions and ART than a trans woman, should he hold such a desire.

DISCUSSION

The GBP in the HFE Act have several profound implications because possibilities for men to gestate a pregnancy now exist. The absence of a vagina may mean that a given pregnancy may culminate in a Caesarean section, but, nonetheless, an established pregnancy could still enable a child to be born (*Alghrani, 2016*; *Jones et al., 2019*). The Act was last amended in 2008; at this time, although such possibility was imaginable (*Teresi and McAuliffe, 1999*),

it may not have been deemed achievable, hence the GBP in the HFE Act. However, due to social and scientific advances such a possibility is now conceivable. This means that intentions within the Act to prevent people with edited genomes from being gestated and born are no longer secure (*Kaur and Border, 2020*, p. 3).

Due to the uncertainty which surrounds how a GRC relates to the prohibitions in the HFE Act; how men, as defined by the HFE Act, i.e. cis men, could use a range of ART to produce a child, and how trans men could also produce a child, are both discussed. The HFE Act is seemingly discriminatory towards trans people; thus, trans women may not be recognized as such, nor may trans men, hence diligence is paid to both possibilities in relation to their respective scientific and social statuses. Even if the HFE Act were to recognize GRC, the contentions would still apply as social and scientific advances dictate that pregnancy and birth may not remain limited to fertile cis women (*Jones et al., 2019*).

First, the possibility that GRC are not recognized by the HFE Act is explored. In this vein, reference to 'men' encompasses cis men and trans women. Men anatomically do not typically have a uterus and because of this cannot typically gestate a pregnancy (*Sparrow, 2008*). However, due to advances in science, uterine transplants are now possible (*Jones et al., 2019*). Because of this possibility, although a uterine transplant is yet to be extended to a cis man or trans woman, a specialist transgender surgeon, Christopher Inglefield, claims that this is now achievable (*Bioethics Observatory, 2019*). His claim is seemingly supported by several researchers who suggest that anatomical differences could be overcome (*Jones et al., 2019*).

Should cis men and/or trans women be able to receive a uterine transplant, this would extend reproductive choices, expand applications of ART and weaken the intent of GBP in the HFE Act. Some researchers argue that heterosexual cis men may consider undergoing a uterine transplant in order to share the reproductive burdens and joys of pregnancy with their partner, and/or to avoid commissioning a surrogate if single parenthood is preferred. They also propose that this option may also appeal to gay couples because both men would be enabled to be part of the reproductive process, and the need for a surrogate would be avoided (*Alghrani, 2016*, p. 640). Denying men this possibility in light of ART could be considered gender discrimination. Such possibilities could be considered unnatural, but then most ART are designed and developed to circumvent biological limitations (*Edwards et al., 1999*; *Sarojini and Marwah, 2015*; *Sparrow, 2008*).

For trans women, a uterine transplant could expand their reproductive capacities, and enable them to fulfil a desire to gestate and parent a genetically related child of their own (*Alghrani, 2016*, p. 639; *Lawrence et al., 1996*). Trans women could regard pregnancy as their final step in aligning their life to their 'acquired gender' (*Alghrani, 2016*; *Parliament UK, 2004*). Thus, if there are no scientific (including anatomical) limitations, denying trans women this capacity could be considered discriminatory and conflict with the Gender Recognition Act. This is because the Gender Recognition Act intends to extend the same legal rights to trans women that cis women are afforded (*Parliament UK, 2004*).

As mentioned in the Results section, cis women are not the only people who may want to prevent disease from being passed on to their offspring; therefore, contending that men and trans women may be driven to achieve this goal via using hGGE technologies too, particularly if they are not prohibited from doing so, is not unfathomable. Furthermore, considering the high levels of support for hGGE to be a legal reproductive choice to prevent disease, as inferred by the presented findings, the technology being sought and used by people who are not explicitly prohibited is quite conceivable.

Second, should GRC be accounted by the HFE Act, contrary to the definitions of men and women within it, trans men could gestate a pregnancy with greater ease than trans women. This is because, although any hormone suppressant treatment may have to be intermitted and/or altered, trans men could still have their own uterus (*Jones et al., 2019*). With recognition to both Acts, hGGE and the GBP, trans men could be recognized as a man by the HFE Act and be extended the same legal rights as cis men and, as mentioned above, would therefore be exempt from any prohibitions on what can be placed inside their uterus. How the GBP within the HFE Act relate to non-binary people would also benefit from clarification. While non-binary identities are yet to be recognized in any UK legislation this is potentially on the horizon.

Related to this, the HFEA has repeatedly conveyed that it is supportive of preserving the fertility of trans and non-binary people (*Human Fertilisation and Embryology Authority, 2018b*). But the HFEA's support does not clarify the legislative situation for trans or non-binary people in relation to the HFE Act and its GBP, which are significant for applications relating to hGGE. With all these possibilities, so long as a man is recognized to have a uterus, whether a cis man or a trans man, whether a congenital or transplanted uterus, the HFE Act 1990 as amended does not prohibit germline cells that have undergone genome editing from being used to establish a pregnancy in such cases, so long as the embryo is transferred into the uterus within 14 days of its development.

Should hGGE technologies continue to develop, men, trans women and/or non-binary people who have genetic conditions could opt to use hGGE as part of their reproductive choices. This is significant because trans and non-binary pregnancies are already a reality, and are becoming increasingly sought (*Hattenstone, 2019*). There are no other prohibitions in the HFE Act to prevent this possibility because there are very few mentions of hGGE at all. Had amendments made to the HFE Act in 2008 been as descriptive for cells that have had their nuclear or mitochondrial DNA altered as they are for ad-mixed embryos (embryos that do not entirely consist of human cells), this argument could be mute. In this context, amending the HFE Act to avoid gender discrimination, and to secure the intentions within the Act, particularly until hGGE is considered to be safe as a preventive intervention for disease, is not only highly recommended, but actually necessary.

The implications of the GBP relating to hGGE in the HFE Act 1990 mean that due to social and scientific advances, cis/trans men, trans women and non-binary

people are not prohibited from gestating pregnancies from which generations with edited genomes could be born. This article therefore concludes that the HFE Act should be amended to secure its intentions and/or to avoid being considered discriminatory towards men, trans people and potentially non-binary people should they become recognized within UK legislation. Specifically in relation to findings from the primary research presented in this article, amendments should seek to avoid any gender-based discrimination. Such amendments would also prevent the GBP from circumventing hGGE being used in conjunction with existing ART before the technology is considered safe enough to prevent disease. If amendments to the HFE Act are not made, several social and judicial matters could ensue due to the ongoing rise in, and awareness of, trans rights activism and non-binary people.

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