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Assessing unborn children's rights in the context of mitochondrial research therapy: A legal analysis

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ABSTRACT

This research investigates the ethical and legal dimensions of Mitochondrial Research Therapy (MRT), an innovative reproductive technology that prevents mothers from passing mitochondrial diseases to their children. By incorporating mitochondrial replacement into the in vitro fertilisation (IVF) process, MRT offers a transformative solution for families at risk of hereditary mitochondrial disorders. The Nuffield Council on Bioethics, an independent advisory body for UK policymakers, endorses MRT as ethically permissible, provided it meets standards of safety and effectiveness, and includes comprehensive support and information for patients. Focusing on the UK, the first country to legalise MRT, this analysis evaluates whether the therapy respects the autonomy and genetic integrity of future offsprings, addressing the rights of embryos and foetuses within existing legal frameworks. Through this analysis, the research highlights the need for ethical considerations that protect the unborn children while advancing the benefits of MRT, ensuring reproductive progress upholds both the rights and well-being of potential offspring.

Introduction

Mitochondrial replacement techniques, a complex area in assisted reproduction,[1] are being developed to help couples at risk of conceiving a child with mitochondrial disease by preventing the transmission of such conditions.[2] MRT,[3] a revolutionary assisted reproductive technique, is designed to prevent the transmission of inherited mitochondrial diseases – foetal disorders passed from mothers to their offspring.[4] Fundamentally, MRT introduces an additional step to the clinically approved IVF process, which dates back to the 1970s after being successfully developed in Boston in 1944.[5] The Nuffield Council on Bioethics, an independent advisory body for UK policymakers, concluded that it is ethically permissible to offer MRT to women at risk of transmitting mitochondrial disorders, as long as the procedures demonstrate adequate safety and effectiveness and are accompanied by appropriate support and information.[6] While this technology offers hope to families at risk of mitochondrial diseases, it raises complex ethical questions concerning the rights and well-being of the unborn. This research explores whether MRT infringes on the autonomy and genetic integrity of future generations. It focuses upon clarifying the nuances of these topics by looking at the rights of embryos and foetuses and analysing the current legal approaches to MRT, with a particular focus on the UK as the first nation to legalise MRT.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, known as the 'Oviedo Convention', is a pivotal international treaty introduced by the Council of Europe in 1997. This Convention holds paramount significance as it seeks to address the intricate ethical and legal dimensions of biomedicine and human rights. Article 18 of the Oviedo Convention is examined to understand its guidance on embryo research, specifically as it pertains to MRT. Article 18 touches on the ethically complex area of research involving human embryos. By analysing the legal framework and protections outlined in the Convention, this analysis considers the extent to which MRT aligns with the standards established for embryo research and explores how these guidelines might impact the practice and regulation of MRT. Additionally, existing literature highlights significant differences between the UK and the US regarding the rights of unborn children. This analysis compares these policies to better understand how each country defines and protects the rights of the unborn children. This exploration identifies potential gaps or inconsistencies in legal protection and highlights areas for improvement, ensuring that the rights and welfare of unborn children are adequately recognised and safeguarded.

Limitation of analysis

This research encounters certain inherent limitations that merit acknowledgement to uphold transparency and reliability. This subject encompasses a broad array of multidisciplinary fields, encompassing law, ethics, reproductive biology, and philosophy. Consequently, owing to the vast scope of these areas, the depth of analysis within each domain may be restricted. The analysis cannot be fully comprehensive in exploring every legal and ethical viewpoint, requiring selective focus to maintain clarity and cohesion. Furthermore, the legal framework governing MRT and unborn children's rights contains notable disparities between countries and regions. Consequently, conducting a comprehensive analysis of all global legal systems poses challenges necessitating a concentration on specific jurisdictions.

Research methodology

The research employs a doctrinal approach, involving a meticulous examination of regulatory instruments relevant to the subject

matter. It utilises a combination of literature review and content analysis of laws and global principles to investigate the applicability of unborn children's rights within the realms of MRT. The sources informing this analysis encompass a range of primary and secondary material, including journal articles, legal precedents, international agreements, legislative texts, reports, academic books, and online resources.

Unborn children's rights

In the analysis of unborn children's rights, it is crucial to understand the terms 'embryo' and 'foetus'. This is essential because while certain laws offer restricted safeguards for the foetus, the legal framework often overlooks the provision of protection for embryos.[7] The term 'embryo' denotes the human offspring resulting from conception up to the eighth week, whereas from the eighth week until birth, it is called a 'foetus'.[8] Research shows that upon fertilisation, an individual's gender and unique genetic identity are determined.[9] According to Pauerstein's well-known obstetrics manual, '[t]he origin of each member in a species involves the process of fertilisation, where two distinct genetic information pools effectively combine to form a new individual'.[10] When the pronuclei of the egg and sperm fuse in a process called syngamy, various inherited characteristics of the future individual are established.[11] In a single-celled human embryo, the complete genetic blueprint of a person is already present.[12] The human embryo, however, is a human being rather than just 'human life'. According to Forsythe, human life can be found in the skin, intestinal tissue, and even the egg and sperm.[13] From the beginning, the embryo has the inherent potential to evolve into a distinct human being,[14] with its growth reflecting its human essence at every stage.[15] On 4 July 2002, Richard Gardner revealed the results of some obscure studies he had conducted in the 1980s. Through his findings, he confirmed that human life begins with fertilisation, and the emergence of the embryonic structure's back and head follows soon after the sperm and egg combine, marking the onset of a new human existence.[16] Examining this piece of work, Pearson makes the following observation: 'What is clear is that developmental biologists will no longer dismiss early mammalian embryos as featureless bundles of cells – and that leaves them with work to do.'[17]

In biology, a single-celled human zygote is considered a separate human entity; however, public and legal discussions can blur the line between these early-stage humans and individuals.[18] The term 'person' refers to a moral or philosophical concept, while the term 'human being' refers to an anthropological concept that is based on biology and species.[19] Bradley Patten explains the difference between 'human life' and 'human being': 'Although an embryo pre-exists in the gametes from which it arises, its life as a new individual must be regarded as commencing at the moment of fertilisation.'[20] Therefore, the scientific evidence supports that, through the process of fertilisation, the early human embryo is unequivocally part of the human species, reinforcing our common humanity (members of the human family) as articulated in the 1948 Universal Declaration of Human Rights.[21] However, it is important to be cautious when applying this concept to therapeutic cloning, particularly if we presuppose the embryo's potential to evolve into a human being.[22] In essence, the concept of potentiality relies on a specific probability of the embryo maturing into a human, following the natural course of development.[23] Previously, it was believed that an embryo could not naturally develop outside the mother's womb, necessitating placement in the uterus for sustained growth.[24] However, recent advancements, such as artificial womb technology and robotic caregivers, challenge this notion by demonstrating the potential for external gestation.[25] While these innovations support foetal development outside the human body, they do not give the embryo the inherent ability for self-sustained development, as it remains reliant on external technology, unlike

natural gestation in the womb. Nevertheless, the mere fact of belonging to the human species bestows upon embryos the privileges and respect inherent in having human dignity.[26] Given the act of killing a child after birth is a breach of human rights, then applying the same philosophical reasoning implies that ending the life of the child before birth should similarly be deemed a violation of the child's right to life.[27] Hence, it is because of its potential to evolve into a full-fledged human that an embryo deserves the same rights and safeguards afforded to any person as a human being.

International framework relating to unborn children's rights

When it comes to protecting the rights of children, the United Nations Convention on the Rights of the Child (CRC) is regarded as the most important document.[28] But its stance on unborn children's rights remains vague. It says nothing about when childhood begins, although in the preamble it specifies that the child, because of physical and mental immaturity, needs special safeguards and care, 'including appropriate legal protection, before as well as after birth'. Article 6 of the Convention also states:

1. States Parties recognize that every child has the inherent right to life, and
2. States Parties shall ensure to the maximum extent possible the survival and development of the child.

Despite the absence of an explanation regarding the inception of these rights, insights for their correct interpretation can be found from the content of paragraph 9 in the preamble, which recommends that children need 'special safeguards and care… before as well as after birth'.[29] In accordance with Article 31(2) of the Vienna Convention on the Law of the Treaties, which is a crucial part of contextual interpretation, an argument could be made that the preamble's provision broadens the protective scope to encompass all manifestations of human life that exist before birth.[30] The preamble, however, is limited to aiding contextual interpretation; it does not have the capability to substantially alter the inherent meaning of a legal term.[31] The *travaux préparatoires*[32] indicate that the preambular paragraph was not intended to broaden the definition of a human being to encompass an unborn child.[33] Because of this, it was determined during the drafting stages that each state would decide whether life should start before birth.[34] However, looking at Article 1 we can see that a child is 'every human being below the age of eighteen years'. If interpreted correctly, it becomes evident that the CRC establishes a maximum age limit for defining who qualifies as a child but does not set a minimum age threshold.[35] However, the application of the CRC in the context of unborn children's rights is subject to the specific legal framework of each country, as these laws may provide additional clarity or limitations regarding the rights of unborn children within the bounds of women's reproductive rights. Most observers believed that the Convention deliberately left the rights of the unborn child open for states to decide their stance upon ratification, provided they respected other international human rights standards.[36]

Notably, there were minimal objections or clarifications to Articles 1 and 6 in pre-ratification comments, and only four countries provided clear definitions of childhood.[37] Argentina and Guatemala interpreted Article 1 to include humans from the moment of conception, while China and the UK stated that the Convention is applicable only after live birth.[38] While the origins of the right to life remain a significant matter, the immediate focus of implementing Article 6 is on determining the actual meaning of the right to life.[39]

Further, if we look at Article 24, it specifies:

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health…
2. States Parties shall pursue full implementation of this right, in particular, shall take appropriate measures: …
(d) To ensure appropriate prenatal… health care for mothers.
According to the language of Article 24, '[s]tates Parties recognize the right of the child… to prenatal… care', the emphasis is on the child as the primary beneficiary of the right to prenatal care, not the woman, as Article 24.1 designates the child as the right-holder.[40] Although the language refers to 'pre-natal… health care for mothers', it does not create a distinct right for the mother's health; rather, it signifies medical care aimed at ensuring the well-being of the unborn child through the mother.[41] These rights include guaranteeing appropriate prenatal care, monitoring the pregnancy and attending to any potential health issues. However, the interpretation and practical implementation of the CRC in this situation would probably depend on how the individual country's legal and moral systems consider unborn children's rights.

Furthermore, the main standard for the protection of human life in general international law is Article 6 of the International Covenant on Civil and Political Rights (ICCPR).[42] In its first paragraph, the Article prescribes, 'every human being has the inherent right to life'. However, the wording of the norm does not define the term 'human being'. During the elaboration of the ICCPR, a joint effort by a group of five states, comprising Belgium, Brazil, El Salvador, Mexico, and Morocco, put forward a proposal to draft Article 6 with the intent to ensure the protection of human life from the moment of conception.[43] Most states rejected the proposal, highlighting the challenges in precisely determining the timing of conception, and underscoring the importance of various domestic laws.[44] Some jurisdictions with liberal abortion laws were concerned that these laws might not adequately protect human life, and thus the *travaux préparatoires* indicate that the intention was not to equally safeguard both born and unborn life.[45]

However, the Human Rights Committee remarked that 'the right to life has too frequently been narrowly interpreted' in its General Comment on Article 6.[46] The committee emphasised that the term 'inherent right to life' should not be narrowly interpreted and, in order to uphold this right, states must take proactive measures, including efforts to reduce both newborn and foetal fatalities.[47] According to Article 6(5), 'Sentences of death shall not be imposed for crimes committed by persons under the age of eighteen and shall not be carried out on pregnant women.' This provision should be interpreted as acknowledging the worth of life in the mother's womb and giving the unborn child a separate status from the mother, especially since other adult women might face capital punishment.[48] As the *travaux préparatoires* stated, 'the principal reason for providing in paragraph 4 [now Article 6(5)] of the original text that the death sentence should not be carried out on pregnant women was to save the life of an innocent unborn child…'.[49] Likewise, the 1955 Secretary-General report acknowledges that 'the purpose of the paragraph was inspired by humanitarian considerations and by consideration for the interests of the unborn child…'. Denial of an unborn child's right to life frequently amounts to torture and is a violation of Article 7 of the ICCPR.[50]

National framework: UK (A comparative analysis with the US)

The European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) is an international treaty established by the Council of Europe in 1950 to protect and uphold human rights and fundamental freedoms in Europe. The UK played a significant role in the development of the Convention, and it was one of the first

countries to sign it. In the UK, the Convention, including Article 2, is incorporated into domestic law by the Human Rights Act 1998.[51] Article 2 of the Convention,[52] which addresses the right to life, is regarded as its most crucial clause.[53] While it might seem that Article 2 is designed to protect unborn life, it has been established that, according to this provision, a foetus does not possess a legal right to life. This was established in the case of *VO v France.*[54] The European Court of Human Rights (ECtHR) maintained that:

> [i]f Article 2 were held to cover the foetus and its protection under the Article were […] seen as absolute, an abortion would have to be considered as prohibited even where the continuance of the pregnancy would involve a serious risk to the life of the pregnant woman. This would mean that the 'unborn life' of the foetus would be regarded as being of a higher value than the life of the pregnant woman.[55]

In contrast to Article 4 of the American Convention on Human Rights,[56] which stipulates that the right to life must be protected 'in general, from the moment of conception', Article 2 of the ECHR does not specify the time frame for exercising the right to life and notably does not provide a definition for 'everyone' whose 'life' is safeguarded by the Convention.[57] In the case *Evans v The United Kingdom*, the court concluded that, as per English law, an embryo is not endowed with independent rights or interests and, consequently, cannot assert a right to life under Article 2, nor could someone assert such a right on its behalf.[58] Accordingly, the embryos in question were deemed not to possess a right to life as defined by Article 2, despite the applicant's assertion that British law permitted her ex-partner to revoke consent for the storage and utilisation of jointly created embryos.[59] Since there is no agreement among the nations regarding the protection of unborn children, Article 2 of the ECHR cannot be expanded to include the protection of a foetus or embryo's life.[60] In English law, women's rights take precedence, so any decision about the foetus requires the mother's consent. Legal clarification occurred after the *St. George's Healthcare NHS Trust v S* case, which dealt with the concern of compelling competent women to undergo Caesarean sections ostensibly for the well-being of the unborn child.[61]

A local authority expressed concern and filed a lawsuit, alleging that the mother's lifestyle was negatively impacting the well-being of the foetus. The judge determined that the court lacked wardship jurisdiction over the unborn child, citing that granting wardship would violate the mother's right to self-determination and result in inappropriate control over the woman and her body.[62] However, under English law, it is explicitly established that the legally consequential moment, at which the foetus is accorded full rights, is the instant of birth.[63] In the case of *C v S* it was said that 'the claim crystallises upon the birth, at which date, but not before, the child attains the status of a legal person, and thereupon can then exercise the legal right'.[64]

In the UK, the legal status of embryos is governed by the Human Fertilisation and Embryology (HFE) Act 1990, which was amended in 2008. This law allows specific embryo-related activities through licences from the Human Fertilisation and Embryology Authority (HFEA) but restricts others, encompassing aspects like embryo development and use. Yet it explicitly bans actions like using or storing embryos past the primitive streak's formation.[65] Sections 3(3) and (4) of the HFE Act allow embryo research within the first 14 days, after which research on the embryo is prohibited.[66] This indicates that the embryo is granted restricted legal safeguards up to day 14, but it does not attain its own legal identity or rights within the legal framework. Without a unique legal identity, the law does not acknowledge its independent rights.[67]

Again, the Congenital Disabilities (Civil Liability) Act 1976 states that a child who has been born has the legal right to sue for any damage it may have experienced while still in utero, if the injury was caused by the breach of a parent's duty[68] or that of another person.[69] The right to sue occurs solely at birth, implying that the child is retroactively attributed legal rights obtained at birth but pertaining to its existence in the womb. This contradicts the fundamental idea that an unborn child possesses no legal rights.[70] However, closer scrutiny of this retroactive application of legal rights under this Act shows that a child is not considered a separate legal entity with rights until its birth. While the unborn child may not have legal rights during gestation, once born, they possess the right to seek redress for injuries incurred during their prenatal life.

The situation is different in the US. In Alabama, a man and an aborted foetus filed a lawsuit against the manufacturer of an abortion pill and the clinic where his former girlfriend obtained it.[71] She used the pill to terminate her pregnancy at six weeks. In the ruling, Madison County Probate Judge Frank Barger acknowledged the legal personhood of the aborted foetus, permitting the man to designate the foetus as a co-plaintiff in his 'wrongful death' lawsuit. Various definitions have been assigned for situations when feticide is applicable.[72] Feticide is defined in Louisiana, as 'the killing of an unborn child, and an unborn child is a member of the human species from the time of fertilisation and implantation until birth'.[73] According to reports, certain American states detain pregnant women for the sole purpose of shielding the unborn from the mother's activities and forcing the mother to have a Caesarean section for the sake of the foetus.[74] However, no such protection for the foetus can be found in the jurisdiction of the UK.

The Abortion Act 1967, which is presently in effect in England, Scotland, and Wales, stipulates that a lawful abortion can be performed up to a maximum of 24 weeks into pregnancy.[75] That means a pregnancy can be legally terminated up to 24 weeks under section 1(1)(a). This denotes the developmental stage when the foetus becomes viable and can sustain life outside the mother's womb.[76] This implies that the legal recognition of a right to life for an embryo is not established until it reaches 24 weeks of gestation. Nevertheless, there is no specific gestational limit for abortions in cases where there is evidence of a fatal foetal abnormality or a substantial risk to the life of the pregnant woman if the pregnancy continues.[77]

In Northern Ireland, a new legal framework was implemented in 2020 through the Northern Ireland No.2 Regulations 2020. Under this framework, abortion is fully legal without conditions for pregnancies up to 12 weeks. Beyond this developmental stage, the legal provisions are essentially aligned with the rest of the UK on abortion limitations. Nevertheless, data indicates that hundreds of women from Northern Ireland continue to travel to England, Scotland, and Wales annually to access abortion services.[78] Another statistic indicates that in 2021, there were 214,256 abortions among women living in England and Wales, marking the highest number of abortions since the implementation of the Abortion Act.[79] The substantial number of terminated pregnancies highlights the absence of legal recognition for unborn children in the UK. Under UK law, it is established that an unborn child is not recognised as a separate entity from its mother[80] and does not attain the status of a person in the context of the law concerning murder and manslaughter.[81]

Unlike the US, where there is a strong emphasis on the protection of unborn children and the recognition of their right to life, the UK's legal framework adopts a different approach. The increasing number of abortions, which has reached the highest levels recorded in recent years, highlights the lack of stringent regulations surrounding the procedure. This

situation has led to a need for some form of regulation to address what some perceive as arbitrary abortion.

Mitochondrial research therapy and the rights of unborn children

Mitochondria are often referred to as the 'powerhouses' of the cell because they generate energy through a process called oxidative phosphorylation.[82] One of the most unique features of mitochondrial DNA (mtDNA) is that it is inherited exclusively from the mother, as the mitochondria in the sperm tail or flagellum typically do not transfer to the offspring during fertilisation.[83] As a result, mitochondria in an individual's cells derive exclusively from their mother's side.[84] Due to its exposure to reactive oxygen species and limited repair mechanisms, mtDNA is more susceptible to mutations compared to nuclear DNA.[85] Mutations in mtDNA can disrupt mitochondria function and energy production, potentially causing inherited mitochondrial disorders across generations. Mitochondrial disorders typically impact high-energy-demanding organs like the brain, muscles, and heart, manifesting in symptoms like muscle weakness, neurological issues, and developmental delays.[86] MRT aims to address and prevent these disorders.

Debates about the ethical and societal implications of modifying the human genome have a long-standing history, and recent advances in genome editing technologies have elevated these previously theoretical discussions.[87] Heritable gene modifications take place when early-stage in vitro embryos or gametes are genetically altered, leading to the birth of a child with a modified genome after being transferred to a uterus.[88] If the child grows up and reproduces using its own gametes, the descendants will inherit the genetically modified genome.[89] On the eve of the Second International Summit on Human Genome Editing in Hong Kong in 2018, a scientist named He Jiankui from Shenzhen, China revealed he had altered early human embryos using genome editing tools before transferring them to the intended mother, leading to the birth of twin girls.[90] He sought to enhance resistance to HIV by targeting and disabling the CCR5 gene, a receptor which is essential for the virus's entry into human cells.[91] What made this experiment groundbreaking was its unprecedented nature; it marked one of the earliest known attempts at modifying the human germline, where genetic changes could potentially be inherited by future generations.[92] However, the announcement also prompted significant debate in the realm of ethics and science. As a result, in December 2019, He Jiankui and two associates were convicted by the Nanshan District People's Court in Shenzhen, China for practising medicine without a licence, as prohibited by Article 336 of the Criminal Law of the People's Republic of China.[93] However, genome editing offers a potential solution for those with hereditary genetic conditions, allowing them to prevent their genetically related children from inheriting the disorder.[94] There exists a relationship between mtDNA and heritable genome editing. While most heritable gene modifications pertain to changes in nuclear DNA, mtDNA presents a unique and separate case. Mutations in mtDNA can lead to mitochondrial diseases, but it is possible to prevent these diseases through heritable genetic alterations that impact mtDNA.[95]

MRT is an assisted reproductive technology that enables a novel movement in a socially and scientifically established reproductive area. MRT is distinct from parthenogenesis,[96] representing a unique approach to sexual reproduction resulting in a single individual.[97] It is one way for women who are at high risk of transmitting mitochondrial disorders to conceive children free from the condition, aiming for healthy children.[98] The most relevant international standard that may come into play when considering the legality of MRT is Article 18 of the Oviedo Convention. This is because Article 18 addresses the contentious subject of embryo research, which

is closely related to MRT. It should be underlined that the Convention does not address the complex ethical and legal status of the human embryo, leaving each state to define 'person' based on its own national laws. This also clarifies why the conflicting language in Article 18.1 is accurate when it specifies that 'where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo'. It is indeed challenging to understand how the 'adequate protection' of embryos and their utilisation as research subjects may coexist.[99] The stipulation in Article 18.2, which prohibits the deliberate creation of embryos for research, reflects concerns about the objectification and commodification of human embryos – treating them as mere research tools rather than as potential human life. Similarly, this ethical concern extends to MRT, as it involves the creation and manipulation of embryos to prevent mitochondrial diseases, raising similar questions about the potential commodification of embryos despite its goal of improving future generations' health. Without a clear framework to distinguish between acceptable practices for research and those that are prohibited, researchers may face uncertainty regarding the legal and ethical implications of their work. The ambiguity surrounding the protection of embryos could create confusion between advancing scientific research aimed at alleviating suffering and adhering to ethical standards that prioritise embryo protection.

Mitochondrial research therapy in the UK

In a significant move in 2015, the UK Parliament reversed its long-standing ban on embryo alterations during IVF, recognising the potential heritability of such changes and permitting mitochondrial replacement to prevent the spread of serious mitochondrial diseases.[100] It is noteworthy that the UK is not a signatory of the Oviedo Convention, because Article 13 stipulates: 'An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.'[101] The decision to legalise MRT in the UK and the HFEA's subsequent regulation of the procedure were based on a number of evaluations of pre-clinical safety and efficacy data, including animal model and human research embryo data, as well as public discussion of the procedure's moral acceptability, evidence of which was subsequently published.[102] Clinics aiming to conduct the procedure must prove their expertise to the HFEA, which subsequently reviews and approves applications on an individual basis.[103] In May 2023, the HFEA officially reported that between one and four children had been successfully born as a result of embryos created through mitochondrial donation.[104] This development marked a significant milestone in the field of reproductive and genetic technologies, demonstrating the practical application and effectiveness of this innovative technique in helping couples overcome mitochondrial-related disorders and have healthy children.

The UK's characterisation of MRTs as distinct from germline genetic modification necessitated a more specific interpretation, with two key differences influencing this 'narrowing'.[105] MRTs only impact the mitochondrial DNA and not the nuclear DNA. Additionally, MRTs involve substitution rather than modification, replacing one complete 'natural mitochondrial genome' with another. The hypothesised normative importance of these differences indicates that, in contrast to nuclear genome editing, MRTs are less prone to be used for enhancing humans, have a limited effect on the identity of the individual produced, and do not introduce 'artificial' aspects into the genetic structure.[106] The Nuffield Council justified its endorsement of MRT, among other reasons, by 'there… [being] a distinct material boundary between mitochondrial and nuclear genes [which] allows regulators to establish an equally clear legal distinction between modifications to the different genomes'.[107] The Chief Medical

Officer (CMO) at the time the Regulation was being implemented in the UK, Professor Dame Sally Davies, provided an explanation of the thinking behind the government's strategy:

> Anything done to DNA that is passed down through the generations is referred to as germline, and mitochondria are passed down from mother to child. This is a germline modification because it is transmitted, but we needed to distinguish between nuclear DNA, which determines our personalities, heights, weights, and whether or not we develop baldness, and the 37 genes in the mitochondria, which are responsible for the cell's energy production and are referred to as the power pack.[108]

The CMO asserts that MRT involves modifying mitochondrial DNA, which is maternally inherited and thus constitutes a form of germline modification.[109] However, she emphasises, unlike modifications to nuclear DNA that influence personal traits and identity, changes to mtDNA primarily affect cellular energy production and do not alter individual characteristics.[110] Likewise, in its consultation during the draft process, the Department of Health noted: 'mitochondrial donation techniques do not alter personal characteristics and traits'.[111]

Maternal Spindle Transfer (MST) and Pronuclear Transfer (PNT) have been endorsed by the UK Parliament as two techniques for mitochondrial donation.[112] In MST, the mother's nuclear DNA is removed from her egg and inserted into a donor egg that has had its nuclear DNA removed, preserving the donor's healthy mitochondria.[113] In PNT, both the mother's and a donor's eggs are fertilised in vitro; the pronuclei are extracted from both zygotes, and the mother's pronuclei are transferred into the donor's enucleated zygote,[114] resulting in an embryo with the mother's nuclear DNA and the donor's healthy mitochondria.[115] Both approaches involve utilising nuclear DNA (which determines individual identity) and healthy mitochondria donations to create eggs or embryos.[116] It is important to distinguish PNT and MST from other in vitro methods with germline editing,[117] such as human reproductive cloning, which is prohibited in the UK.[118] As MST and PNT procedures result in offspring inheriting nuclear DNA from both parents and mtDNA from a donor, they do not involve editing nuclear DNA or altering traits governed by nuclear genes, making them distinct from traditional germline editing.[119] The Nuffield Council on Bioethics identifies the primary ethical justification for the use of PNT and MST, as the potential to prevent serious health issues associated with mtDNA disorders in affected women.[120]

The HFE Act clarified parental rights by excluding mtDNA donors from any parental claims and preventing courts from granting parental rights based only on mtDNA contributions.[121] The HFE Act also addressed issues relating to children's rights by granting MRT-conceived children restricted access to non-identifying data about their mtDNA donors and vice versa.[122] To clarify the reason for not addressing the right to know, the Nuffield Council says:

> [s]ince mitochondria do not undergo recombination, and mitochondrial inheritance is strictly maternal, any one of the donor's close female family members could have served as a substitute mitochondrial donor without affecting the mitochondrial genome inherited by the resultant child. Consequently, on both the pragmatic and ontological reading of the criterion, mitochondrial donation does not result in a unique genetic connection between donor and child. Therefore, no right to know arises.[123]

Moreover, the HFEA stated, '[a]s mitochondria are thought not to be responsible for a person's characteristics (beyond their health), information about a mitochondria donor's details and identity should only be disclosed on a basis of mutual consent through a system without a statutory standing'.[124] However, an analysis shows that both the HFEA and the Nuffield Council arguments fail

to justify denying children created using donor mtDNA the right to know their genetic heritage.[125] This is due to the empirical evidence indicating potential transmission of personal characteristics through mtDNA, leading to resemblances between donor and child, and the existence of a unique genetic connection with offspring through mtDNA, according to plausible accounts.[126] For instance, the assumption that mitochondrial donors are interchangeable overlooks heteroplasmy – the presence of multiple mtDNA variants in different tissues.[127] Since mtDNA ratios vary across ova, the specific make-up inherited by the child depends on the individual donor, creating a non-fungible genetic link. This challenges the claim that mitochondrial donation does not justify a right to know.

Additionally, in sperm donation cases involving monozygotic triplets (identical triplets) genetic testing cannot distinguish the exact donor. Yet, denying the child's right to know in such cases while granting it to others seems inconsistent.[128] However, there are other arguments against the right to know in cases of mitochondrial research therapy. The arguments highlight that mitochondrial transfer is the only option for women at risk of passing on mitochondrial diseases. It suggests that guaranteeing the right to know one's mitochondrial donor may discourage this treatment, leading some to risk having children with severe mitochondrial diseases for genetic relatedness.[129] Not legally recognising this right still allows open donor arrangements. Consequently, it becomes more enticing for those thinking about mitochondrial donation.[130] Nevertheless, there are significant reasons why children should have the right to know their origin, as it is crucial for their identity development. The right to know one's origins is fundamental for ensuring that children can fully understand their identity and heritage, which plays a vital role in their overall well-being and personal growth.[131] Additionally, the CRC affirms this right in its provisions, particularly in Articles 7 and 8, emphasising the importance of knowing one's identity and maintaining family relationships.[132] The right to identity involves the protection of all aspects of one's identity, where the violation of any element leads to a violation of the right to identity as a whole.[133] This emphasises that knowing one's origins is a vital part of a child's comprehensive and true sense of self.

In the UK, the supply of identifying information to offspring resulting from mitochondrial donation is prohibited. Section 31ZA of the HFE Act grants MRT-conceived children the right to request only non-identifying information about their mtDNA donors once they reach the age of 16. Releasing identifiable information is permissible only when the donor voluntarily chooses to waive their anonymity. Notably, UK law previously upheld donor anonymity in IVF cases, but later amendments prioritised the child's right to know their genetic origins over donor privacy.[134] Given this shift, the UK should consider whether a similar approach to prioritising a child's right to know their genetic origins should be applied to MRT donor anonymity.

Australia recently became the second jurisdiction globally to legalise MRT.[135] The Mitochondrial Donation Law Reform (Maeve's Law) Bill 2021 enables individuals with a family history of mitochondrial disease to utilise assisted reproductive techniques, preventing the transmission of mitochondrial disorders.[136] However, unlike the UK, Australia acknowledged the right to know the origin. According to Section 29A of Mitochondrial Donation Law Reform (Maeve's Law) Act 2022 a child born through mitochondrial donation can apply for information about the donor from the age of 18. The prevailing position of the UK concerning the right to know in the context of mitochondrial donation appears to be inflexible. Considering the complex concerns surrounding MRT and the right to know, a policy change may be necessary in the UK to

strike a balance between individual rights and public health considerations. A practical approach to addressing the right to know in MRT involves instituting a case-by-case assessment system, acknowledging the uniqueness of individual circumstances.

Unborn children's rights under MRT

The concern that it would be possible to change the 'essential features' of a future person, thereby breaching the child's right to an open future, is one of the most significant (non-safety) arguments against germline alteration.[137] Because of this, mtDNA modification has generated less ethical debate than germline modification of nuclear DNA. The defence would be that, in contrast to mtDNA, nuclear DNA carries the building blocks for human characteristics.[138] However, some research, albeit not without criticism, suggests links between the mtDNA and cognitive capabilities.[139] According to other writers, mitochondria may perform a crucial but unidentified biological function in addition to energy production.[140] While it remains speculative, mtDNA could potentially influence the expression of nuclear genes, subsequently impacting the essential characteristics of offspring.[141] Furthermore, selecting a child's genetic make-up infringes upon their right to an open future. According to Habermas, genetic modifications might predetermine certain life goals, posing a threat to individual autonomy.[142] It threatens the child's ability to define their own path, as they may perceive themselves as fulfilling predetermined parental expectations and desires.[143]

In the event that mtDNA is proven to affect a child's characteristics, ensuring the protection of the rights of children who undergo the mtDNA process would become the priority. Right to health is a *sine qua non* (an essential requirement) for every child even before birth, which in some cases protects the unborn; for example, in certain American states, pregnant women can be detained in order to shield the unborn from the mother's actions, and they may be forced to undergo a Caesarean section to protect the foetus.[144] There are numerous benefits of MRT for protecting the future child from mitochondrial disease. It is appropriate to only allow modifications that broaden the child's potential pathways, ensuring they are not inherently directed towards a specific life path.[145] In other words, genetic changes should be considered only if they are intended to prevent serious diseases.[146] It is logical to assume that a child facing severe neurological issues, or muscle disorders, for example, might see these conditions as obstacles to achieving many life aspirations. However, if MRT can prevent the harmful impacts of the mtDNA mutation safely, the child could potentially have broader life opportunities.[147] Therefore, MRT can be viewed as a blessing for the future child if it is used exclusively to address severe health issues, ensuring the child's well-being and quality of life.

Conclusion and recommendations

When considering the rights of the unborn, the primary right that emerges is the right to life, as articulated in Article 6 of the CRC and ICCPR. However, these international agreements do not explicitly address whether this right applies to the unborn, leaving it largely to the discretion of individual state laws and regulations. During the development of the CRC, there was a proposal to protect human life from the moment of conception. Nonetheless, it is essential to recognise that portraying the right to life of an unborn child as absolute is a misconception.[148] All human rights must be carefully balanced against the rights of others. Therefore, when conflicts arise, such as those involving the rights of women to life, mental and physical health, and privacy, a thorough assessment is necessary to determine the prevailing right.[149] This is why the ECtHR consistently refuses to interpret the right to life, as recognised in the ECHR, as an absolute right for an unborn child. Laws on this matter differ between nations, allowing

states considerable flexibility under the Convention, especially in the context of abortion. Yet, there is a shared understanding among states that the embryo or foetus is inherently human.[150] An analysis on the status of embryos indicates that, given their potential to become human beings, they should be granted rights equivalent to any other individual. The ECtHR acknowledges that the potentiality of being and its capacity to become a person require protection in the name of human dignity, even though it does not confer full 'personhood' with the 'right to life' under Article 2.[151]

Examining UK laws reveals a minimal recognition of rights for the unborn. The right to life for the unborn is particularly limited in the UK, as evident in multiple legal cases. UK law prioritises women's autonomy in abortion decisions but increasing abortion rates raise concerns about children's rights**.** Unlike in the UK, certain US laws have historically recognised foetal rights in specific contexts.[152] However, abortion rights in the US have undergone significant legal changes. The constitutional protection established in Roe v Wade[153] was overturned by *Dobbs v Jackson Women's Health Organization*,[154] allowing individual states to impose restrictions or bans on abortion. To strike a balance between women's rights and children's right to life, the UK should consider implementing stricter regulations to ensure that abortions are not carried out without valid reasons. Northern Ireland's abortion laws, which permit abortion up to 12 weeks of gestation, offer a potential model for achieving this balance. Other parts of the UK could benefit from revising their laws accordingly. However, it is essential to note that strict laws on abortion can potentially infringe upon the rights of women. For instance, in the case of *Tysiac v Poland*, a Polish woman with severe myopia was denied the option of an abortion despite medical warnings about the serious risk to her eyesight if she carried the pregnancy to term.[155] The ECtHR identified that Polish law lacked clarity concerning lawful abortion, resulting in prolonged uncertainty and significant distress for the applicant. This situation emphasises the significance of establishing clear guidelines for when the termination of a pregnancy may be deemed lawful. It is important to remember that excessively stringent abortion laws can also jeopardise women's rights, underscoring the need for a balanced and thoughtful approach that respects both individual autonomy and the rights of the children. The continued Irish migration to access abortion services highlights the potential consequences of restrictive laws, as women may be forced to seek services elsewhere rather than being supported within their own legal system. Therefore, any revision of abortion laws in the UK must not only aim to regulate access but also ensure clear, accessible guidelines that prevent unnecessary hardship while safeguarding both women's rights and the interests of unborn children.

Additionally, Article 24 of the CRC emphasises the right to health, particularly prenatal care for mothers, but its implementation can vary between countries due to their respective laws. A broader interpretation suggests that this care ultimately benefits children. For instance, in the UK, the Congenital Act allows a child to seek legal action against their mother for prenatal harm, but this right is only applicable after birth. However, there is no inherent reason why this right could not be explicitly recognised before birth, given that newborns are in no better position than foetuses to initiate legal action. This highlights a potential gap in legal recognition that could be addressed to ensure greater protection of children's rights from the earliest stages of development.

Besides, Article 18 of the Oviedo Convention lacks clear guidance on the status of embryos, and the minimum standard for their protection plays a critical role in shaping the legal landscape for MRT. As advancements in reproductive technologies continue to evolve, the need for updated regulations that adequately address both the ethical

considerations of embryo protection and the potential benefits of research, such as MRT, becomes increasingly important. It is essential to establish international principles to address this issue effectively, prompting a revision of Article 18. MRT, currently legal in the UK, stands as a groundbreaking reproductive assistance tool aimed at enhancing the health of future children by eliminating mitochondrial disease traits. While there is criticism suggesting that MRT may compromise the identity of children, the life-saving potential of this technique outweighs these concerns. Children with severe neurological or muscle impairments often perceive their condition as a hindrance to their life goals. If germline modification can safely prevent the detrimental effects of mitochondrial mutations, it opens up more possibilities for these children. Therefore, the UK's decision to legalise MRT with proper regulation is a significant step forward. Nevertheless, there are concerns that the HFE Act in the UK does not adequately recognise children's right to know their origins. The act prohibits the disclosure of identifying information to children, primarily to maintain the donor's privacy. In contrast, Australia, the second country to legalise MRT, acknowledges the right to know one's origin by permitting the disclosure of identifying information to children once they reach the age of 18. In alignment with Verona Principle 11, which pertains to surrogacy, ensuring that surrogate mothers and genetic donors provide accurate identifying information and supporting open surrogacy arrangements becomes crucial for safeguarding identity rights and access to origins.[156] There is no real justification for distinguishing between these two reproductive contexts on this issue. Consequently, disclosure should be extended in the UK to include children born through MRT, encouraging donors to reveal their identities by default. However, securing the child's ability to know their origins could also be balanced with the benefits of anonymity associated with donation within MRT by putting such details behind protective access measures in which the regulator mediates. This practical approach could involve a case-by-case assessment system, acknowledging the uniqueness of individual circumstances and enabling the default disclosure to be departed from only when the circumstances warrant it.

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[47] United Nations, Human Rights Instruments, 'Compilation of General Comments and General Recommendations' Adopted by Human Rights Treaty Bodies (1982) HRI/GEN/1/Rev.9 (Vol. 1) (adopted 30 April 1982).
[48] Society for the Protection of Unborn Children (n 15).
[49] General Assembly, Draft International Covenants on Human Rights: Report of the Third Committee to the 12th Session of the General Assembly, 5 December 1957, A/3764 §18.
[50] Article 7 states, '[n]o one shall be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation'.
[51] Section 1(1) and Schedule 1 Part I of The Human Rights Act 1998 (c 42) received Royal Assent on 9 November 1998 and came into force on 2 October 2000.
[52] Article 2 of ECHR, '1. Everyone's right to life shall be protected by law…'
[53] In the case of *McCann and others v United Kingdom*, Grand Chamber (GC) Judgement, 'Article 2 ranks as one of the most fundamental provisions in the Convention – indeed one which, in peacetime, admits of no derogation under Article 15…' *McCann and others v United Kingdom*, GC judgement of 5 September 1995, § 147, with reference to *Soering v United Kingdom*, judgement of 7 July 1989, para 88. See also Douwe Korff, 'The Right to Life: A Guide to the Implementation of Article 2 of the European Convention on Human Rights' (Council of Europe 2006).
[54] V*O v France* (2005) 40 EHRR 12.
[55] Montgomery and Cornock (n 37).
[56] Organization of American States (OAS), American Convention on Human Rights, 'Pact of San Jose', Costa Rica, (adopted 22 November 1969). As stated in its preamble, the Convention aims to establish in this region, under democratic institutions, a system that upholds personal freedom and social justice, founded on the fundamental rights of individuals.
[57] Council of Europe: European Court of Human Rights, Guide on Article 2 of the European Convention on Human Rights - Right to Life, 31 December 2020.
[58] *Evans v United Kingdom*, 43 EHRR 21 European Court of Human Rights.
[59] Council of Europe (n 57).
[60] ibid.
[61] *St George's Healthcare NHS Trust v S* [1998] 2 FLR 728.
[62] *Re F (in utero)* [1988] Faro 122.
[63] Sophie Windsor, 'The Legal Status of the Foetus' (2017) 25(6) British Journal of Midwifery 406.
[64] *C v S* QB 135, 1988.
[65] Primitive streak of a human can be understood as a structure that forms during the earliest stage of development in a growing embryo.
[66] Montgomery and Cornock (n 37).
[67] ibid.
[68] Section 1 of Congenital Disabilities (Civil Liability) Act 1976.
[69] ibid, s1(7).
[70] *Paton v British Pregnancy Advisory Service Trustees* [1979] QB 276. In this case Sir George Baker noted '[t]he foetus cannot, in English law, in my view, have a right of its own at least until it is born and has a separate existence from its mother'. See also *St George's NHS Healthcare Trust v S* [1998] 3 WLR 936.
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[72] Camilia Pickles, 'Feticide: Continuing the Search for a Unified Approach to the Unborn' (2017) 80 Journal of Contemporary Roman-Dutch Law 44.
[73] Sections 14.1.32.5.A and 14.1.2(11) of the Louisiana Revised Statutes Annotated.
[74] Pickles (n 72).
[75] British Medical Association, 'The Law and Ethics of Abortion' BMA views, September 2020 (March 2023 update).
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[77] Abortion Act 1967, s1(1)(d).
[78] England and Wales (n 76).
[79] ibid.
[80] *Re F* (n 62).
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[83] Anon, 'New Route to Evolution: How DNA From Our Mitochondria Gets Into Our Genomes' (2022) University of Cambridge, <https://www.cam.ac.uk/research/news/a-new-route-to-evolution-how-dna-from-our-mitochondria-works-its-way-into-our-genomes> accessed 28 March 2025.
[84] ibid.
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[86] Françoise Baylis, 'Human Nuclear Genome Transfer (So-Called Mitochondrial Replacement): Clearing the Underbrush' (2017) 31(1) Bioethics 7.
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[90] The Royal Society (n 87).
[91] Eric S Lander, 'Brave New Genome' (2019) 380(10) The New England Journal of Medicine 971.
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[97] Andy Greenfield, '25th Anniversary of Cloning by Somatic-Cell Nuclear Transfer Cloning, Mitochondrial Replacement and Genome Editing: 25 Years of Ethical Debate since Dolly' (2021) 162(1) Reproduction F69.
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[108] House of Commons Science and Technology Committee (HCSTC), Oral Evidence: Mitochondrial Donation, HC 730, 22 October 2014, 25.
[109] Department of Health, Health Science and Bioethics Division, 'Mitochondrial Donation: A Consultation on Draft Regulations to Permit the Use of New Treatment Techniques to Prevent the Transmission of a Serious Mitochondrial Disease from Mother to Child' (February 2014) para 1.5.
[110] ibid.
[111] ibid, para 1.27.
[112] The Nuffield Council on Bioethics (n 107).
[113] ibid, 34.

[114] An enucleated zygote refers to a fertilised egg cell from which the nucleus has been removed.
[115] The Nuffield Council on Bioethics (n 107) 32.
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[117] The Nuffield Council on Bioethics (n 107) 36.
[118] Human reproductive cloning entails creating a genetically identical copy of a human. The UK explicitly prohibits reproductive cloning under the Human Reproductive Cloning Act 2001, which was later repealed and replaced by the Human Fertilisation and Embryology Act 2008. See more Dr Zoe Bolton, 'Discipline-Hopping: UK Law and Emerging Reproductive Technologies' (4 August 2023) The Future of Human Reproduction, https://wp.lancs.ac.uk/futureofhumanreproduction/discipline-hopping-law/
[119] The Nuffield Council on Bioethics (n 107) 57.
[120] ibid, 52.
[121] Rosa J Castro, 'Mitochondrial Replacement Therapy: The UK and US Regulatory Landscape' (2016) 3(3) Journal of Law and the Bioscience 726.
[122] ibid.
[123] Reuven Brandt, 'Mitochondrial Donation and "The Right to know"' (2016) 42(10) Journal of Medical Ethics 678, 681.
[124] HFEA, 'Mitochondria Replacement Consultation: Advice to Government' March 2013.
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[131] Michaeal Freeman, 'The New Birth Right?: Identity and the Child of the Reproductive Revolution', (1996) 4(3) International Journal of Children's Rights, 273. Samantha Besson, 'Enforcing the Child's Right to Know Her Origins: Contrasting Approaches under the Convention on the Rights of the Child and the European Convention on Human Rights' (2007) 21(2) International Journal of Law, Policy and the Family 137.
[132] Article 7 states that,
1. The child shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by his or her parents.
2. States Parties shall ensure the implementation of these rights in accordance with their national law and their obligations under the relevant international instruments in this field, in particular where the child would otherwise be stateless.
Article 8 states that,
1. States Parties undertake to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognized by law without unlawful interference.
2. Where a child is illegally deprived of some or all of the elements of his or her identity, States Parties shall provide appropriate assistance and protection, with a view to re-establishing speedily his or her identity.
[133] Cappucine Page, 'Artificial Womb Technology and the Safeguarding of Children's Rights Through an Analysis of the Right to Identity' (2017) LLM thesis, Supervised by Professor Julia Sloth Nielsen, Faculty of Law, Leiden University 14.
[134] Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004, SI 2004/1511.
[135] Ainsley Newson, 'Australia's Careful Step Towards Legalising Mitochondrial Donation' BioNews 9 July 2018, https://www.progress.org.uk/australias-careful-step-towards-legalising-mitochondrial-donation/ accessed 28 March 2025.
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[137] Bredenoord et al (n 1).
[138] Donald S Rubenstein et al, 'Germ-Line Therapy to Cure Mitochondrial Disease: Protocol and Ethics of In Vitro Ovum Nuclear Transplantation' (1995) 4 (3) Cambridge Quarterly Healthcare Ethics 316.
[139] Pierre L Roubertoux et al, 'Mitochondrial DNA Modifies Cognition in Interaction with the Nuclear Genome and Age in Mice' (2003) 35(1) Genet 65.
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[147] Bredenoord et al (n 1).
[148] Alston (n 31).
[149] ibid.
[150] Article 2 Right to life, View Whole of: Lester, Pannick & Herberg: Human Rights Law and Practice Chapter 4, The European Convention on Human Rights, <https://www.lexisnexis.co.uk/products/lester-pannick-and-herberg-human-rights-law-and-practice.html> accessed 28 March 2025.
[151] ibid.
[152] For example, Unborn Victims of Violence Act of 2004, 18 USC § 1841 (2004). Also, in *State v Merrill* is 450 N.W.2d 318 [Minn. 1990], the Minnesota Supreme Court concluded that the state's unborn child homicide statutes did not violate the Equal Protection Clause of the Fourteenth Amendment of the U.S. Constitution and were not unconstitutionally vague.
[153] *Roe v Wade*, [1973] 410 U.S. 113.
[154] *Dobbs v Jackson Women's Health Organization* [2022] is 597 U.S. 215.
[155] *Tysiąc v Poland* (Application no. 5410/03) ECtHR 2007.
[156] International Social Service – General Secretariat, 'Principles for the Protection of the Rights of the Child Born through Surrogacy (Verona principles)' 25 February 2021.