



15 North Bank Street, The Mound
Edinburgh EH1 2LS
SCOTLAND, UK
E-mail: Mail@schb.org.uk

Date: 21 May 2014 – UK Department of Health

Consultation: ‘Mitochondrial Donation’

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the **United Nations Universal Declaration of Human Rights** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

The SCHB's response can be shared internally with other UK Department of Health policy teams who may be addressing the issues discussed. They may contact the SCHB again in the future and the SCHB gives permission to do so.

The SCHB is very grateful to the UK Department of Health for this opportunity to respond to the consultation on **‘Mitochondrial Donation’**. It welcomes the Department of Health's intention to promote public consultation, understanding and discussion on this topic.

Scottish Council on Human Bioethics Response

Question 1: Regulation 2 defines the removal or insertion of nuclear DNA involved in mitochondrial donation. Do you agree with this definition?

Scottish Council on Human Bioethics Response

The UK Department of Health defines Maternal Spindle Transfer (MST) and Pronuclear Transfer (PNT) as follows:

“Maternal spindle transfer (MST): The “maternal spindle” is the group of maternal chromosomes within the egg, which are shaped in a spindle. MST involves removing the spindle from the mother’s egg before it is fertilised by the father’s sperm. The spindle is then placed into a donor egg with healthy mitochondria (from which the donor’s spindle, and therefore her nuclear material, has been removed).”

“Pro-nuclear transfer (PNT): The pro-nucleus is the nucleus of a sperm or an egg cell during the process of fertilisation after the sperm enters the egg, but before they fuse. PNT involves removing the pro-nuclei (nuclear material) from a newly fertilised egg (which is regarded as an embryo under the Human Fertilisation and Embryology Act 1990) that has unhealthy mitochondria. The pro-nuclei are then transferred into a donated embryo, with healthy mitochondria, that has had its own, original pro-nuclei removed.”

Note: The SCHB has asked UNESCO's International Bioethics Committee for an opinion on MST and PND. In this regard, because of its international responsibilities, it would be appropriate for the UK Department of Health to support the development of an ICB opinion on the procedures. It would also be considerate of the Department of Health not to publish its response to the consultation entitled **Mitochondrial Donation** until the IBC's opinion is published.

Though the expression 'Mitochondrial Donation' is used in the **2008 Human Fertilisation and Embryology Act**, the SCHB believes that the UK Department of Health's characterisation of Maternal Spindle Transfer (MST) and Pronuclear Transfer (PNT) as 'mitochondrial donation' is deeply misleading and reflects a manipulation and misunderstanding of what is really being suggested. It represents a lack of professional discernment in the Department of Health as to its role in the context of a democracy in helping the general public understand what the procedures actually mean from a biological perspective.

The SCHB would like to question why the UK Department of Health is continuing to use the ambiguous term of 'mitochondrial donation' when this has already been shown to potentially mislead the general public.¹ This can have very serious repercussions and undermine the democratic process.

Certainly the more detailed biological description of both these procedures provided by the Human Fertilisation and Embryology Authority (HFEA) as part of its public consultation made it abundantly clear that it is the chromosomes that are transferred during both procedures, and not the actual mitochondria.²

Moreover, it is noted that it is not just new mitochondria that are being used in a defective unfertilised or fertilised eggs but a whole new unfertilised or fertilised egg emptied of its maternal spindle or pronuclei, respectively. Mitochondria only form a small part of these new eggs.³

The mitochondria are certainly not taken out of one egg and safely transplanted into another egg, from which all or most of the latter's mitochondria have already been removed.

It is, therefore, not so much a process of 'mitochondrial donation' or 'mitochondrial transfer' but of 'chromosomal transplantation'.

The UK Department of Health mentions in its consultation that:

"2.1 On 28 June 2013 the Government announced that it intended to move forward with regulations to allow mitochondrial donation to prevent the transmission of serious mitochondrial disease between mother and child. The Chief Medical Officer for England, Professor Dame Sally Davies, said:

Scientists have developed ground-breaking new procedures which could stop these diseases being passed on, bringing hope to many families seeking to prevent their future children inheriting them. It is only right that we look to introduce this life-saving treatment as soon as we can."

Again, the SCHB believes, that this is an inappropriate distortion of the facts since there is no question of 'saving lives' through the procedures. Instead, it is only certain lives that are brought into existence through MST and PNT. This reflects an unacceptable lack of discernment and even misinformation on behalf of the Chief Medical Officer.

Question 2: Regulations 4 (eggs) and 7 (embryos) only allow mitochondrial donation where all the nuclear DNA is transferred from an egg or embryo to another egg or embryo from which all the nuclear DNA has been removed. Do you agree with this description and restriction?

¹ Calum MacKellar, Questions relating to 'mitochondrial replacement', BioNews, 741, 10 February 2014, http://www.bionews.org.uk/page_395064.asp

² See: HFEA, New techniques to prevent mitochondrial disease, <http://mitochondria.hfea.gov.uk/mitochondria/what-is-mitochondrial-disease/new-techniques-to-prevent-mitochondrial-disease/> (Accessed on 27 January 2014)

³ Mitochondria only constitute 15 to 35 per cent of a cell's total mass. See: Mitochondria, Wellcome NEWS, Spring 2012, p. 24.

Scottish Council on Human Bioethics Response

The SCHB believes that characterising Maternal Spindle and Pronuclear Transfer as 'mitochondria donation', as is done in the UK Department of Health's consultation, is deeply misleading and reflects a manipulation and misunderstanding of what is really being suggested.

Though the SCHB believes that MST and PND should be prohibited, it does agree, however, with the above restriction.

Question 3: Regulations 5 (eggs) and 7 (embryos) require that, in order to agree that mitochondrial donation can go ahead, the HFEA must decide if there is both a particular risk that the egg or embryo of the patient has a mitochondrial abnormality and a significant risk that a person with the particular mitochondrial abnormality will have or develop a serious physical or mental disability, a serious illness or other serious medical condition. Do you agree that the HFEA should have this role?

Scottish Council on Human Bioethics Response

The SCHB believes that characterising Maternal Spindle and Pronuclear Transfer as 'mitochondria donation', as is done in the UK Department of Health's consultation, is deeply misleading and reflects a manipulation and misunderstanding of what is really being suggested.

Furthermore, the SCHB is of the opinion that the HFEA should not be able to decide that Maternal Spindle and Pronuclear Transfer should take place because of the significant biological and social risks associated with the procedures.

Question 4: Do you agree with the principle that centres should not be permitted to undertake mitochondrial donation without first obtaining authorisation to do so from the HFEA ?

Scottish Council on Human Bioethics Response

The SCHB believes that characterising Maternal Spindle and Pronuclear Transfer as 'mitochondria donation', as is done in the UK Department of Health's consultation, is deeply misleading and reflects a manipulation and misunderstanding of what is really being suggested.

The SCHB is of the opinion that centres should not be permitted to undertake Maternal Spindle and Pronuclear Transfer.

Question 5: Do you agree that people donating eggs and embryos for the purposes of mitochondrial donation should *not* have the same status as those donating eggs and embryos for use in fertility treatment but rather regarded more like organ or tissue donors?

Scottish Council on Human Bioethics Response

The SCHB does not agree that people donating eggs and embryos for the purposes of mitochondrial donation should have a different status to those donating eggs and embryos for use in fertility treatment.

Moreover, framing the procedure so that a comparison is made to organ donation is false and misleading. This is because with organ donation a life is already in existence whereas in the case of chromosomal transplantation between unfertilised or fertilised eggs, the very creation of life is being considered which is completely different from a philosophical and ontological perspective.

One of the most fundamental questions which arises from the use of Maternal Spindle and Pronuclear Transfer is the fact that at least three individuals are participating in the creation of human life. From this perspective, and although chromosomal DNA is extremely important in the creation of a being, it is

impossible to just reduce the concept of parenthood to the persons who contributed to this chromosomal DNA.

This is because without an enucleated egg or fertilised egg from another couple, no new life would ever have existed. From an ethical perspective, chromosomes by themselves have no real value as such. They only become ethically meaningful if they are transferred into an enucleated fertilised or unfertilised egg and left to develop. In this regard, all those participating in the process of bringing a life into existence may be considered, in some form and to varying degrees, as the 'real' creators of the creature. They may then also experience some or all the corresponding aspects of parenthood bonds and mutual belonging which arise between creators and their creatures.

In the case of Maternal Spindle or Pronuclear Transfer, it is not only what is being used that is important (and whether DNA, cytoplasm or any other material is considered) but the amount of individual participation in the creative process be it at a biological or even manipulatory level. A participation which could then also give rise to creator-creature (parent-child) bonds.

For example, a hypothetical experiment can be considered when two identical twin women are being treated at the same IVF clinic and there is some mix up with their eggs. Assuming for the sake of the hypothetical experiment that the women's eggs were exactly the same from a genetic perspective, there would be no genetic way to tell which woman the eggs came from. If a son, for example, was born from one of these eggs, could it not be assumed that, when he grows up, he may want to know which twin's egg was fertilised to bring him into existence? This would happen even though both women produced similar eggs from a genetic perspective. It would surely be important for the child (and the mother) to know which of the eggs was actually used. This means that it is not only the chromosomes or what is found in the genes that matters but also the fact that a certain person brought into existence a certain child through cause and effect.⁴ In other words, that a certain life brought into existence another life.

This is important since it also reflects the manner in which historically, and just until a few decades ago, individuals have understood who their ancestors or offspring were in matters, for example, of the inheritance of a crown. At that time, no one knew of the existence of chromosomes nor did anyone understand the manner in which biological heritage functioned but they did comprehend that a certain life brought into existence another life.

Again, it was never so much chromosomes or genes that mattered in a historical context but the fact that a certain person brought into existence another through cause and effect.

With Maternal Spindle and Pronuclear Transfer the same understanding would exist. In other words, parenthood cannot just be reduced to chromosomes. Instead it is all those who are the cause, including from a biological perspective, of the existence of a child (including the egg donor) who can be considered as parents.

Implications for Personal Identity

It is noteworthy that as soon as persons become aware of their existence and are not affected by any serious mental disorders, they usually ask themselves questions about who they are. Of course, the answer to such questions may continually be changing and the quest for identity may never really reach a final conclusion.

But one of the most important aspects of this identity is related to a person's understanding of his or her origins of existence. For example, individuals may want to identify who caused them to exist (and their ancestors) as well as their biological, social and cultural origins in seeking to recognise, understand and make sense of who they really are.

⁴ Another example is if an adoptive child seeking out his biological father discovers that there is a match for paternity with a certain man but then discovers that this man is not his father but the twin brother of his biological father. The discovery that this man is, in fact, his uncle will be a matter of great significance even though the genetic heritage of both twin brothers is the same. What the child in search of his biological identity is seeking is not merely genetic information of a certain kind but also the truth about the manner of his conception, information about the relationship between his biological father and mother, his kin, siblings, grand-parents, and a great deal more. Jacqueline A. Laing, *Artificial Reproduction, Blood Relatedness, and Human Identity*, *The Monist*, Vol. 89, No. 4, (p 548-566). p. 551-552.

When parents, children or other relatives, who have been separated for some reason, eventually seek to re-connect with each other, their reasons for doing so are often difficult to articulate. They frequently struggle themselves to understand what they are actually looking for though they do recognise that it is something which, to them, is very important. In some cases, of course, they would like to know if they are at risk of having a genetic or other biological disorder but many studies indicate that they are also doing this out of 'curiosity' which may reflect a deeper reason such as a search for identity, to know more about themselves or 'emotional significance'.

It is indeed recognised that people, who do not have any genealogical roots, may often experience a deep sense of genealogical void or bewilderment; of being cut off from the causes and reasons for their existence which helps them build their identity.

As a result, individuals usually regard these ancestors and family relatives as being a single community who are 'cemented' together. For example, children realise that their existence originated from the personal existences of their ancestors and that their own existence is inherently tied to these previous existences. Without these parents or ancestors they would not exist. As a result they begin to understand that a long chain of ancestors resulted in their existence. It is as if one large communion between the child and his or her ancestors was present, in a kind of single block, who are all the cause of each other's existences down the ages (the cause may be genetic, gametal such as an emptied egg or something else). People appreciate that because they actually exist because of all their forefathers they owe their existence to them in some way. There is a sense of being dependent on, and even belonging to, these earlier existences. That all these past existences are seen, in some way, as part of the 'whole' existence of the child. The child knows that he or she only exists because of his or her ancestors and the prior continuum of descent.

In some form, all these existences come into a kind of communion in which there are deep relationships of unconditional acceptance but also responsibility. And this communion does not only exist between parents and their child but with grandparents, siblings, cousins and other family members.

With natural reproduction, the 'real' creators and the chromosome providers are the two same persons. However, with a number of new fertility procedures, such as the one being proposed, the identity of the 'real' creators becomes very complex and may vary quite considerably. Thus, a real risk exists that the future child may be confused as to the manner in which he or she understands who his or her creator parents really are. This may be important for him or her to establish a healthy sense of identity.

The UK Department of Health mentions in its consultation that:

“1.24 The dominant DNA (the nuclear DNA) in any child born from these new techniques would be that of the mother and the man providing the sperm (usually the father). Although it would be the case that DNA from three people (the mother, the man providing the sperm and the egg donor) would be present in the child, only a tiny percentage of the child’s DNA would come from the egg donor. Most importantly, the residual DNA from the donor would only be mitochondrial DNA so would not affect the resulting child’s personal characteristics and traits. This is because mitochondrial DNA only contains genes that are essential for normal mitochondrial function; personal characteristics and traits are derived from the nuclear material.

1.25 This was reflected in the HFEA’s report of its public dialogue, in which most contributors rejected the “three parent IVF” idea for these reasons. The Nuffield Council on Bioethics report similarly said that “mitochondrial donation does not indicate, either biologically or legally, any notion of the child having either a third parent or a second mother”.

1.27 The proposed mitochondrial donation techniques only allow for unaltered nuclear DNA to be transferred to an egg or embryo that has unaltered healthy mitochondria. The key consideration is that these techniques only substitute, rather than alter, a very limited number of unhealthy genes in the “battery pack” of the cells with healthy ones. Most importantly, mitochondrial donation techniques do not alter personal characteristics and traits. As the aim is that children born as a result of mitochondrial donation, and their offspring, would be free of

serious mitochondrial disease, it would though be a form of germ line modification or germ line gene therapy, as recognised by reports produced by the HFEA and the Nuffield Council on Bioethics.”

In response, the SCHB notes that the HFEA and Nuffield Council on Bioethics were wrong to suggest that “*mitochondrial donation does not indicate, either biologically or legally, any notion of the child having either a third parent or a second mother*”. They misunderstand the very concept of kinship which cannot be reduced to the personal biological characteristics and traits of a person but must also include his or her personal identity. An appropriate appreciation of the meaning of kinship, and how this strongly influences the manner in which a person understands his or her identity, is reflected in the above discussion.

Part of the identity of a person is based on knowing his or her origins including who was responsible for bringing him or her into existence (i.e. the parents). This cannot be reduced to the origins of the chromosomes but must also take into account all those who were the original cause of a person’s life and existence.

A broad societal discussion concerning the relationship between ‘being a creator’ and parenthood while trying to understand these parent-child bonds is, therefore, necessary when the creation of human life by novel means is contemplated. After all, it is because these creator-creature bonds are seen as extremely important by many couples that they are seeking fertility treatment and making sure that they have a child ‘of their own’.

Question 6: Regulation 10 provides that the HFEA should tell a person aged 16, on request, if they were born following mitochondrial donation. Do you agree with this?

Scottish Council on Human Bioethics Response

The SCHB agrees that the HFEA should tell a person aged 16, on request, if they were born following chromosomal transplantation.

Question 7: Regulation 10 also provides that the information that the HFEA should provide in response to such a request should not identify the mitochondrial donor and be limited to screening tests carried out on the donor and about her family medical history, and any other non-identifying information that the donor has provided with the intention that it is made available in these circumstances. Do you agree with this approach?

Scottish Council on Human Bioethics Response

The SCHB disagrees with this approach. The HFEA should provide in response to a request from a person born from Maternal Spindle and Pronuclear Transfer identifying information for all the individuals responsible for bringing him or her into existence. This includes all the egg donors as well as the man who participated in creating the healthy embryo in pronuclear transfer. This is because the person born from MST and PNT may consider all these 3 or 4 persons as his or her biological parents and he or she may want to know, or even have a relationship with, them in order to develop a healthy psychological identity.

Question 8: Regulation 13 provides that the HFEA should tell a mitochondrial donor, on request, when a child has been born from their donation, how many and their sex. Do you agree with this approach?

Scottish Council on Human Bioethics Response

The SCHB agrees that the HFEA should inform, on request, a person who participated in biologically bringing into existence a child when this child has been born and their sex.

Question 9: Do you have comments on any other aspect of the draft regulations?

Scottish Council on Human Bioethics Response

Traditional human procreation does not take place out of thin air. It takes place through the participation of the man and the woman as whole persons. More specifically, this participation takes place through the means of reproductive cells (sperm and egg cells).

In this regard it is important to consider how these reproductive cells can be understood in the context of reproduction. This is not an easy matter but, generally, each reproductive cell may be considered as a kind of representative of each of the partners in the procreative process. As such, each sperm cell becomes a representative of the whole man and each egg cell becomes a representative of the whole woman.

When parents procreate in a normal way they also give of themselves wholly and unconditionally in the sense that it is not only a portion of the procreating person that takes part in the procreation. It is the whole person that takes part. In other words, when partners participate in the act of procreation they give of themselves to, and accept, the other partner totally, completely and unconditionally in their entire existence. The procreators do not withhold anything from themselves.

This means that when sperm and egg cells participate in the creation of a new person, they express the complete fusion of the whole persons, the parents, from whom they were produced.

When sperm and egg cells participate in the creation of a new being, they can then be considered as 'ambassadors' in the same way as a political ambassador represents, in his or her person, the whole of a country.

Moreover, it should be recognised that the unreserved acceptance between the partners with all their gifts and limitations should also 'expand' onto the child. This means that when partners in a couple accept each other for 'better or for worse' including all their biological disorders, they should unconditionally accept any child resulting from their relationship. This includes all the child's potential disorders, since he or she is brought into existence by the unconditional acceptance of the partners' sperm and egg cells which represent them.

Of course, sperm and egg cells have no moral value of their own but when they come together to form an embryo, their representative wholeness cannot in any way be dismissed as unimportant. On the contrary, it is fundamental since it is the reproductive cells that are the means for procreating another specific 'whole' living child.

This also means that if the sperm and egg cells were significantly modified in a technical manner, such as with Maternal Spindle Transfer, questions can be asked whether they would still represent the wholeness of the partners from whom they originated. Would they not be seen, instead, as being foreign in the same way as if the reproductive cells of a foreign man or woman (i.e. from outside the couple) were used? The procreative process may then be taking place with reproductive cells that no longer represent the partners and could be seen as an intrusion into the exclusive relationship of the couple.

Parents want children of their own

The desire by parents to have children 'of their own', or at least as much as possible 'of their own', is the driving force behind the popularity of fertility clinics throughout the world.

In addressing the issues raised by the regulation of Maternal Spindle and Pronuclear Transfer, it is very important to examine the deep bonds that exist between parents and their offspring. For example, many parents, as the responsible partners in the creation of life, know intuitively that they belong to the child and that the child, in receiving life, belongs to them, i.e., there exists a sort of mutual belonging.

The deep sense of loss or incompleteness felt by parents who are unable to be directly responsible for the creation of life in their child is one of the underlying reasons that many seek assisted reproduction rather than adoption. In other words, the fact that prospective parents even consider, let alone undergo, expensive procedures for artificial reproduction indicates the importance they attach to the

biology of creation. Such parents are aware, even if subconsciously, that the lack of biological connection may prevent them from feeling a sense of belonging with the child or the child with them.

From a sociological perspective, MST and PNT are being proposed because couples want children of their own. But that is exactly not how the children may see it.

The children born from these procedures may not accept that they only have two parents.

Instead they may want to know and have parental relationships with all the 3 or 4 persons who brought them biologically into existence.

The SCHB has a lot of sympathy and compassion for the persons affected by mitochondrial disorders who are being promised MST and PND as a means to having their own children since they are being misguided about the ability of these procedures to give them children 'of their own'.

It may also be the case that parents who use Maternal Spindle and Pronuclear Transfer may be bringing a child into the world for their own sakes without fully considering the eventual wishes of the future child. That is, the child may want to know and/or have a relationship with all his or her biological parents. Though the social or chromosomal parents may concede to tell their child the truth when they are older, they would then have to understand that the child may wish to see and know his or her gametal parent(s) (the donor(s) of the eggs or the fertilised eggs) and express a sort of affection which he or she may already experience. The child may also experience difficulties towards his or her chromosomal or gametal parents with the possibility of feeling a sense of rejection.

Therefore, the possibility of promoting chromosomal transplantation in order to address mitochondrial disorders should not be envisaged until the two following questions have been satisfactorily addressed:

- the wish most couples express for a child of their own, and
- the important bonds that exist between the biological parents and the child.

If it remains unclear why parents want to have a child of their own, then it remains unclear why Maternal Spindle and Pronuclear Transfer should even be contemplated.

Maternal Spindle and Pronuclear Transfer Contravenes International Law

The SCHB notes that the techniques on offer are not about treating people who are ill but about shaping future children and generations. It is also of the opinion that there are serious social and ethical implications to changing the germ line in the way proposed by Maternal Spindle and Pronuclear Transfer.

Because parents would be intervening, with intent, into the genome (i.e. the complete set of genes, including chromosomal and mitochondrial genes) of their children in Maternal Spindle and Pronuclear Transfer, the procedures could be considered as germ-line interventions. This means that genetic modifications may be passed on to a child and all subsequent descendants.

It would be the first time such intentional genetic modifications of descendants is considered and would open the door to further genetic alterations of human beings with unforeseeable consequences. Thus, for the UK to go it alone, without consulting its international partners, and allow both these procedures would create a very serious precedent. It would open the door to germline interventions and result in grave risks for the future.

The SCHB notes that any intervention seeking to modify the human genome of a person before he or she is created is contrary to international law, including the three following legal instruments:

(A) The United Nations Education, Scientific and Cultural Organization (UNESCO) - *Universal Declaration on the Human Genome and Human Rights* (Adopted on 11 November 1997) indicates that:

Article 24: That 'germ-line interventions' could be considered as a practice that would be 'contrary to human dignity'.

(B) Council of Europe (47 Countries) - Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To The Application of Biology and Medicine (ETS – No. 164, Entered into force on 1 December 1999) indicates that:

Article 13 – Interventions on the human genome

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.

In this regard, the Explanatory Report for Article 13 mentions that:

“91. Interventions seeking to introduce any modification in the genome of any descendants are prohibited. Consequently, in particular genetic modifications of spermatozoa or ova for fertilisation are not allowed. Medical research aiming to introduce genetic modifications in spermatozoa or ova which are not for procreation is only permissible if carried out in vitro with the approval of the appropriate ethical or regulatory body.

92. On the other hand the article does not rule out interventions for a somatic purpose which might have unwanted side-effects on the germ cell line. Such may be the case, for example, for certain treatments of cancer by radiotherapy or chemotherapy, which may affect the reproductive system of the person undergoing the treatment.”

(C) The EU (27 Countries) Directive on clinical trials (2001/20/EC)

This states in Article 9(6) that:

“No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity.”

Bearing in mind the UNESCO, Council of Europe and European Union Statements it would be very important to spell out the international implications of the UK unilaterally pursuing germline genetic engineering. For any female offspring conceived using such techniques in the UK, questions arise relating to the limits that might be necessarily placed on their reproductive freedoms should they choose to eventually live in other countries in order to prevent germline alterations being transmitted beyond national borders.

Furthermore, for the Department of Health to consider allowing MST and PNT without undertaking any safety investigations so that it does not come under the definition of a clinical trial (and therefore not governed by the Clinical Trials Directive) would very likely be seen as irresponsible and even reckless by the general public.

The UK Department of Health mentions in its consultation that:

“1.28 Some commentators have suggested that the introduction of mitochondrial donation might conflict with some provisions of international law.

1.29 In bringing forward regulations to enable mitochondrial donation we have been mindful of the UK's obligations under international law. We do not consider that permitting mitochondrial donation, aimed at preventing serious hereditary conditions, would be contrary to human dignity as envisaged by Article 24 of the UNESCO declaration.

1.30 It is important to note that the UK Parliament has expressly provided for the possibility of regulations enabling mitochondrial donation and that it is our view that this power is compatible with the European Convention of Human Rights.”

In this respect, the SCHB is of the opinion that making sure that only certain persons are brought into existence in a eugenic manner significantly undermines the very basis of human equality and human dignity.

Furthermore, the SCHB disagrees that MST and PNT is compatible with the European Convention on Human Rights. Should a case be brought to the European Court of Human Rights (ECHR) related to MST and PNT, it is inevitable that the judges of the ECHR will base their decision on Article 13 of the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To The Application of Biology and Medicine (see above).

Maternal Spindle and Pronuclear Transfer Represent Eugenic Practices

Both MST and PND could be considered as different forms of eugenic practices since the genome of future children are being intentionally modified through the procedures. Eugenic procedures are defined as strategies or decisions aimed at affecting, in a manner which is considered to be positive, the genetic heritage of a child, a community or humanity in general. As such they would contravene Article 3 of the **Charter of Fundamental Rights of the European Union** (Proclaimed in Nice on 7 December 2000) which indicates that "*In the fields of medicine and biology ... the prohibition of eugenic practices, in particular those aiming at the selection of persons*" must be respected.

When a eugenic choice between bringing into existence a disabled or non-disabled person is being considered, it is impossible to separate these persons from their physical characteristics. Any choice in this regard which then becomes public will be seen as very significant by the disabled community since it would suggest that they should also not exist. Even once they are born, the very identity of persons and the manner in which they understand themselves as individuals cannot be dissociated from their physical characteristics. In summary, there is a real danger of discrimination to suggest that disabilities, which cannot be separated from persons, should not be brought into existence. This is because the disorder's existence cannot be dissociated from a person's existence. Instead, it is all persons with or without a disability who should be able to be brought into existence without favouritism, discrimination or bias. In other words, saying that a disorder should not exist, should never mean that a person with such a disorder should not be brought into existence.

Maternal Spindle and Pronuclear Transfer Involves the Destruction of Embryos

The SCHB notes that a significant ethical question would arise if human embryos are destroyed during this procedure.

In this regard, the **UK Human Fertilisation and Embryology Act 2008** defines an embryo in Article 1: (1) (b) as: "*an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.*"

For Maternal Spindle and Pronuclear Transfer to be accepted for clinical use, it is unavoidable that many human embryos will be created solely for research purposes that will, eventually, be destroyed. This creates a serious ethical problem since the **Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with Regard To The Application of Biology and Medicine** (ETS – No. 164, Entered into force on 1 December 1999)⁵ indicates that:

Article 18: The creation of human embryos for research purposes is prohibited.

In this regard, the Explanatory Report for Article 18 mentions that:

"116. The article does not take a stand on the admissibility of the principle of research on in vitro embryos. However, paragraph 2 of the Article prohibits the creation of human embryos with the aim to carry out research on them."

At present, out of the 47 countries of the Council of Europe only **two member states** (the United Kingdom and Belgium) have publicly indicated that they have no intention, at present, of signing or ratifying this convention. This is because, amongst other things, it would prohibit the creation of human embryos for research through cloning or other procedures (which the UK has already legalised) so that experiments can take place on them for up to 14 days after their creation.

⁵ This is a legally binding document when ratified by a country. So far, 29 Member States have ratified this Convention with another 5 signing their intention to ratify. The UK has not signed or ratified this Convention.

Furthermore, if Pronuclear Transfer were to be accepted as a form of routine treatment and because UK law defines an embryo as “an egg that is in the process of fertilisation”, the procedure would require that at least two embryos are destroyed, each time, to reconstruct a third embryo with new healthy mitochondria. This would be seen as deeply offensive and unacceptable to the millions of people in the UK who believe that personal life begins at the moment of creation of the embryo.

Further Risks with Maternal Spindle and Pronuclear Transfer

It should also be noted that assisted reproduction is not risk-free for the woman giving the eggs since egg retrieval procedures may risk ovarian hyperstimulation syndrome following aggressive hormonal treatments.

Conclusion

The SCHB is of the opinion that the law should not be changed to allow Maternal Spindle and Pronuclear Transfer to take place. This is because, the proposal is:

- misleading the general public through the use of the term ‘mitochondrial donation’
- too early
- contrary to international legal instruments
- unclear with respect to consequences
- genetic engineering which alters the gene line irrevocably
- a precedent that will lead to further engineering and designer babies
- a suggestion that creates far more problems than it could ever hope to solve, even if the technology does what it says it will do.

Finally, the SCHB notes that new alternatives to both Maternal Spindle and Pronuclear Transfer are already being pursued by scientists in the treatment of mitochondrial disorders which can be considered as far less controversial.⁶ These should be examined and developed instead of considering Maternal Spindle and Pronuclear Transfer.

⁶ Anonymous, Correcting human mitochondrial mutations, 13 March 2012, e! Science News, <http://esciencenews.com/articles/2012/03/13/correcting.human.mitochondrial.mutations>, (Accessed on 20 August 2012).