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**The Need for Donor Consent in Mitochondrial Replacement**

Abstract:

Mitochondrial replacement therapy (MRT) requires oocytes of women whose mitochondrial DNA will be transmitted to resultant children. These techniques are scientifically, ethically and socially controversial; it is likely that some women who donate their oocytes for general IVF usage would nevertheless oppose their genetic material being used in MRT. The possibility of oocytes being used in MRT is therefore relevant to oocyte donation, and should be included in the consent process when applicable. In present circumstances (especially because MRT is still an emerging technique) specific consent should be obtained. However, once MRT becomes more routine such consent could be incorporated into the general consent process for oocyte donation. The alleged lack of fully informed consent for MRT from the oocyte donor in the first baby born via the technique would, if accurate, be an ethical failing and should be avoided in any future practice of MRT.

Keywords: Mitochondrial Replacement; Informed Consent; Oocyte Donation; IVF

**Introduction**

In a historic development, the first child produced via a mitochondrial replacement therapy (MRT) was born in late 2016. [1] This technique involved removing the maternal spindle[[1]](#footnote-1) from an intended mother’s oocyte and a donor’s oocyte, but leaving the mitochondria behind. The maternal spindle from the intended mother’s oocyte was then inserted into the enucleated oocyte of the donor.

The resultant child thus had nuclear DNA from its intended mother and father, but mitochondria from an oocyte donor. The aim was to allow the mother to have a child with whom she was genetically related, without risking transmission of a condition called Leigh’s Syndrome. Leigh’s Syndrome can be transmitted from mothers to their children due to mutations in mitochondrial DNA.[[2]](#footnote-2)

However, this particular use of MRT came under almost immediate criticism. Mexico was seemingly chosen because it was a relatively unregulated environment – the fertility specialist involved reportedly said he chose Mexico because “there are no rules”. [3] Mexican statutes that would prohibit the procedure were not engaged because the mitochondrial transfer itself occurred in vitro in the US, while the resultant embryo was then exported and implanted in Mexico. [4,5] Though the child was healthy, the procedure actually involved some carryover of potentially disordered mitochondrial DNA from the intended mother.[[3]](#footnote-3) [6] Some have questioned whether there was IRB approval for the whole protocol (split between the US and Mexico) or just the in vitro portion occurring in the US, [7] though Zhang has insisted that proper IRB approval was obtained. [8] And recently the FDA has sent a letter to the fertility specialist involved, demanding that he notify the agency of the steps he has taken or intends to take to address a “violation” of its rules in relation to his marketing of MRT in the US, and his exportation of altered embryos. [9]

But most important for this article’s purposes is the allegation that the oocyte was obtained from a general pool of anonymous oocyte donors who apparently were not informed of the particular possibility of MRT. In an editorial accompanying the publication of the live birth, the editors noted:

Although the egg donor reportedly signed a standard egg donor consent form, a copy of this form received by RBMO shows that the use of the donated eggs specifically for spindle transfer (for MRT) is not mentioned. [10]

In this article, I will argue in favour of ensuring oocyte donors give adequate informed consent for MRT. Informed consent could potentially take different forms, such as being part of a larger disclosure of potential uses of donated oocytes, or being given an option to opt in/out during the donation process. However, given the sensitivities involved with MRT, specific consent from mitochondrial donors should be obtained. Direct solicitation of donors solely for MRT is most preferable, though other forms of consent that discuss MRT are still superior to a generic oocyte consent process that does not mention MRT.[[4]](#footnote-4)

The present argument relates to a broader question of whether oocyte donors should be informed of the potential research uses of resultant embryos, particularly controversial procedures like embryonic stem cell research that necessitates the destruction of the embryos. [13–16] MRT, like embryonic stem cell research before it, is a controversial procedure that may raise serious objections from potential oocyte donors. And even for less controversial research uses, it is good practice to let oocyte donors know that excess resultant embryos may be used for research rather than clinical purposes.[17] Due to these similarities, the below argument for donor consent in MRT applies roughly the same reasoning used in the literature defending requirements for gamete donor consent for embryonic research: the information is relevant to many woman’s decision to donate, and as such should be disclosed during the consent process. This in turn relies on a more general principle that the consent process should include transmission of potentially relevant information. But with MRT, there is arguably a more pressing need for donor consent, as MRT is a very novel method many donors will be unfamiliar with, and has caused considerable international controversy.

**Informed consent and oocyte donation**

As a pillar of ethical clinical care and research, requirements for informed consent appear in numerous national and international regulatory and guidance documents.[18–22] A wide variety of accounts of the nature and grounding of informed consent have been given,[23–26] but these are outside the scope of this argument. For present purposes we will assume the value and importance of informed consent, and focus on how serves at least two functions: to respect patients’ autonomy and protect them from undue harm.

The process of oocyte donation is not trivial. It is time-consuming and requires donors to take a series of medications that can cause significant side-effects, including fatigue, mood swings, sleep problems and bloating. [27] About one in twelve donors will have minor complications requiring medical attention, with a further 0.7% experiencing serious complications like ovarian hyperstimulation syndrome, infections or ruptured ovarian cysts. [28] It also involves being the genetic parent of an individual one may never meet, let alone have a relationship with. Donors must weigh these significant costs against any compensation provided for the donation, as well as the potential to greatly benefit a family struggling with infertility.

By informing oocyte donors of the purpose and use of her oocytes, the consent process enables women to choose whether these risks and burdens are worthwhile. This may not just be a cost/benefit analysis, but also a question of whether the decision reflects her values and worldview. Even if how the oocyte is used would not affect the donor, she has an interest in ensuring that use is one she is generally comfortable with.

Framed differently, oocyte donors should be provided with all material information in order to make a decision. Material information is information that, if provided, could potentially influence a given decision – in this case the donation of oocytes.[[5]](#footnote-5) Failure to provide material information may invalidate informed consent, since information that could influence a decision was withheld. This is not a mere theoretical concern – withholding of material information can harm oocyte donors, insofar as they are induced to undergo burdens they might have avoided had they been fully informed of how oocytes may be used. Similar concerns over potential harms and violations of autonomy undergird calls for donors to be informed of possible research uses and destruction of resultant embryos.[13,15]

A key part of communicating material information will be appreciating donors’ reasonable expectations, and ensuring those expectations align with what is actually going to happen to their oocytes. This will mean provision of information about MRT only makes sense for fertility clinics that engage in MRT, which at present is a very small number. But if a clinic begins to open the door to MRT, it must ensure its consent process is amended at the same time.

Beyond provision of information, the informed consent process may also afford donors a greater or lesser degree of control over how their oocytes will be used. Donors have an interest in this control for the same reason they have an interest in provision of information: to ensure that the donation of oocytes is indeed worth the risks and burdens, and to ensure it is aligned with their values. One key way different practical approaches to consent discussed below differ is in terms of how much control is afforded to donors.

**Potential donor objections**

We then must establish whether the possibility of an oocyte being used in MRT is material to the decision to donate. Some evidence may be found in a recent study by Kristin Engelstad and colleagues, which surveyed American women who had donated oocytes for standard IVF treatment (along with potential recipients) about their attitudes concerning MRT. 87% expressed willingness to hypothetically donate their oocytes for MRT, with 13% unwilling.[29] Support for MRT among potential donors is therefore high – but not universal. Put another way, these numbers suggest that there is perhaps a 13% risk that women donating oocytes for general IVF purposes would not want to do so for MRT. The exact number of donors who object to MRT will likely vary by context and culture, but the main point is that it will not be a trivial percentage.

But survey data only tells part of the story. To fully appreciate why we should inform potential oocyte donors of the possibility of use in MRT, we need to examine the reasons that underlie potential objections to MRT. Theoretically, some information that is material to a decision to donate may nevertheless be permissibly withheld because its provision would be pernicious. (see Footnote 4 above)

Some objections to MRT are medical or scientific – as the approach is nascent and experimental, there are worries that something could go wrong. In particular, there is a risk of mitochondrial carryover causing mitochondrial disease in resultant children even after the procedure is used. Or the procedure could have other damaging effects on oocytes that cause problems not yet anticipated or foreseen. And these damaging effects could be passed on to future generations.

These risks to offspring do not accrue to the donor. Nevertheless, she may feel responsible for them by participating in a process that enabled the harms to come about.[[6]](#footnote-6) Participating in potentially risky research and causally contributing to as-yet-unknown harms may not be something she is comfortable with.

Other objections to MRT are social or ethical. An instructive consultation of over 1,800 individuals in the UK on the acceptability of MRT found a general divergence in opinion. [32] Ethical and social objections to MRT included that it:

* Involves the destruction of embryos (true of pronuclear transfer (PNT), the form of MRT approved in the UK, though not maternal spindle transfer (MST), the one used in Mexico)
* Involves playing God and overstepping our interference in natural processes
* Confuses natural genetic relationships by creating ‘three parents’
* Opens the door to ‘designer babies’ by allowing adjustments to the human genome

These objections are not frivolous or trivial, and may reflect core views about the value of life and the role of the ‘natural’.

Are those reasons suggested in the HFEA study applicable to oocyte donors? It might appear implausible, in particular, that such women would object to the destruction of embryos; it is quite common in IVF practice for excess or poorly formed embryos to be destroyed. Yet we shouldn’t take that understanding for granted – one study of oocyte donor consent forms in the US found that fewer than half of fertility clinics disclosed the possibility of embryo destruction to donors. [15] An oocyte donor might be unaware of this destruction, and based on an ethical objection to embryo destruction avoid donating. And it has recently been argued that there are potentially differential ethical objections to MST and PNT because only the latter necessarily involves embryonic destruction. [31] In light of this possibility, any consent regime discussed below should also specify whether the process might involve PNT, and thus destruction of an embryo, or MST, which does not necessitate embryo destruction.

The other objections involve features more unique to MRT. While IVF in general is unnatural, in a certain sense, mitochondrial replacement could be seen as a greater deviation from nature. Traditional IVF still involves insemination by one egg and one sperm; MRT goes well beyond that by involving a further transfer of a nucleus between oocytes or resultant embryos. This leads to the popular characterization of the resultant child as having three genetic ‘parents’, an unusual and unique phenomenon that could go well beyond traditional family structures that are preserved by IVF. While characterizing oocyte donors in MRT as ‘parents’ has been disputed, as mitochondria is a very small percentage of one’s overall DNA, [33], others have defended the three-parent characterisation. [34] And further worries may exist that MRT will open the door to eugenic pursuit of genetically enhanced beings.

For present purposes we need not adjudicate whether MRT actually involves three genetic parents, or whether having three genetic parents is indeed morally or socially objectionable. What matters here is that some donors will plausibly hold such views. That is to say, some donors might refuse to donate oocytes if they believed they might become a ‘third’ genetic parent. Just as we should respect the right of donors to donate in accordance with their own moral values, we should also respect their right to donate in accordance with their own metaphysical views about parentage.

There are, then, a variety of potential ethical, social and medical objections that oocyte donors may have concerning MRT. It is not possible with presently available data to assess exactly how many donors would have such an objection in all contexts, but the survey data and UK consultation cited above suggests this number would not be trivial. As such, in order to protect donors from undergoing a risky and burdensome procedure they would avoid had they been fully aware of the potential for MRT, oocytes should only be obtained from those who have been adequately informed of the possibility of MRT.

**Practical application**

The question now becomes: in what manner should informed consent be obtained for mitochondrial donors? There are at least three options for obtaining consent: Provide information; opt-in/out; and solicitation.

*Package deal:*

During the consent process for women donating oocytes for general use in IVF, they would be informed about the possibility their oocytes could be used for MRT. This should include more than a superficial statement or perfunctory discussion, but instead go into some of the risks and benefits of the experimental procedure, whether MST or PNT (and thus embryo destruction) might be employed, as well as the nature of the genetic contribution to the resultant child. Signing the donor consent form would be a ‘package deal’ that also gives permission for oocytes to be used in MRT.

Provision of information about MRT to oocyte donors should be considered a basic ethical minimum, if those oocytes might potentially be used in MRT. It provides the relevant material information to donors, who can then use that information to determine whether oocyte donation is still personally acceptable. However, it is somewhat *too* minimal, for two reasons.

One, by having the information combined with ‘standard’ oocyte donation information in donor consent materials, it can more easily be buried or overlooked as just more of the ‘fine print’. Conscientious IVF clinics could get around this by emphasizing the possibility verbally, but as a governance mechanism this may be unreliable and difficult for relevant oversight bodies to enforce.

Two, the ‘package deal’ aspect is somewhat problematic. Some donors may have moderate objections to MRT, outweighed by their support for more traditional IVF or the appeal of payments for their donation. This approach respects their ability to make this weighty choice in an informed manner, but it does not afford donors much control and may still expose them to unnecessary complicity in a process to which they object. This is unnecessary because the other two options do not tie donation to general IVF to donation for MRT.

*Opt-in/out:*

Under this approach, the above information would be provided, but there would be an option for women to choose whether or not to allow their oocytes to be involved in MRT. Oocytes could only be used in MRT from women who have explicitly said ‘yes’ (opt in), or if they fail to say ‘no’ (opt out) after being prompted.

The opt in/out approach avoids both the concerns with mere information provision, especially if donors must state either yes or no during the consent process – i.e., it is a forced choice. By forcing donors to make a choice, attention is called to the possibility of MRT. This may elicit more attention to the details surrounding MRT, and prompt queries for further information. It also prevents unwanted complicity by providing more control to the donor – a woman who objects to MRT can nevertheless donate her oocytes for general IVF purposes.

Still, nesting MRT in a broader consent form may lead to some details becoming obscured. Adding more and more information to consent materials may make the process unduly lengthy and burdensome; for practical reasons, it is likely that IVF clinics would have to keep the information preceding the opt in/out somewhat brief. MRT can take several forms (such as maternal spindle transfer, pronuclear transfer or polar body transfer), each of them involving complex biological processes and their own ethical nuances. A more thorough process would be desirable to ensure donors fully understand their options.

*Specific Recruitment*

Oocyte donors could be specifically recruited to participate in MRT, rather than oocytes obtained from the general oocyte donor ‘pool’. Consent materials specific to MRT would be given to women considering donation. Oocytes could only be used from women who gave their specific and express agreement to it, via this dedicated process.

Specific recruitment allows for a relatively robust consent process that might not be feasible with combining the consent process into general oocyte donation consent. The actual use of oocytes would be narrowly defined (including whether MST or PNT is to be employed), so more time can be devoted to how they will be used, the risks involved, and some of the concerns that may arise.

A major practical downside of the specific consent approach is that it requires more resources to be devoted when soliciting MRT donors. Rather than using a large existing pool of oocyte donors, clinics would have to specifically solicit women to participate in a very narrow intervention. However, given that mitochondrial disorders addressable by MRT are very rare, this extra recruitment should not pose an especially large burden on researchers. While some are opposed to MRT, many others are supportive and finding willing donors should not be very difficult.

A more troubling downside of specific consent is that may lead to extra cycles of ovarian stimulation and retrieval. Whereas the first two options draw on a pool of donors who have otherwise agreed to donate, this approach supplements that with a dedicated pool of MRT donors.[[7]](#footnote-7) This means more physical burdens for donors to undergo and risks for them to take.

Such extra cycles could be avoided by having potential donors undergo two full consent procedures simultaneously, for both regular IVF and MRT. The oocytes could then be made available for both procedures. But this process could unduly lengthen the consent process when, for the majority of donors, their oocytes would not be needed for MRT.

**Conclusions**

Requiring informed consent for mitochondrial donors is an intuitive application of standard biomedical ethics principles, just as oocyte donors should when applicable be informed of other controversial uses of resultant embryos such as stem cell research. However, the apparent failure to obtain proper consent for MRT from donors in the first child born via MRT is of significant concern. Review boards approving future protocols of this nature should ensure such donor consent for MRT is properly obtained.

This case also provides some ancillary, non-decisive reasons to favour regulated legalization of MRT. To avoid the prohibition on clinical trials of MRT occurring in the US, Dr Zhang was driven to use a cross-border approach (with oocyte donation occurring in the US, but implantation occurring in Mexico) to perform the experimental procedure. But this poorly regulated approach facilitated many of the allegations of problematic aspects of the procedure, including informed consent. [35] Contrast this with the UK, where by regulation donor consent for MRT must be obtained. By allowing the procedure to occur under regulation, the UK will ensure that MRT can occur in an environment that allows more appropriate stakeholder engagement and follow-up with those born.

This suggestion is somewhat familiar to one argument for legalizing abortion: prohibiting abortion simply pushes many women into procuring the procedure illegally, which is usually significantly more dangerous. As in that case, we shouldn’t take such arguments to be sufficient for regimes to permit MRT. The downside of incentivizing unregulated MRT abroad may be outweighed by the human and resource cost of allowing it in one’s borders. Nevertheless, driving MRT into unregulated environments where, among other things, proper consent may not be obtained is at least one consideration that should be considered as countries debate whether to follow the UK’s lead and offer MRT in a regulated environment.

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1. The maternal spindle contains the nuclear DNA that, when combined with the father’s sperm, will be passed on to the resultant child. Mitochondrial DNA by contrast is passed entirely from the mother’s mitochondria alone. Nuclear DNA accounts for the great majority of our inherited genetic material, but mitochondrial DNA plays an important role in cellular energy generation. [↑](#footnote-ref-1)
2. MRT may also be used as an infertility treatment; indeed, the second case of MRT in the Ukraine was for such a purpose, and also involved a relatively unregulated environment [2], though the donor consent regime has not been reported. All the arguments in this paper are meant to apply to MRT for either fertility or disease prevention purposes; the precise purpose of MRT should be a part of the consent regime advocated below. [↑](#footnote-ref-2)
3. While the amount of carryover may be small, it presents some risk of emergence of the disorder later in life, as well as transmission to future generations. [↑](#footnote-ref-3)
4. This article will focus on the use of ‘fresh’ donated oocytes, rather than stored oocytes. Current evidence suggests superior clinical outcomes with the use of ‘fresh’ oocytes, and as such it should be preferred in the near term.[11,12] But if stored oocytes are to be used, the arguments contained here imply that re-consent would be appropriate. While at the point of donation of stored oocytes risk to the donor has passed, it is nevertheless disrespectful to use donated oocytes in a manner for which donors did not consent. [↑](#footnote-ref-4)
5. It might be argued that some material information may be permissibly withheld if its provision would be pernicious. For example, some donors could have racist views and would prefer to only direct donations to benefit those of their own race. It may seem problematic to accede to such pernicious demands for information. Two points may be made in response. One, respecting autonomy may require acceding to pernicious preferences – just as we must respect the racist patient’s decision to refuse care from physicians of particular races. Two, none of the objections to MRT discussed in the next section are pernicious. Therefore, even if we accept this potential exception to the materiality rule in informed consent, it does not apply to the present case. [↑](#footnote-ref-5)
6. Tina Rulli has argued that MRT to prevent transmission of mitochondrial disease cannot be said to benefit resultant children, because the process itself affects the identity of the resultant child; it does not prevent mitochondrial disease in a particular child, but instead causes a child without mitochondrial disease to be born instead of a different child with mitochondrial disease. (Rulli, 2017; see also Palacios-González, 2017) A similar point could be made, that no child is harmed by failed MRT that results in children with mitochondrial disease. Nevertheless, what is relevant here is not whether harm was caused to a particular individual, but rather whether the donor may feel complicit in a bad outcome. Non-identity arguments like Rulli’s are unlikely to assuage this perception. [↑](#footnote-ref-6)
7. This issue might be obviated if MRT donors would have instead donated to a general pool, had MRT not been available. But specific recruitment for MRT could also attract donors who would not otherwise consider donating, perhaps because of the novelty of the procedure or more effective marketing techniques adopted to a dedicated MRT research project. [↑](#footnote-ref-7)