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Can reproductive genetic manipulation save lives?

Abstract:

It has recently been argued that reproductive genetic manipulation technologies like mitochondrial replacement and germline CRISPR modifications cannot be said to save anyone’s life because, counterfactually, no one would suffer more or die sooner absent the intervention. The present article argues that, on the contrary, reproductive genetic manipulations may be life-saving (and, from this, have therapeutic value) under an appropriate population health perspective. As such, popular reports of reproductive genetic manipulations potentially saving lives or preventing disease are not necessarily mistaken, though such terminology still requires further empirical validation.

Keywords: life-saving; CRISPR; mitochondrial replacement therapy; gene modifying technologies

**Introduction**

There is a lively debate over the reproductive use of reproductive genetic manipulation technologies (rGMTs) such as mitochondrial replacement techniques (MRT) and gene editing via CRISPR raging in academic circles as well as the popular media. Both popular and academic contexts are important. As nations deliberate over whether to legalise these controversial interventions, as the UK has done in the case of MRT, (Le Page 2016) media discussion in democratic societies contributes to citizens’ critical examination of the relevant arguments and in turn affects the pressure they put on their representatives to enact appropriate policies. Those media reports frequently rely on comment from bioethicists, who have been discussing the issues in more detail and can provide informed arguments for the relevant positions in the debate. Ideally, then, the two can feed into one another – media discussions incorporating academic debates, and academic debates taking into account popular confusions and concerns in their own writings to provide further clarification and ensure more nuanced discussion of the issues.

In this context, it is quite relevant that media reports have often framed rGMTs as potentially saving lives threatened by heritable disease. (Shoot 2015; Hamzelou 2016; Joseph 2016; Ali 2018; He 2018) ‘Life-saving’ language arguably bolsters the argument for rGMTs by making it analogous to other experimental medical treatments that are often deemed acceptable, even if risky, due to their great prospect of benefit. And some bioethicists have endorsed similar language in popular as well as academic publications. (Caplan 2015; Savulescu et al. 2015; Wrigley et al. 2015; Mintz et al. 2018) This may include the term ‘life saving’ itself, or other benefit-based language such as ‘therapy’, ‘treatment’, ‘prevention of disease’ and so forth.[[1]](#footnote-1)

Some have critiqued certain forms of rGMT on the grounds that it affects the identity of resultant children, and so cannot be said to benefit them. (Zohar 1991; Wrigley et al. 2015) While this concern has previously met with pushback in the literature (Elliot 1993; Holtug and Sandøe 1996), it will not be examined in great detail here. One difficulty with the non-identity objection is that it proves too much. Widely adopted novel technologies such as the introduction of smartphones or vaccines are generally identity-affecting due to the direct or indirect impact they will have on society, including individuals’ reproductive actions and choices. As Tina Rulli has recently noted, accepting the non-identity problem would have the unpalatable implication of being unable to critique the impact of widely adopted technologies on well-being. (Rulli 2017)

However, after side-stepping the issue of identity, Rulli offers a novel argument that, in the context of preventing heritable genetic conditions via rGMTs, talk of saving lives and related language is mistaken. On her view, the concept ‘saving lives’ requires that, counterfactually, someone would die earlier without the intervention. Because is not inevitable that someone would die if rGMTs were unavailable, rGMTs do not save lives. (Rulli 2017; Rulli 2019)

Against this, I will argue that Rulli is mistaken to dismiss life-saving-talk on counterfactual benefit grounds. In the first instance, it is not clear that the counterfactual condition is required for an intervention to be considered life-saving. The counterfactual may be relevant, though, in establishing the magnitude of an intervention’s therapeutic value.

The intervention of choice makes evaluating that counterfactual difficult if not impossible in individual cases. However, we can adopt a more expansive notion of ‘lives saved’ that is probabilistic, factoring in the possibility that no one will be saved (or otherwise benefitted) by a given instance of rGMT. This probabilistic sense of ‘saving lives’ is appropriate because it coheres with claims of major, society-altering interventions that save lives. It also retains a central, accurate and morally relevant implication of ‘saving lives’ and related language: uptake of rGMTs could lead to a reduction in mortality and burden of disease.[[2]](#footnote-2) This language, though, is contingent on there being an actual reduction in mortality and burden of disease – a claim that requires further empirical validation.[[3]](#footnote-3)

**The brief explanation for how rGMTs ‘save lives’**

Some women with significantly disordered mitochondria are at high risk of passing that disorder onto their children (mitochondrial DNA is entirely inherited from mothers). MRT has primarily been designed as a means to ensure that women affected by significant mitochondrial disorders can have healthy children of their own (though the techniques have also been applied to more general cases of infertility). (Wolf et al. 2015) One form of MRT accomplishes this by transferring nuclear (but not mitochondrial) DNA from the intended mother’s oocyte into a healthy donor oocyte with nuclear DNA removed. The oocyte is then fertilized in vitro. (Amato et al. 2014) Another form transfers nuclear DNA from an embryo created by fertilizing the intended mother’s oocyte, into an embryo created by fertilizing by a different, mitochondria-disease free oocyte. (Craven et al. 2010) These techniques may be said to be life-saving because the resultant child would (if the process is successful) not inherit a devastating and potentially fatal mitochondrial disease.

The potential life-saving uses of directly altering the DNA of embryos via CRISPR or a similar technique are substantially wider. One use is to prevent the inheritance of monogenic disorders, especially in cases where preimplantation genetic diagnosis (PGD) yields too few disease-free viable embryos or is not viable for other reasons. (Daley et al. 2019) More prospectively, PGD is of limited utility for diseases with at a polygenic basis – where onset is affected by multiple genes. Advanced applications of CRISPR could be used to edit multiple genes at once to minimise the likelihood of a disease occurring later in life. (Campa et al. 2019) In either case, the result is similar as with MRT – the prevention of (in some cases, life-threatening) disease in resultant children.

**The case against ‘saving lives’**

Rulli offers the following two-part definition:

For an intervention *X* to count as a treatment or cure, in addition to it being the case that (a) if *X* is administered, it will help soothe, heal, or remedy someone’s illness, it is also the case that (b) if *X* is not administered, a person will suffer more or die earlier than if it had been. (Rulli 2019, 1076)

(b), the counterfactual condition, is crucial for her argument that rGMTs do not save lives. It is easily met for traditional cures and treatments, where there is an existing person who would be benefitted by an intervention (if it is indeed effective). They would be worse off without the intervention than if the treatment had been administered. This is not a simple conceptual point, but of great moral importance: the fact that *someone is greatly benefitted* by an intervention is a very strong reason to allow the intervention, or invest resources to generate such interventions. And if *someone’s life is saved* by an intervention, this creates a sense of urgency that will provide even more reason to allow it, as well as justify greater resources for research and development.

The difficulty for rGMTs is that, unlike in traditional cases, parents have three options: conceive a child with rGMTs, conceive a child without rGMTs, or conceive no children at all. The existence of the third option means the counterfactual is not met: it is not inevitable that a child will be conceived. In fact, whether to conceive at all is a choice open to the parents.

In the case of heritable diseases where rGMTs are the only way to have healthy child genetically related to both parents, this removes the moral urgency of rGMTs. Unavailability of rGMTs will not necessarily lead to children dying sooner, as parents may undertake a number of alternatives: conceive using donor egg or sperm, adopt a child, or forego having children entirely. All these options have costs, to be sure, but the life of a child is no longer at stake. Given these lowered stakes, and the fact that there are considerable objections to rGMTs (relating, e.g., to safety, efficacy, equity, unnaturalness and opening the door to eugenics), Rulli concludes that allowing and/or investing in the development of rGMTs is not justified.

**Conceptual difficulties**

An immediate concern with Rulli’s account is that the strict counterfactual requirement in her definition does not track ordinary usage of terms like cure or therapy. Normally, merely ‘soothing, healing or remedying someone’s illness’ is sufficient. This becomes clear when reflecting on cases of overdetermination of harm, where two distinct causes (such as illnesses) would both cause the same bad effect in a person. One might cure an illness, but an equivalent harm still accrues because of an independent cause of the same harm. The intervention may nevertheless be considered curative, even if for other reasons the cure makes no difference to the outcome.

For illustration, suppose a nefarious scion aims to kill their ailing parent, who is currently able to survive only with the aid of a ventilator and an IV drip, in order to quickly inherit their substantial estate. The scion conspires to inject a subtle poison into the IV drip in order to kill the parent. However, if the parent manages to survive the poison, the scion will then turn off the ventilator to ensure the job is done; and if the parent manages to breathe on their own without the aid of the ventilator, the scion will in desperation simply suffocate them with a pillow. In this case, we can still sensibly say that the ventilator is a therapeutic, life-saving device, even though the parent will not live any longer due to its presence – they are inevitably doomed by the scion’s plans, once set in motion.

At another point, Rulli considers the counterexample of prenatal consumption of folic acid to prevent neural tube defects. (Rulli 2019, 1080) This case also appears to fail the counterfactual condition, insofar as there exists a third option for a prospective parent (have no children), which makes it not inevitable that someone would benefit from the folic acid. Yet we generally have no problems saying folic acid is therapeutic and saves lives.

In response, Rulli appears to shift the goalposts: folic acid has “therapeutic value” in virtue of being inexpensive and widely available. The intervention’s existence unambiguously makes many people’s lives go better. rGMTs by contrast are expensive and of questionable efficacy at present, and it is unclear how many actual cases of disease would be prevented by a given intervention (more on this point below).

As a response to the conceptual question of whether rGMTs can save lives, availability and accessibility are beside the point. Experimental, unproven and very expensive remedies may still qualify as treatments. A life-saving cure may be out of reach of the vast majority of the population, and so not worth investment or development. But it would nevertheless be a cure.

The counterfactual condition, instead, affects the *value* of a cure or therapy. In the scion case, the medical interventions arguably lack value because they will not end up benefitting the patient. By contrast, folic acid is of high therapeutic value due to the scope of benefits compared with a counterfactual where it is not utilized. The counterfactual condition might not directly undermine claims that rGMTs are curative or therapeutic, but rather establish how valuable rGMTs are as therapies or cures. So, even if Rulli is mistaken conceptually, and rGMTs are potentially life-saving, we should take seriously the question of how to *quantify* those life-saving benefits.

**Population health considerations for rGMTs**

We cannot effectively establish the therapeutic value of rGMTs by asking, for individual cases, whether a particular child’s life was saved. This is because of the intervention of choice, as Rulli notes. Any parents who opt for rGMTs might have instead chosen not to conceive at all. The openness of this choice in turn leaves the question of therapeutic value open – and, to some extent, unknowable.

However, support for rGMTs to prevent disease and save lives need not be predicated on the idea that particular, inevitably existing individuals will be benefitted. Rather, the goal could be framed at the population level – to reduce the burden of disease in society. Or more realistically, within a subgroup, to reduce the morbidity and mortality of disease-sufferers within that subgroup.

This sense of ‘saving lives’ is not too obscure. It is the sense in play with many policies that focus on larger numbers of people, when the policy goal is to *reduce mortality rates*. Judgment of the success or failure of such reductions do not rely on considering counterfactual features of particular individuals’ lives; the broad-level effects are sufficient to justify them. (Childress et al. 2002; Nolte et al. 2012) This avoids the considerable difficulty we might have in demonstrating whether a given individual would or would not have been born absent the availability of rGMTs, as what would matter instead were the broad social effects of the technology’s availability. Instead, with a population-level account, we can appeal to more readily accessible statistical and sociological evidence to establish whether and to what extent an intervention is life saving (as discussed in more detail in the next section).

Rulli dismisses a population-level approach that focuses on reducing morbidity or mortality rates on the grounds that we should not treat reproductive choice as settled when “assessing the moral reasons we have with regard to this choice”, and that such rates would be empirically speculative. (Rulli 2019, 1080) On the first point, Rulli addresses a different question than what is under discussion. To be sure, just as it cannot answer whether a particular child’s life was saved by rGMTs, a population-level approach cannot directly address whether individuals have good reason to make use of rGMTs. But the question here is not whether individuals should make use of rGMTs. It is whether rGMTs will save lives, and thereby have substantial therapeutic value. This in turn can help address the broader policy questions at play in the debate over rGMTs – whether to allow them, fund them, and so forth. A population-based approach does not take the choice as fixed per se (behaviour change can and should affect appropriate policies), but it can reasonably integrate our best evidence about what choices people will likely actually make.

As for empirical speculation, it should be quite unsurprising that the life-saving potential of any intervention would turn crucially on a variety of empirical facts. The precise sort of empirical evidence needed is the focus of the next section.

**Saving lives and rGMTs**

It remains to be shown that rGMTs really could save a substantial number of lives at a population or subpopulation level. While it is certainly possible and even plausible that rGMTs might do so, further empirical study is needed to fully demonstrate that fact. We should not dismiss the life-saving potential of rGMTs, as Rulli does. But nor can we assume it ex ante.

This is because even the population-level understanding of saving lives involves a counterfactual, namely that mortality rates for some subset of the population would be lower if the intervention were available than if it were not. But is that really the case for rGMTs?

First and foremost, it would have to be demonstrated that children born via rGMTs have lower mortality and morbidity rates than children born from the same parents via traditional conception. The entire viability of rGMTs for treatment of heritable diseases rests on this question. The HFEA in the UK gave such an affirmative analysis on this issue in the case of MRT, (HFEA 2014) while a few have argued similarly for the utility of CRISPR. (Smith 2020) And initial reports indicate the first children born via MRT and CRISPR are indeed healthy. (Zhang et al. 2017; Begley 2018) However, those first human cases of rGMTs were roundly condemned as overly risky and unethical. In the case of CRISPR, mosaicism and poor understanding of the function of the targeted gene has led to concerns of harm being caused. (Cohen 2019) Given the evidence base, it is not unreasonable to make claims that rGMTs may in the future, once further developed and refined, reduce mortality and morbidity in certain subpopulations with rare heritable disorders, but a proper evaluation of such claims is outside the scope of this paper.

Even if we become confident in the relative safety and efficacy of rGMTs, population-level claims of lives being saved further depend on the actions of prospective parents who would utilize rGMTs if they are made available. Crucially, what would they do if, conversely, rGMTs are *not* available? Consider three (non-exhaustive) alternatives to rGMTs:

1. Parents would instead adopt a child, or choose to remain childless, and there are no further individuals created. In such circumstances, we have what is known as a ‘different numbers case’ – slightly fewer members of the population in the relevant counterfactual. Comparing different numbers cases is notoriously difficult, but in any case it is unlikely that fewer individuals would die prematurely in these circumstances. If anything, adoption should somewhat increase the life prospects of the child being adopted, potentially reducing their mortality rates and leading to more lives saved than if rGMTs are undertaken.
2. Parents would instead undergo IVF and solicit a donor egg or sperm that is free of heritable disease. We then have a simpler same-numbers case, but there is likely to be little difference in terms of lives saved: a child born from a donor gamete and born via rGMT are similarly likely to be healthy. Indeed, given that rGMTs are still experimental and somewhat risky, using a donor will be safer.
3. Parents would instead conceive a child naturally, and that child inherits the mitochondrial disorder. In this case there is indeed a strong case to be made for a given rGMT saving lives. The rGMT will likely result in a healthy child with a more typical survival likelihood, while natural conception will likely result in a child with much lower likelihood of survival (along with other significant morbidity effects). At the population level, more children would likely die prematurely under (3), making it accurate to say rGMTs would save lives.

So, if almost always (1) and (2) obtain, the live-saving value of rGMTs would be very limited, even within a subpopulation of individuals with rare heritable diseases. But on the contrary, if (3) obtains with regular frequency, then substantial life-saving claims of rGMTs would be justified. A crucial question then is whether (3) would really occur at least some of the time, if a particular rGMT for a particular disease were made available in a given country – and how frequent it would be undertaken, compared with (1) and (2).

This claim is indeed put forward by Art Caplan in an article for Wired, in the context of MRT for mitochondrial disease:

The need for the procedure is real. Somewhere around 4,000 children per year in the United States are born with a type of mitochondrial disease. Many do not survive more than a few months. Mitochondrial transplants would help prevent these diseases. So why not use them? (Caplan 2015, 20)

However, it is not immediately clear whether any of those 4,000 children’s parents would really avail themselves of MRT were it available. IVF is itself expensive, burdensome, and many will have moral objections (whether sound or not) to MRT, sometimes referred to as ‘three-parent IVF’. And notably, many of those 4,000 children will have a form of mitochondrial disease that would be preventable by preimplantation genetic diagnosis, a presently available technique. Given some of them did not undergo PGD, why should we expect they would undertake MRT? Perhaps the only ones undergoing MRT are those who would otherwise opt for (1) or (2).

One could point to a recent US study that found 90% of carriers of mitochondrial disease would be interested in using it to have a child. (Engelstad et al. 2016) However, that particular question was only asked of a small subsample (21 individuals) of mitochondrial disease carriers who were considering having children. And it was not framed in a way that clearly suggests (3) over (1) or (2) – perhaps they would prefer to undergo MRT if available, but absent MRT will use IVF or adopt. Further study on precisely how many individuals fall under (3) would be needed to properly validate and quantify the claim that MRT saves lives.

Nevertheless, the preceding provides some non-decisive evidence that a non-trivial number of individuals fall under (3). There are a large number of potential patients who could undergo MRT, and there is significant support among those with mitochondrial disease for the approach. Claims about preventing disease or saving lives are thus not outlandish, but better evidence base would be welcome.

The percent of those utilizing rGMTs who fall under (3) is also likely to vary depending on the disease and particular technology involved. In any given context, it would be sensible to weight the life-saving value of the technology by the percentage who would choose (3) if rGMTs were not available. The resultant figure would bear some analogy to the concept of ‘number needed to treat’ in medicine: the number of individuals (in this case embryos) that would have to be modified in order to prevent one case of a heritable disease. That figure will in turn be central to cost-benefit analyses to determine whether a given treatment is worth the risks and costs involved.

**Conclusion**

It is important, as critics of rGMTs have pointed out, for bioethicists and the popular media to be careful in the terms used to frame the debate. Inaccurate terms may give inaccurate impressions of what the interventions will actually do.

This does not mean we should excise the language of ‘saving lives’ from academic and popular discussions of rGMTs. It may be that rGMTs do not always save the life of individuals who would otherwise die, or that determining whether an individual was saved is unknowable. But there is a probabilistic, population-level sense of saving lives that can potentially be ascribed to rGMTs. And the term highlights a morally salient feature of rGMTs – namely, that for a subset of parents who would otherwise conceive a child with a heritable disease, it could reduce the mortality rate (along with the other various deleterious symptoms) of their children. The life-saving potential is relevant for several pressing debates surrounding rGMTs: Whether they should be permitted in the first place; whether resources should be invested into their research and development; and under what conditions (if any) they should be deployed in practice.

In academic articles and engagement with the media, bioethicists should therefore be careful with their language, and allow that the life-saving impact must be weighted by the odds that a child with a disease would be conceived absent the genetic intervention. It will also be worthwhile for research to be conducted to determine what, exactly, those odds are for varying diseases and populations, which can meaningfully inform policy and resource allocation. This does not mean that rGMTs should necessarily be permitted or promoted, as it still could be that the risks, negative social impact or opportunity costs outweigh the lives saved and other benefits provided. But reductions in mortality should at least be considered in public and academic debates.

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1. While this article will focus on the terminology of ‘saving lives’, the arguments are meant to apply *mutatis mutandis* to most benefit language pertaining to children born via rGMTs. [↑](#footnote-ref-1)
2. This would comport with focusing on rGMTs’ purported positive impact on societal welfare and overall morbidity/mortality rates. For an application of this more societal-level approach to benefit to MRT, see (Wrigley et al. 2015) [↑](#footnote-ref-2)
3. This argument could also be run to show that preimplantation genetic screening, i.e., selecting only embryos for implantation that are free of significant genetic disorders, may be a life-saving intervention. But rGMTs are the focus of this paper because of the life-saving claims surrounding it that have been made; while this language is not used as much for genetic screening, by this argument it might be acceptable to use such language in that context as well. [↑](#footnote-ref-3)