REPRODUCTION

Just another reproductive technology? The ethics of human reproductive cloning as an experimental medical procedure

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Human reproductive cloning (HRC) has not yet resulted in any live births. There has been widespread condemnation of the practice in both the scientific world and the public sphere, and many countries explicitly outlaw the practice. Concerns about the procedure range from uncertainties about its physical safety to questions about the psychological well-being of clones. Yet, key aspects such as the philosophical implications of harm to future entities and a comparison with established reproductive technologies such as in vitro fertilisation (IVF) are often overlooked in discussions about HRC. Furthermore, there are people who are willing to use the technology. Several scientists have been outspoken in their intent to pursue HRC. The importance of concerns about the physical safety of children created by HRC and comparisons with concerns about the safety of IVF are discussed. A model to be used to determine when it is acceptable to use HRC and other new assisted reproductive technologies, balancing reproductive freedom and safety concerns, is proposed. Justifications underpinning potential applications of HRC are discussed, and it is determined that these are highly analogous to rationalisations used to justify IVF treatment. It is concluded that people wishing to conceive using HRC should have a *prima facie* negative right to do so.

maximum penalty of imprisonment for 15 years.¹ Many other nations prohibit HRC.²

Nevertheless, there are people prepared to clone humans and women who are prepared to gestate cloned babies. In 2001, Italian embryologist Dr Severino Antinori and American reproductive physiologist Dr Panayiotis Zavos announced their intention to begin cloning humans, claiming that 200 couples had volunteered to participate in their experiment.³ Despite almost universal condemnation of the practice, Antinori claimed that he was willing to carry out his plans “in a remote country or even on board a ship moored in international waters”.³ Yet the two have since ceased their partnership, and neither has been able to clone a child to term.

Although HRC has been widely outlawed, we must question the validity of the largely emotive and speculative arguments typically proffered to justify a ban on the technology. Vague notions of HRC being an assault on human dignity,⁴ absurd fears of cloning an army of Hitlers⁵ or even more rational concerns about the long-term psychological well-being of clones are not suitable starting points for an analysis of the ethics of HRC. I will focus on concerns about physical safety, and not on psychological issues, although I will briefly return to the issue of psychological well-being in my conclusion. Rather than hastily dismissing HRC as morally shocking, I believe it is more appropriate to consider HRC as an experimental reproductive technology. Surely, issues relating to the physical safety of HRC in the experimental stage would be critically important to consider before the procedure takes place. Papers that deal with these issues, however, tend to adopt a preconceived notion of HRC as unethical.^{6,7} Importantly, debate on the ethical acceptability of HRC rarely examines in any considerable depth the analogy of in vitro fertilisation (IVF), either in its early days as an experimental reproductive technology or as an established reproductive technology.

This paper discusses the importance of concerns about the physical safety of children created by HRC and draws comparisons with concerns about the safety of IVF. I will not discuss in detail the physical safety of the gestating mothers of clones. The risks involved would include those currently associated with IVF and possibly other, as yet unknown, risks. Therefore, as with trials of other experimental procedures, it would be critical to gain informed

Human reproductive cloning (HRC) by somatic cell nuclear transfer (SCNT) has not yet resulted in any live births, excluding the claims of Clonaid, an organisation run by a religious group, the Raelians. These claims have not been verified and are widely believed to be false. The procedure entails the creation of a human (the “clone”) with the same genotype as an existing human, the aim being to allow the clone to develop to term (in contrast with so-called therapeutic cloning, where the clone does not develop past the embryonic stage). Throughout the world, there is widespread belief that HRC is unethical, as indicated by the views of many in the general public and scientific community, and in the government legislation. In Australia, for example, “creating a human embryo clone” and “placing a human embryo clone in the human body or the body of an animal” are both outlawed under the Prohibition of Human Cloning Act 2002, each carrying a

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Abbreviations: ART, assisted reproductive technology; HRC, human reproductive cloning; IVF, in vitro fertilisation; SCNT, somatic cell nuclear transfer

consent from prospective gestating mothers. A model to be used to determine when it is acceptable to use HRC and other new assisted reproductive technologies (ARTs), balancing reproductive freedom and safety concerns, is proposed. Justifications underpinning the potential applications of HRC are discussed, and it is determined that these are highly analogous to rationalisations used to justify IVF treatment. It is concluded that people wishing to conceive using HRC should have a *prima facie* negative right to do so.

PHYSICAL SAFETY OF CLONES

As no human has yet been cloned to birth, the only data available on the physical safety of cloning by SCNT are from experiments on non-humans. In 1996, Dolly the sheep became the first mammal to be cloned by SCNT. Much has been made of the inefficiency of the experiment in which Dolly was cloned. Of the 277 attempts to fuse an adult sheep cell nucleus with an egg, only 27 embryos developed normally for a week.⁸ When these were implanted into the wombs of 13 sheep, only Dolly survived to birth. This represents a tremendously inefficient use of eggs, and a loss of embryos and fetuses far exceeding that in natural reproduction.

Since the birth of Dolly, other mammals have been cloned by SCNT. Although the success rate of cloning by SCNT varies between species (and among studies on the same species), the published data indicate that it is universally low. Griffin⁹ estimates that between 1% and 4% of cloned embryos develop into liveborn animals, noting that this excludes even less successful attempts that remain unpublished. Although many cloned animals die before birth, little is actually known about the abnormalities that cause these deaths. This is because most reports on cloning abnormalities focus exclusively on the few fetuses that survive to birth.⁷ Evidence exists that epigenetic mechanisms are the cause of most abnormalities in cloned mammals, whether or not they survive to term. Genetic factors, which are irreversible, are those relating to the sequence of genes and number of copies of chromosomes. Epigenetic factors, determined by events beyond the level of genetic information, include reversible chemical changes to the genome that are reset during early development. In a given cell not every gene is "active". Genes can be "switched on and off", as the need arises, by epigenetic mechanisms. In cloning by SCNT, the donor somatic cell is at a different stage of maturity compared with embryonic cells; therefore the pattern of gene activation needs to be reset. Thus, epigenetic factors are critical in reproductive cloning by SCNT because, if the genetic "clock" of the donor somatic cell nucleus is not properly reset, the cloned embryo cannot develop normally.⁷ Screening embryos for epigenetic disorders is, however, not currently feasible, as knowledge about the mechanisms behind these abnormalities is limited. To complicate matters, even if this knowledge were to improve, different cells in the developing embryo often express different epigenetic defects (known as a "mosaic" pattern of expression).⁷ Hence, taking a single cell from an embryo to screen for epigenetic disorders would be inadequate. Jaenisch and Wilmut⁶ believe that epigenetic screening methods for the "quality control" of cloned embryos will not be available "in the foreseeable future".

The relevance to HRC of findings from non-human cloning studies is, however, unclear. From non-human cloning experiments, it has become apparent that some abnormalities seem to be unique to a certain species. Studies of cloned mice, for example, have indicated that these mice are more prone to obesity.¹⁰ In addition, attempts to clone some species, such as rhesus monkeys, have failed, whereas species such as sheep, cattle and mice have been successfully cloned. Perhaps the best model on which to base hypotheses about the safety of

HRC (without actually cloning humans) would be non-human primates. So far no primate has been born by SCNT. In December 2004, it was confirmed that cloned rhesus macaque embryos had developed until the blastocyst stage, representing the most advanced stage achieved in cloning non-human primates. The blastocyst stage is the stage at which stem cells are produced and is critical in therapeutic cloning experiments, which aim to derive stem cell lines from cloned human embryos.¹¹ All attempts at reproductive cloning failed in the experiment. In any case, the findings led some to caution against the application of data obtained from any experiments on non-humans.¹¹ Some, such as Colman,¹² are adamant that the differences "in the reproductive physiology and embryology between different mammalian species, including humans" are so great as to permanently devalue the pertinence of animal cloning experiments to HRC. Space does not permit discussion of the ethics of experiments involving cloning of non-human animals, although this is another important consideration.

The bottom line is that until HRC is seriously attempted, the success of the procedure will not be known. HRC may be more or less successful than cloning of other mammals. Yet, although the unpredictability of the procedure in its experimental stage would act as a deterrent to some who may otherwise wish to conceive using HRC, this is not in itself reason to prohibit the technology. I do not believe that the likely loss of embryonic life in the early stages of HRC would render the practice inherently immoral. Embryo wastage may be important from the point of view that achieving a birth with minimal embryo wastage would reduce the costs (related to money, time and convenience) associated with the procedure. Economic costs may have salient ramifications if people conceiving with HRC receive state funding, an issue beyond the scope of this paper. IVF, a reproductive technology widely accepted in many societies, includes considerable embryo wastage even almost three decades after the birth of Louise Brown, the first IVF baby. Indeed, even traditional procreation entails considerable loss of embryonic life. On average, only between one in three and one in five embryos survive to term.¹³ As Savulescu and Harris¹⁴ have argued, "embryo wastage *per se* cannot be an objection to reproductive cloning for those who accept natural reproduction".

The harm to clones that survive to term is more complex. The only clones harmed by HRC would be those for whom life would not be worth living. Although it is difficult to say just how awful a life would have to be for non-existence to be preferable, it is reasonable to assume that only extreme, untreatable anguish would render a life not worth living. Very few conditions cause such suffering. One example is Tay-Sachs disease, a fatal, untreatable neurodegenerative disease. It is unlikely that many cloned humans born while the technology is still in its infancy would have such a horrendous quality of life, on the basis of the fact that the most severely defective embryos and fetuses would probably not survive to term. Most unborn humans with severe chromosomal disorders are spontaneously aborted.¹⁵ Furthermore, women gestating clones would have the option of aborting a fetus diagnosed as having a condition incompatible with a worthwhile life. Thus, the likelihood of HRC resulting in the existence of lives not worth living seems fairly remote and is not a major consideration against the procedure.

But what of the clones who would be born with defects such that their lives would be of a low quality (relative to, say, the population average), although superior to non-existence? A notable number of the clones can be in this category. These cloned people would not have existed without the procedure that also resulted in their decreased well-being. Parfit¹⁶ described such a dilemma as the

non-identity problem. If we accept that a woman has the right to bear a child by the traditional method of procreation knowing that it will have suboptimal health (eg, as the result of a parent's genetically transmissible condition or the mother's health status), then it would not be wrong to use HRC to create a child for whom life would be worth living, but who would probably have suboptimal health. Either case would be acceptable, provided no reasonable alternative method of procreation exists. Savulescu¹⁷ has discussed the principle of procreative beneficence. This moral obligation requires that if prospective parents can choose between bringing two children into the world, and one child can be expected to have greater well-being than the other, the child who would have the greater well-being should be chosen. Savulescu,¹⁷ however, writes that there may be instances in which a right to procreative autonomy overrides the duty of procreative beneficence. Thus, although this principle may have intuitive merit, it is not a strong argument against all applications of HRC. It is useful here to draw a parallel with IVF. A recently published meta-analysis of papers investigating the risk of birth defects in infants born by IVF found, on average, a 30–40% greater risk of birth defects associated with the technology.¹⁸ Yet, few people would seriously suggest that IVF, with all the benefits it has brought to infertile people, should be banned on the basis of these findings.

Edwards,¹⁹ a pioneer of IVF, in his commentary on a 2001 Washington conference on cloning, described how “strong language and deep passions abounded, just as in a conference—also held in Washington—on the ethics of IVF thirty years ago”. At the forefront of the trepidation about IVF in the 1970s were questions about the procedure's safety. Some believed that Edwards and Steptoe had “performed immoral experiments on the unborn”. Edwards¹⁹ rejects a comparison between early safety concerns over IVF and those relating to HRC, claiming that HRC is “unlike IVF in its accompanying embryological disasters in animals”. Yet this may not be an especially relevant observation. Elsewhere, recounting the early years of IVF, he has recalled that during this time “studies on human embryology and IVF had far outstripped comparable work on animals ... embryos of many animal species could still not be grown to blastocysts in vitro”.²⁰ If IVF studies on non-humans were limited then obviously there would be little possibility of widespread embryological disasters occurring in non-human subjects. On the other hand, there were clearly difficulties in establishing the technique in humans. Several years of failed attempts—including one attempt that resulted in an ectopic pregnancy in 1976—preceded the first successful replacement of an IVF embryo into a recipient's uterus.²⁰ Furthermore, intracytoplasmic sperm injection, which currently “accounts for nearly half of all assisted reproductive treatments in the United States”,²¹ was introduced without an experimental phase, “partly because animal models were thought to be unsuitable”.²²

Thus, IVF has come to enjoy widespread acceptance despite early failures and a lack of data on non-humans. Although HRC poses its own unique procedural risks and challenges, it also stands to benefit from improvements in embryo-culturing techniques that have occurred since IVF was introduced. Furthermore, the opportunity exists to monitor the outcome of HRC and other new ARTs in a more systematic and knowledgeable fashion compared with earlier ARTs.

DETERMINING WHEN IT IS ACCEPTABLE TO USE HRC AND OTHER NEW REPRODUCTIVE TECHNOLOGIES

I have thus far established that, from a scientific perspective, great uncertainty surrounds HRC. The outcome of early trials

of the procedure cannot be predicted, and this would deter many from using the technology to procreate. I have, however, also argued that the prospect of HRC resulting in the creation of lives not worth living seems low. Although HRC may not currently be a particularly practical method of procreating, it does not necessarily follow that people should be denied a right to attempt to reproduce in this manner.

Suggested model for balancing reproductive freedom and safety concerns about ARTs

Although space does not permit detailed discussion on the importance and scope of reproductive freedom, it suffices to say that the right of a person to choose whether or not to reproduce, and the manner in which they do so, is one of the most fundamental rights a person has.²³ It follows that, if someone is to be denied this liberty, there must be a good reason. In the case of new ARTs such as HRC, I propose the following model to assist in deciding whether people's freedom to procreate with the particular technology should be upheld. The model identifies different categories of risk to children produced by ARTs and corresponding levels of justified restriction on reproductive autonomy.

Consider the following three types of situation:

- *Situation I:* a high possibility of the ART resulting in the creation of lives not worth living (where this is known for certain to be the case either before procreation with the particular ART is attempted or after early trials have occurred).
- *Situation II:* an indeterminate possibility of the ART resulting in the creation of lives not worth living (as suspected before trials have occurred, where the level of risk cannot be known for certain).
- *Situation III:* a low possibility of the ART resulting in the creation of lives not worth living (a fact established after trials have occurred).

For the above situations, the following should apply:

- *Situation I:* no person has the right to procreate using the ART, because the known risk to children created by the ART of having a life not worth living clearly outweighs the rights of people to exercise their reproductive freedom.
- *Situation II:* procreation using the ART is acceptable in specific circumstances. There is a possibility of harm to children created by the ART, but the degree of risk is not high enough or well enough established to outweigh reproductive freedom. As there is some risk, the right to reproductive freedom should not be exercised carelessly. In particular, people should use the ART only when there is no reasonable alternative for them. Of course, what counts as a “reasonable alternative” will be contestable, and will require further specification.
- *Situation III:* procreation using the ART is acceptable in a broader sense. The risk to children is known to be low and is not sufficient to outweigh reproductive autonomy. This is determined on the basis that the level of risk of producing a life not worth living is roughly similar to (or less than) that of the traditional method of procreation. Further, regarding lives with suboptimal well-being (but where life will be worthwhile), traditional procreation that will probably result in such lives is tolerated by society, even where there are reasonable alternative means of procreation (eg, gamete donation, IVF or adoption).

I suggest that HRC in its current state fits into situation II, given what is known from animal models and the uncertainty of their relevance to humans. Two examples of “specific circumstances” where HRC would be an acceptable method of procreation (as required in situation II) are outlined later. These

examples give an indication of what would count as having no reasonable alternative means of procreation.

If HRC were in situation III, there would be no need to outline specific justifications for using the procedure to have a negative right to procreate in this manner. I, however, contend that we do not know enough about the risks to children to place HRC in situation III.

According to this model, the only reason for preventing all use of HRC or other ARTs would be where a high likelihood of creating lives not worth living exists (situation I). Some may argue that detrimental effects to society could be a good enough reason to prevent the use of ARTs such as HRC, or to require specific justification for their use. In the case of HRC, such objections are highly implausible, although an analysis of these objections is beyond the scope of this paper (for a rebuttal of the commonly stated objection that HRC would reduce genetic diversity, see Pence²⁴). This would include the hypothetical situation where safety concerns are found to be underestimated once trials of the ART have taken place. But again, evidence from animal models is too uncertain to justify placing HRC in situation I.

Equal consideration for all forms of reproduction

One practical difficulty with the above is defining the terms “high” possibility and “low” possibility. A plausible way to deal with this is to suggest that a high possibility of an ART resulting in the creation of lives not worth living can be defined as that which is greater than the chance of this occurring in traditional reproduction. As has been discussed elsewhere,²⁵ it is inconsistent to demand unrealistically stringent safety standards of HRC and other ARTs when, for example, people carrying a variety of genetic disorders are not prevented from passing on these disorders to offspring created by traditional procreation. To ensure consistency, society ought to grant equal consideration to all forms of reproduction or, in other words, our intuitions and prejudices about technologies should not taint our assessment of whether a particular method of reproduction is acceptable.

Other models for regulating HRC have been proposed. Robertson²⁶ suggested that HRC should be accompanied by a commitment, on the part of those requesting use of the technology, to rear the resulting offspring. Robertson²⁶ insists that such a policy would prevent people “from creating clones to be used as subjects or workers without regard for their own interests”. Furthermore, Robertson²⁶ suggests that this ought to “assure the child a two-parent rearing situation—a prime determinant of a child’s welfare”. This claim is contestable, though further discussion is not possible here. Yet such a policy may be unnecessary and, anyhow, would not prevent poor parenting. Laws preventing child abuse would apply to cloned children, just as they apply to all others. McGee and Wilmut²⁷ have put forward the “adoption model” as a way of regulating HRC. According to this model, people intending to procreate using HRC would be required “to seek prior approval from a regional authority or court”, and possibly be “required to undergo psychological testing, home visits or other pre-screening”.²⁷ They claim that this model strikes a balance between views that focus on the safety of cloned children and those that emphasise reproductive freedom. The adoption model, however, has some major shortcomings.

To begin with, although the welfare of existing children (who have rights) is central to the process of adoption, this is not the case with HRC and other forms of reproduction. No rights can be attributed to the future people who will be created by HRC or other reproductive methods because these are entities that do not yet exist. In adoption, the alternative that the child does not come into existence is lacking, but this is a key feature of the HRC situation.

Secondly, there is no good reason why people wishing to procreate using HRC or other ARTs should be required to undergo an extensive selection process, whereas people reproducing the traditional way are exempt from this. If the adoption model is to apply for people intending to use ARTs, on the basis that it is necessary to protect the well-being of children, then it should apply to all prospective parents. To claim otherwise is to claim that people wishing to use ARTs are inherently more likely to be poor parents or to have malign motives for having children. No evidence, however, exists to support this, and in the absence of evidence the claim is unjust.

Most importantly, although models such as those put forward by Robertson, and McGee and Wilmut, are invariably posited under the provision that HRC ought to be “safe enough”, and are accompanied by the suggestion that current levels of safety would be unacceptable, no specific guidelines for defining “safe enough”, or for letting us know when this time arrives, are ever mentioned. Neither the adoption model nor the commitment-to-rear model provides any sort of answer to the question of when even people with the best parenting intentions can justifiably use HRC. This is the question that I am attempting to discuss. Thus, I believe that my model allows for greater clarity in deciding when it would be acceptable to trial HRC or any other novel ART.

JUSTIFIABLE APPLICATIONS OF HRC

Here, I will outline two specific circumstances in which HRC would be an acceptable method of procreation (as required in situation II of my model). I will consider the desire to have a genetically related child for “intangible” reasons (eg, to contribute to the creation of a new life), as well as the value placed on genetic relatedness for more tangible reasons (eg, to create a “saviour sibling” for a sick child).

HRC for genetically related offspring

An example where HRC, but not other methods, could allow people to have fully genetically related children is where a woman has viable gametes but her male partner does not. Here, the nucleus from one of the male’s somatic cells could be transferred to one of the female partner’s oocytes and the result would be a genetically related child with no third party (or “foreign”) DNA. There are other people, also desiring genetically related children with minimal “foreign” DNA, for whom HRC could also be the desirable method of procreation—for example, single people or homosexuals. Alternatives such as gamete donation would reduce the degree of the child’s genetic relatedness, as they introduce DNA from a third party, and hence would not constitute a reasonable or equivalent alternative for those to whom genetic relatedness to their children is of major importance.

Savulescu²⁸ suggests that although genetic relatedness “may have some instrumental value”, it is overvalued. Although some commentators have criticised the value attributed to genetic relatedness, many prospective parents strongly desire genetically related children. Elsewhere, Kahn²⁹ has criticised “the current strong social trend towards a fanatical desire for individuals not simply to have children but to ensure that these children also carry their genes”. Similarly, the primary reason many people undergo IVF treatment is the desire to contribute genetically to their offspring. Just as a claim to reproductive freedom is valid when IVF is used for this purpose, it would also be valid for those wishing to use HRC.

HRC for the creation of saviour siblings

The creation of saviour siblings already occurs, either by taking a chance with traditional procreation or by IVF.³⁰ Although I will not enter the broader debate on the morality of creating saviour siblings, clearly the method used is not

morally relevant. Whether IVF or HRC is used, I believe that the practice is morally acceptable.

There are some instances where HRC would be the preferred or only method for the creation of saviour siblings. For example, if an adopted child with leukaemia (of non-genetically transmitted aetiology) needed a bone marrow transplant, and no compatible bone marrow or gamete (for IVF) donors were available, HRC could be an option. The parental duty of beneficence to existing children would be a compelling justification to use HRC under these circumstances. There would be no reasonable alternative.

CONCLUSION

Although the uncertainties surrounding HRC in its experimental stages would strongly deter many from using the technology, some people may wish to conceive in this manner. I have put forward a model to aid in the determination of when it is ethically acceptable to use HRC and other new ARTs, in view of the physical risks to children who may be born as a result. I have argued that current physical safety concerns should not act as a barrier against all applications of HRC. Concerns about psychological well-being—for example, that children who are cloned would have to deal with the suffocating expectations of parents and others as a result of having a known genotype—seem to be largely speculative. Such psychological sequelae would be less likely in the two applications of HRC I have outlined, neither of which has the aim of creating a person to replicate the physical or intellectual feats of an existing person. In any case, these adverse effects could be the result of poor parenting, stemming from erroneous attitudes, rather than because of any intrinsic aspect of the technology. I have aimed in particular to deal with the question of whether it would be ethically acceptable even for good parents with appropriate attitudes and correct understandings to use HRC in an attempt to procreate.

The model I have outlined supports a *prima facie* negative right to conceive using HRC, given the current level of scientific knowledge about the effects on children created as a result. That is, people wishing to reproduce by cloning should be able to do so, provided that there is no reasonable alternative, and trials of HRC as an experimental medical procedure should not be prohibited. Whether people should have a positive right to use HRC, which would imply state funding for the procedure, is worthy of further debate, but is beyond the scope of this paper. It may be that if HRC were to become an established reproductive technology in a particular society that subsidised, say, IVF treatment, there would be a compelling case to introduce analogous subsidies for HRC.

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