

Human somatic cell nuclear transfer and reproductive cloning: an Ethics Committee opinion

Ethics Committee of the American Society for Reproductive Medicine

American Society for Reproductive Medicine, Birmingham, Alabama

This document presents arguments that conclude that it is unethical to use somatic cell nuclear transfer (SCNT) for infertility treatment due to concerns about safety; the unknown impact of SCNT on children, families, and society; and the availability of other ethically acceptable means of assisted reproduction. This document replaces the ASRM Ethics Committee report titled, "Human somatic cell nuclear transfer and cloning," last published in *Fertil Steril* 2012;98:804–7. (*Fertil Steril*® 2016;105:e1–4. ©2016 by American Society for Reproductive Medicine.)

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"Reproductive cloning" is defined as the use of technologies, including somatic cell nuclear transfer (SCNT), to create offspring with the shared genomic material of the original person. "Therapeutic cloning" uses these same experimental techniques for therapies other than reproduction (such as research, embryonic stem cell lines, or creation of solid organs for transplant).

Soon after the announced birth in 1997 of Dolly, the lamb cloned from the mammary cells of an adult ewe, research groups announced that they had cloned mice, calves, and other animals by using differentiated somatic cells (1–3). In the cloning technique used to produce Dolly, the nucleus of a somatic cell of the ewe was transferred to a sheep oocyte from which the nucleus had been removed, and the cells were fused through electrofusion to produce offspring that shared the genome of the original ewe. Research into the science of reproductive SCNT is progressing as investiga-

tors clone additional species by using the original and related methods. Other research is investigating techniques such as parthenogenesis, transference of mitochondrial DNA, chimeras, or interspecies SCNT-derived human embryos.

The prospect of using reproductive SCNT to produce human beings has evoked extensive debate among lawmakers, academicians, ethicists, religious leaders, international and national agencies, professional societies, and others. Whether human reproductive SCNT will ever be undertaken will depend on such factors as the safety and efficacy of the procedure, presence or absence of laws or governmental regulation, perceptions of procreative rights, adherence to a voluntary moratorium against human cloning, consumer interest, and the intensity and extent of ethical objections.

Reproductive SCNT has been inefficient in non-human species, with relatively few births reported in veterinary studies. It also has been associated

with harmful complications in most mammalian species including high fetal and neonatal death rates and/or imprinting and developmental disorders (4, 5). Although concerns about fetal and neonatal safety alone make the application of reproductive SCNT to human procreation unethical at present, improvements in cloning may make safety concerns be only a temporary barrier to reproductive SCNT. Moreover, researchers have proposed using SCNT to generate embryonic stem cells for persons who need tissues or organs, which raises issues not addressed in this report (6–9). The development of SCNT for such therapeutic purposes, in which embryos are not transferred for pregnancy, could produce the knowledge necessary to make reproductive SCNT safe and effective (10). Research in the therapeutic realm is proceeding, with at least one research laboratory reporting the successful derivation of human embryonic stem cells by somatic cell nuclear transfer (11).

Consensus about the ethical acceptability of reproductive SCNT does not and likely never will exist, but it is appropriate to think prospectively about the ethical issues that reproductive SCNT would raise if

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preclinical data suggested the procedure was safe and effective and researchers sought to conduct human trials (12, 13). Ongoing debates about the ethics of reproductive SCNT have revealed that some observers regard human reproductive SCNT as morally unacceptable in all circumstances, others see merit in reproductive SCNT in certain circumstances, and still others await more information before making judgments about the ethical status of the procedure.

OBJECTIONS TO REPRODUCTIVE SCNT

One position holds that reproductive SCNT is unethical in all situations. This belief has contributed to proposals for restrictive legislation, which have passed and been enacted in several states in the United States (14). According to this perspective, reproductive SCNT violates deeply cherished values and traditions. Natural conception or forms of assisted reproduction other than reproductive SCNT involve the conception of a child through the mixing of genetic lineages. Reproductive SCNT, on the other hand, involves the production of a child through an asexual procedure using an existing genome. This process represents a fundamental departure from natural or assisted conception in which a child's genome is unique from either parent. For those who subscribe to this perspective, no situation would justify reproductive SCNT because the act itself is considered immoral. Some of those who object to reproductive SCNT believe that reservations about human cloning should be respected as a barometer of what is intuitively unacceptable (15).

ARGUMENTS IN SUPPORT OF REPRODUCTIVE SCNT

Another position defends the use of reproductive SCNT in medically based circumstances, provided that the safety of the procedure can be established (16–18). According to this perspective, reproductive SCNT differs only in degree from other assisted reproductive technologies, and it is ethically defensible for specific groups of patients, such as infertile individuals or couples at medical risk or those who object to donor gametes on religious, moral, cultural, emotional, or other grounds. In the case of infertile couples in which one or neither partner can produce gametes, two situations might apply. If the male partner cannot reproduce with his spermatozoa, reproductive SCNT with his somatic cell would enable him to have a genetic tie with the child. His partner would have a biological tie if she donates the recipient oocyte or gestates the child. If the female partner cannot reproduce with her ova, transferring the nuclear DNA from her somatic cell to an enucleated donor oocyte would allow her to have a genetic relation to the child, although her partner would not. In these situations, reproductive SCNT would allow infertile couples to conceive children who are genetically related to them, which is a reason that couples seek assisted reproductive technology (ART) services. According to this perspective, reproductive SCNT would meet an infertile couple's desire to participate biologically in the development of a new human being, and the process thus could nurture the emotional bond between the partners. If conceiving a child with the genes of at least one partner is highly important for infertile couples, or if

they have reservations about using the gametes of anonymous donors, reproductive SCNT might be a welcome alternative for them.

In the case of couples at genetic risk, reproductive SCNT could be used to avoid passing a serious genetic disease on to their offspring. If both the male and female partners are carriers of autosomal-recessive disease traits, one partner's somatic cell could be used to conceive. If one partner has an autosomal-dominant disease, the unaffected partner's somatic cell could be used. Reproductive SCNT would offer an alternative for at-risk couples who decline to transfer only unaffected embryos after preimplantation genetic diagnosis or to terminate a pregnancy after prenatal testing and a positive result for the disease in question.

OTHER ETHICAL CONSIDERATIONS

Other perspectives fall somewhere between the positions discussed above. Persons who withhold judgment about reproductive SCNT pending further information generally presume that reproductive SCNT is unethical at present because of the safety risks posed to the fetus and child, but they are not yet ready to approve or bar the procedure (6). They voice concern about the potential impact of reproductive SCNT on offspring, families, and society, and they are as yet to be persuaded that reproductive SCNT would serve a valid family or reproductive need.

Impact on Children

If reproductive SCNT were available, its impact on offspring would presumably vary depending on family dynamics and other features of each situation. The effect could be inconsequential, or it could be positive if the child shared the genome of a beloved parent and enjoyed a special kinship with that parent. Although the child would share the parent's nuclear DNA, the child would be an individual in his or her own right because the child would experience unique circumstances of gestation, rearing, and education. In addition, the child would grow in a singular uterine environment and inherit the mitochondrial DNA of the oocyte donor. Again, these reflections assume that current complications associated with reproductive SCNT can be overcome, which is highly speculative at present. Yet this seems in the distant future because conditions such as fetal death, premature aging, and significant developmental disorders are obstacles to using the healthy adult's genome for reproductive SCNT.

The effect of reproductive SCNT alternatively may be psychologically harmful for children. Despite counseling to the contrary, rearing parents might harbor undue expectations about the child's personality or believe that the child should be identical to the somatic cell donor. This risk is more likely if a fertile couple sought reproductive SCNT to replicate a person's genome because the couple values the donor's genetic traits, but it is also a risk if infertile couples used SCNT. In either case, harmful typecasting might result. Reproductive SCNT also might give children who know the traits of their genome donors too much information or unrealistic expectations about the future, which would be an especially difficult problem if the

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