

CEJA Report 1-I-94 Pre-Embryo Splitting

INTRODUCTION

Recent medical developments have enabled scientific researchers to split human pre embryos into genetically identical sibling embryos. While this procedure has been in use with animals since the 1980's, its recent application to human genetic material has posed new ethical and legal dilemmas and sparked a public debate concerning the proper role of reproductive technologies in our society (*The Washington Post*; November 16, 1993:Z12).

The issue of human pre-embryo splitting was raised in October 1993 when George Washington University researchers reported their success with the procedure at a meeting of the American Fertility Society (*The Washington Post*; November 16, 1993:Z12). The researchers had divided pre-embryos which were fertilized by more than one sperm and which therefore could not have completed gestation.¹ As public awareness of this medical breakthrough became widespread, many ethicists and other commentators questioned whether there were any appropriate uses of this technology. Concerns were raised not only about simple pre-embryo splitting to increase the likelihood that in vitro fertilization would result in a newborn but also about hypothetical situations in which human adults could be cloned or babies could be made to order with particular characteristics (*Time*, November 8, 1993:65-70; *Newsweek*, November 8, 1993:60-62,64-66).

This report will examine the uses of pre-embryo splitting (more popularly described as "cloning"), the benefits and possible harms, and the ethical issues which this technique raises.

DEFINITIONS

The term "pre-embryo" is used in this discussion because it most accurately describes the stage of development at which splitting can occur. The pre-embryonic stage lasts approximately 14 days after the initial penetration of the ovum by a sperm. The pre-embryonic stage ends when the primitive streak first appears, signaling the point at which only a single biological individual may result.^{2,3}

The term "splitting" is preferred over "cloning" for several reasons. The term cloning is typically used popularly to refer to the technologically infeasible technique of taking a single cell from a human already born or from a deceased person and using it to reproduce a genetically identical human being. In addition, when used to refer to existing methods for amplifying pre-embryos, the term cloning covers several different techniques of embryo multiplication.⁴

The first two techniques involve the procedure of "splitting" or "twinning" embryos.⁵ "Blastomere separation" involves the division of a four-cell or eight-cell pre-embryo into the individual totipotent cells (blastomeres), or groups of such cells, which comprise it.⁵ A two-cell pre-embryo can be divided into two blastomeres, a four-cell pre-embryo into four blastomeres and an eight-cell pre-embryo into eight blastomeres. In the method used by the George Washington researchers, the pre-embryo's zona pellucida is dissolved, and the individual blastomeres are coated with an artificial zona pellucida.¹ In effect, then, the pre-embryo is "split" into its constituent cells which then may continue to develop. However there are important limitations to blastomere separation. It is often difficult to efficiently obtain human pre-embryos, either by uterine flushing or in vitro culture.⁶ Once a blastocyst is obtained, its constituent cells rapidly lose their totipotency so, given current scientific understanding, one pre-embryo can yield a maximum of four viable pre-embryos via blastomere separation.⁵ In addition, many pre-embryos are destroyed in the process of separation. For example, blastomere recovery rates average less than 60% for frozen and in vitro fertilized (IVF) cattle pre-embryos,^{7(p.33)} although George Washington researchers

were able to recover a higher percentage in their work. A final limitation is that relatively few preembryos reach the embryonic stage.⁷ Currently, in human IVF procedures, only about 20% of embryo transfers lead to live births so that even fifteen viable pre-embryos would lead to around three live infants.^{5(p.20)}

The splitting of blastocysts (multi-layered pre-embryos at the last stage before implantation)⁵ is referred to as "embryo splitting". In this technique, a blastocyst is bisected into two multicellular groups of non-totipotent cells, each of which is nurtured to encourage further development.^{4,5} Since cattle blastocysts can be easily obtained by uterine flushing, embryo splitting is the preferred means of embryo multiplication in the cattle industry. However, embryo splitting yields only 1.0 to 1.52 pregnancies per original embryo, a yield less than the ideal rate of 2.0 due to the inevitable loss of some cells by the splitting process.^{8(p.28,64)} This inefficiency, coupled with the need for expensive technology and the lack of an embryo-sexing procedure has led to a decline since the mid-1980s in the number of dairy cattle registered from split embryos.⁸

Nuclear transplantation, the most technically advanced form of embryo multiplication, involves the transfer of the nuclear material of a cell of the pre-embryo to an unfertilized oocyte which has its maternal chromosomes removed. For example, in one such nuclear transfer technique, a blastomere is extracted from a pre-embryo and transferred to an enucleated recipient oocyte.⁷ The blastomere-oocyte complex is then chemically treated to induce fusion, generating a cloned pre-embryo which may undergo further development.⁷ Nuclear transplantation is not yet an efficient process; less than 11% of pre-embryos derived from IVF donor cells developed into blastocysts.^{7(p.33)} Nonetheless this technique has led to the birth of several live calves which appear to be normal apart from an abnormally high birth weight,^{4,5,7} although 20-30% have exhibited persisting non-genetic disorders.⁶

Given these considerations, it is not clear whether any of these techniques will ever be a useful adjunct for reproductive purposes. Nevertheless it is important to consider the ethical issues in pre-embryo splitting because future developments in medical knowledge may result in a more effective method of embryo multiplication for humans as well as animals.

JUSTIFICATIONS FOR PRE-EMBRYO SPLITTING

Infertility affects approximately 2.4 million married couples in the United States.⁹ A number of conditions may result in infertility: blocked or damaged fallopian tubes, ectopic pregnancies, ovulation problems, endometriosis, immunologic disorders, low sperm count, sexually transmitted diseases, and advanced age.^{9(pp.6,61-82),10} Although adoption and surrogacy may be available to infertile couples, in vitro fertilization is often the only option that would allow both parents to contribute genetically to their child.

If the technique is improved to the point of proven clinical efficacy and safety, splitting of preembryos could serve as an important adjunct to in vitro fertilization by eliminating the need for the woman to undergo two kinds of medical risks. First, pre-embryo splitting can reduce the need to give drugs to the woman to stimulate ovulation. Ordinarily, during the in vitro fertilization process, women are given drugs that stimulate ovulation in a way that produces multiple ova for retrieval; by transferring a few fertilized ova at one time to the woman's uterus, physicians can increase the chances that one of the pre-embryos will actually implant and develop into a child. With pre-embryo splitting, since multiple pre-embryos can be obtained from one ovum, there might be less of a need to employ ovarian stimulant drugs with their various health risks such as possible increases in the rate of development of breast¹¹ and ovarian cancer. Indeed, a recent study found an increased risk of ovarian tumors in women who had taken the ovulation-inducing drug clomiphene for a year or longer.¹² Second, pre-embryo splitting reduces the need to subject women to the ovarian retrieval process. Often, because only around 5%-10% of ova end up as a child after in vitro fertilization,⁶ the woman may undergo several ovum retrieval processes before she gives

birth. With pre-embryo splitting, only one ovum retrieval procedure might be needed. In sum, pre-embryo splitting may permit women to undergo in vitro fertilization in a way that poses a smaller health risk to themselves.

Access to risk-reducing medical procedures is not only desirable, it is usually a matter of right. Fundamental moral principles require that patients be permitted access to medical procedures that reduce their risk of injury. To be sure, individual rights are not without limits; accordingly, it might be possible to justify the withholding of risk-reducing procedures if doing so would serve some important social goal. However, because every person deserves full dignity and respect, it is generally wrong to use people as a means to accomplishing social goals, even very worthy ones. Under constitutional law, it is generally not permissible to force one person to assume a health risk so as to enhance the health of another person.¹³ For example, people may not be conscripted into medical research to advance scientific knowledge.

In addition to enhancing the woman's fundamental right to be free of unnecessary health risks, pre-embryo splitting might enhance the woman's ability to exercise her fundamental right to reproduce. For example, if because of unrelated gynecologic disease or chemotherapy for nongynecologic cancer a woman loses her ovulatory capacity after undergoing in vitro fertilization, pre-embryo splitting of any frozen preembryos might increase the likelihood that the woman will give birth to a genetically related child. Patients should not be denied access to medical procedures that enhance their ability to reproduce. Because procreation is "one of the basic civil rights" of individuals,¹⁴ it generally is not permissible to restrict a person's reproductive freedom unless there is a compelling social interest that can be advanced by the restriction. While the right to control procreation has been more extensively developed in the context of preventing procreation (e.g., contraception and abortion),^{15,16} it is also of critical importance in the context of undergoing procreation. For many infertile couples, the emotional toll caused by their inability to conceive children is devastating.^{9(pp.8,37)} Infertility is a serious and often emotionally debilitating medical problem; consequently, infertile couples will often go to great physical and financial lengths in their efforts to conceive. If the technique is improved, pre-embryo splitting can substantially increase the chances that an infertile couple will eventually have children. For some couples, the ability to split a pre-embryo might be their last hope for conception in which they both are genetically related to the child. In addition, because pre-embryo splitting can potentially limit the need for repeated ovum retrieval procedures and therefore could decrease the costs of in vitro fertilization, pre-embryo splitting may make in vitro fertilization more affordable and hence more accessible.

Pre-embryo splitting may also facilitate the process of pre-implantation genetic diagnosis.^{6,17} In general, it is permissible for couples to screen pre-embryos for genetic disease.¹⁸ If the pre-embryo is found to have such a disease, the couple can choose to discard or destroy the pre-embryo prior to implantation. Pre-embryo splitting could be used to create genetically identical pre-embryos destined for testing rather than transplant. This could increase the efficiency of pre-implantation diagnosis by either enabling all testing, with its attendant risks to the pre-embryo, to occur on a pre-embryo that was not destined for transplantation¹⁷ or by doubling the amount of DNA available for genetic analysis.⁶

While it is not clear to what extent these possibilities are scientifically compelling,⁶ the potential benefit conferred by an increase in the effectiveness of screening for genetic disease warrants consideration.

Apart from considerations about the potential benefits of pre-embryo splitting as a clinical procedure, pre-embryo splitting may be an important research tool.⁶ Pre-embryo splitting could lead to the formation of a genetically-identical pool of research subjects, an asset currently unavailable. This could enable research on important topics in developmental biology which are currently beyond the capabilities of biomedical science, such as a study of the impact of differing environmental conditions, irrespective of genetic influence, on the development of pre-embryos.⁶ To the extent that this research would benefit future

clinical practice, pre-embryo splitting could be valuable beyond its direct application to reproductive technologies.

ETHICAL CONCERNS

Several ethical concerns have been raised about pre-embryo splitting. These concerns reflect important social values and must be given serious consideration in shaping social policy on the use of pre-embryo splitting. The ethical concerns should lead to some restrictions on pre-embryo splitting, but they do not justify a wholesale prohibition on the practice.

Preserving individuality. Critics of pre-embryo splitting have observed that splitting deprives the original pre-embryo of its unique genetic identity. As a result, two or more persons may be born with the same genetic make-up, each of them having had their individuality compromised. Because there is intrinsic value in the fact that each person has a unique identity, loss of that unique identity may undermine the essential worth and dignity that comes from a person's individuality. This is an important concern, and it deserves serious consideration.

Nevertheless, the concern about individuality does not justify a prohibition of pre-embryo splitting. Although without question Human individuality is a critical value that should be carefully safeguarded, splitting of pre-embryos does not seriously threaten human individuality. There is something special about having a unique set of genes, but that is not what we value when we value human individuality. Rather, by valuing individuality, we demonstrate our respect for every person's freedom to exercise self-determination, to make choices in accordance with their own values and to have those choices accepted by society.¹⁹ The freedom to be a creator rather than an object of the will of others is an essential element of peoples' efforts at defining their characters and assuming responsibility for their actions.²⁰

In addition, what is responsible for a person's individuality is not simply the person's genetic makeup but a combination of genetic predispositions, environmental factors, the choices that the person makes in life and the effects of those choices in shaping the individual's personality.^{21,22} Genes are indispensable to individuality, but they do not determine individuality. There is a crucial distinction between genetic uniqueness and individual uniqueness.¹⁷ Monozygous, or "identical", twins have much in common, including identical genes, yet they also have much that distinguishes them and makes them unique individuals.²³ Furthermore, these individuating characteristics become more pronounced as environmental influences diverge (as they would in the case of genetically identical siblings raised at different times and hence in dissimilar family units). While 12% of monozygous twins raised in the same household have IQs which differ by more than 15 points, this figure doubles to 24% when the children are raised separately.^{23(p.142)} Likewise, among pairs of monozygous twins, concordance rates for major diseases such as diabetes and bronchial asthma rarely exceed 50%, and, in the case of certain types of cancer, can be as low as 17.4%.²³ An obvious consequence of such statistics is that there are many pairs of identical twins who do not share identical medical histories. Yet it seems implausible to suggest, as is implied by concerns that the replication of a genotype will destroy individuality, that a twin who has undergone the physiological and psychological strain of a bout with cancer or a chronic disease is in a meaningful sense the "same" individual as a second twin who, while genetically identical to the first, has not been faced with that challenge. This implausibility becomes more acute when one considers the way in which the course of a disease changes the character of interactions with others and the effect of such a change on the development and self-definition of the individual. Indeed, what is critical about individuality is not what people *are* but how they are *treated*, and identical genetic makeups do not prevent different persons from being treated as individuals.

Avoiding psychological harm. Critics of pre-embryo splitting raise concerns about the possibility that individuals will suffer psychological harm from having genetically identical siblings, particularly if the

identical pre-embryos are implanted several years apart.

Concerns about psychological harm do not justify prohibitions against pre-embryo splitting. Genetically identical siblings have always existed, and, while there are undoubtedly both psychological advantages and disadvantages to having a genetically identical sibling, studies have shown that identical twins have fewer psychological problems than other children.¹⁷

Nor is there reason to think that significant harm would result if the genetically identical sibling comes from a pre-embryo that had been frozen for several years after the splitting. It has been suggested that the older siblings will be harmed by the knowledge that their individuality has been compromised. Yet, as discussed above, genetic makeup is only a part of individuality; just as people enjoy sharing the same parents with their siblings but also enjoy having ways to distinguish themselves from their siblings, the older siblings will benefit both from the similarities and differences they have with the younger siblings. It has also been suggested that the older siblings will be harmed by the way they are treated by others, that others will see them less as individuals. However, it is difficult to see why others would stop treating the older sibling as an individual simply because a genetically identical younger sibling has been born. Indeed, the age difference should cause others to expect fewer similarities in the siblings than if they were born at the same time.

Although it may be true that some persons with genetically identical pre-embryo siblings in cryopreservation may not want those pre-embryos to be used by their parents, children do not have veto power over their parents' decisions to bear other children. Undoubtedly, many children do not want their parents to have additional children, and older children may suffer from the loss of attention that occurs when younger siblings are born as well as from the strain on household resources that results when parents have to support additional children. Our society generally places control over the welfare of children or potential children in the hands of the parents. It is presumed that parents are the best situated to look out for their child's interests and, without further evidence that preembryo splitting is harmful to the children who are born through this method, the gamete providers should have the ability to decide whether or not to have their pre-embryos split in an effort to increase their chances of reproducing.

As for the younger siblings, it has been suggested that they will be harmed by the expectations others have for them to develop in the same way as their identical older siblings. But, people's expectations for a child are frequently shaped by their view of the child's older siblings, even when the siblings are not genetically identical, and this has never been considered a reason to prohibit parents from having additional children. Further, it is difficult to see how an argument could be made that it would not be in the interest of the younger sibling to be born because it would suffer psychological harm. If the pre-embryo can be said to have interests in being or not being born (and it is not clear that this is a meaningful conjecture) then the advantages in being born would outweigh the risk that psychological harm might complicate life.²⁴

Finally, given the rights at stake, we should be very careful about limiting the splitting of pre-embryos because of purely speculative concerns. As discussed, if improved, pre-embryo splitting can reduce the health risks of in vitro fertilization and facilitate the exercise of reproductive rights. Consequently, restrictions on pre-embryo splitting must be justified by clear and compelling social interests. Theoretical harms that are unsubstantiated by any evidence and that are at best highly speculative do not meet such a standard.

Genetic engineering. There is concern that parents will split their pre-embryos, implant some immediately and save the rest to see how the first child turns out. If the parents are happy with the first child, they will then use the other pre-embryos. This concern about trying to predetermine the characteristics of one's children is an insufficient reason to prohibit pre-embryo splitting. First, because of the risks, costs and

low success rates of in vitro fertilization, women or couples are unlikely to use such in vitro fertilization techniques unless they cannot have children otherwise. Second, even among those persons who use in vitro fertilization, basing future use of sibling pre-embryos on the development of the first child is likely to be rare. Most couples want to have their children reasonably close together so that they can keep their child bearing and raising within a limited number of years. However, it would take many years before parents could know how the first pre-embryo will have turned out. In addition, as discussed, individuality is highly valued, and parents generally share this value. Indeed, it is very common for parents to want two children, one girl and one boy. Even among couples that want multiple boys or girls, there is likely to be a preference for children who are genetically different. Third, society permits individuals a great deal of latitude in raising their children. Parents may influence their children's personalities by choices for schooling as well as extracurricular activities. There must be limits to the freedom of parents to shape their children, but, because of the myriad non-genetic influences on a person's development, splitting pre-embryos should not be viewed as exceeding those limits.

There is particular concern that parents will split pre-embryos and save them as a back-up in case their children become candidates for an organ transplant. It is indeed troubling that parents might bear a child not for its own sake but to serve another child's interests. Yet, we generally do not restrict a person's ability to procreate because we think that their motives for having children are insufficiently laudable. We do not require parents to disclose their reasons for having children, nor do we demand that only certain reasons will suffice. Many factors are weighed by a couple when deciding whether or not to conceive a child, and many of those reasons go beyond having a child for its own sake. Some people gain a sense of purpose or self-esteem by having children; others have children to carry on their bloodline and ensure genetic continuity.^{25,26} We do not restrict fertile couples from reproducing in cases where they have questionable reasons for having a child even though their reasons are less compelling than saving a child's life. If there is a need to prevent couples from using a pre-embryo to procreate an organ donor for an existing child, then the restriction should be on the later use of the frozen pre-embryo, not on the practice of splitting pre-embryos. The likelihood that couples will use pre-embryos in this way is so small that it does not justify prohibiting pre-embryo splitting entirely. Rather, this potential problem can be addressed by safeguards or by moral persuasion to discourage inappropriate use of pre-embryo splitting.

Marketing Pre-embryos. Commentators have observed that pre-embryo splitting could result in a market for frozen pre-embryos. Infertile couples might seek the pre-embryos of prominent individuals or of people who have children that seem desirable. Again the answer to this concern is not to prohibit pre-embryo splitting; rather, as with the commercial sale of organs and babies, the sale of pre-embryos should be prohibited by law.

Mass eugenic scenarios. It has been suggested that pre-embryo splitting might be used for mass eugenic purposes. While such activities certainly should be prevented, prohibiting pre-embryo splitting for reproductive purposes is not an appropriate prophylactic measure. People with eugenic purposes will be able to use the technique of pre-embryo splitting even if it is not available for reproductive purposes; we should not adopt prohibitions on legitimate reproductive activities when the prohibitions will not prevent the kinds of harms with which we are concerned. Rather, we need to take other steps to prevent eugenic abuses. We do not prohibit surrogate decision-making in the withdrawal of life-sustaining treatment because of concerns that a family member who is a primary beneficiary of the patient's will might act in their own best interests rather than in those of the patient. Instead, we permit the practice of surrogate decision-making while implementing other measures to directly counter the risk of potential abuses.

CONCLUSIONS

For the foregoing reasons, the Council issued the following opinion on pre-embryo splitting at the June 1994 Annual Meeting of the House of Delegates:

2.145 PRE-EMBRYO SPLITTING. The technique of splitting in vitro fertilized pre-embryos may result in multiple genetically identical siblings.

The procedure of pre-embryo splitting should be available so long as both gamete providers agree. This procedure may significantly increase the chances of conception for an infertile couple or for a couple whose future reproductive capacity will likely be diminished. Pre embryo splitting also can reduce the number of invasive procedures necessary for egg retrieval and the necessity for hormonal stimulants to generate multiple eggs. The use and disposition of any pre-embryos that are frozen for future use should be consistent with the Council's opinion on frozen pre- embryos. (Opinion 2.141)

The use of frozen pre-embryo identical siblings many years after one child has been born raises new ethical issues. Couples might wait until they can discover the mental and physical characteristics of a child before transferring a genetically identical sibling for implantation, they might sell their frozen pre-embryos based upon the outcome of a genetically identical child, or they might decide to implant a genetically identical sibling based on the need to harvest the child's tissue.

The Council does not find that these considerations are sufficient to prohibit pre-embryo splitting for the following reasons:

(1) It would take many years to determine the outcome of a child and most families want to complete their childbearing within a shorter time.

(2) The sale of pre-embryos can and should be prohibited.

(3) The small number of couples who might bear identical siblings solely for purposes of harvesting their tissue does not outweigh the benefits which might be derived from pre embryo splitting. Additionally, it is not evident that a sibling would have negative psychological or emotional consequences from having acted as an organ or tissue donor. Indeed, the child may derive psychological benefits from having saved the life of a sibling.

To the extent possible, discussion of these issues should be had with gamete providers prior to pre-embryo splitting and freezing so as to inform the prospective parents of possible future ethical dilemmas.

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