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POLICY STATEMENT*

ETHICAL ISSUES IN ASSISTED REPRODUCTION

*Joint Canadian Fertility and Andrology Society/Society of
Obstetricians and Gynaecologists of Canada Report*

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SPERM SORTING FOR MEDICAL AND NON-MEDICAL REASONS

INTRODUCTION

In the 1990 report, *Ethical Considerations of the New Reproductive Technologies*, the SOGC and CFAS endorsed two positions regarding medical intervention by sperm selection to influence or determine the sex of a prospective child: i) that techniques continue to be developed and offered to prospective parents “for use in the prevention of certain (X-chromosome linked) genetic disorders” which are serious, untreatable and prematurely fatal, such as Duchenne muscular dystrophy or Lesch-Nyhan syndrome; and ii) that possible consequences, should sex preselection become widely utilized for reasons that are not medically indicated, be further investigated, with specific respect to the non-therapeutic desire purposively to have a child of a particular sex. In light of medicine’s responsibility to respond to serious genetic diseases, the new Joint Committee concurs with the first of these positions. However, it finds the recommendation to be inadequate in addressing the associated techniques’ current lack of scientific validity and the uncertainty of their safety for either the mother or child. Accordingly, the Committee has developed a more detailed position. With respect to the issue of interventions for nonmedical reasons, the Committee opposes such practices whenever they encourage or support unethical treatment of individuals.

METHODS

The diverse methods for trying to assure that a child is of a certain sex can be divided into four basic categories. The first includes techniques which require no intervention by, or reliance on, the medical community-at-large or its technology. Such methods are often labelled as folkloric because their origins date back centuries, and because they have been used in diverse, non-technological cultures. Included in this category are

special diets and complicated coital practices. The second category is preselection methods used to mechanically separate X-bearing sperm from Y-bearing sperm, or to produce an increased proportion of either type of sperm. Once fertilization has occurred, selection methods, as in the third category, can involve DNA analysis of IVF embryos prior to implantation (pre-implantation genetic diagnosis). Only embryos of the desired sex would subsequently be transferred to a woman’s uterus. If IVF has not been involved, abortion is a possible option after determination of the fetus’ sex by either chorionic villus sampling (CVS) or amniocentesis.

Sex preselection methods have the potential to produce an unaffected healthy child without resorting to embryonic, fetal or infant selection. The appeal of sperm sorting is further increased by several expectations: its reliability, relative cost effectiveness, efficiency and theoretical simplicity. If a very high reliability rate could be ensured, sperm sorting would virtually preclude recourse either to embryo disposal or abortion, two procedures which are not unanimously accepted across society as ethically resolved.

CANADIAN EXPERIENCE

Very few Canadian institutional facilities or medical practitioners offer or provide sex preselection methods in cases where there is no risk of inheriting a serious disease. Detailed statistics are limited, however, in 1995, Health Canada reported only two private clinics which used sperm sorting operating in the Toronto area, both on a fee-for-service basis. In response to this relative shortage, some Canadians choose to travel to private American clinics to obtain such services.

The only published national survey of Canadians’ attitudes to these issues, taken in 1992, was originally conducted to respond to the concern that availability of such interventions would ultimately create a sex mal-

distribution in the general population. Although it did reveal a somewhat larger minority who wanted a male first-born child by comparison to those who wanted a female first-born, the strongest preference among respondents was to have an equally balanced number of boys and girls in a family. Potential use of techniques to influence a prospective child's sex was considered by a sizeable minority, but factors of cost and invasiveness would readily deter many from actual use. In summation, no overall skewed preference for either sex was found, and only a minimal interest was identified in using any sex preselection or selection technique.¹

INTERNATIONAL EXPERIENCE

Private sex preselection and selection services are available in the United States, Europe, Africa and Asia. While the exact number of such clinics worldwide is unknown, a survey of relevant medical literature would suggest that less than one hundred are in operation.

In many countries, traditional cultural values and norms judge a male to be of greater socio-economic worth than a female. China and India are two countries long recognized for obvious male bias and privilege and, consequently, widespread female abuse and infanticide. These values and actions have been reinforced, respectively, by China's one-child family planning programme, and India's continued custom of marriage dowries.

In western industrialized nations, there appears to be no consistent public response to the morality of non-therapeutic preselection or selection methods. Most researchers and many physicians approve of these techniques because of their potential to meet various personal desires of couples or individuals. Other practitioners and feminists disapprove of these methods because of their potential to reinforce sexist preferences, or to objectify both a prospective child and the special relationship between parent and child. A review of attitudinal surveys since the 1930s reveals a general, sustained and marked preference for male children over female children, for male first-borns, and for more males if there is an unequal number of children in a family.²⁻⁴

The prevalence of sexist attitudes correlates with the world-wide prevalence of patriarchal societies. The structure of patriarchy relies on the predominantly male-oriented distribution of power and, consequently, the distribution of liberties and opportunities. Objectifica-

tion of children can stem from the socio-economic benefits and burdens associated with child-rearing, as well as from adopting a consumerist perspective (as opposed to a commitment perspective) towards family structure. In most countries, economic priorities and expanding consumerism can markedly influence the status of, and expectations for, families and their members.

CRITICAL ANALYSIS

There are two separate issues to be addressed in this paper: the acceptance of sperm sorting as a valid technique for prevention of genetic disorders; and the provision of preselection services for non-therapeutic reasons, and specifically for sex selection, by the medical community (in contrast to private sponsorship). Before discussing specific techniques, the fundamental decision to intervene as early as possible to prevent certain inheritable diseases demands its own justification. The objectives of medical technology in detecting genetic markers for serious diseases are in accord with the moral principles of beneficence, non-maleficence and autonomy: the first two relating to the great extent and degree of untreatable suffering likely to be endured by the potential child in a shortened life, if born with certain congenital disorders; and the last relating to each prospective parent's freedom of individual reproductive behaviour (although this freedom is not absolute in most societies), and direct responsibility for the consequences of such freedom. Thus, genetic diagnoses and interventions do have ethical warrant.

A) THE TECHNICAL VALIDITY OF SPERM SORTING

There are several methods being investigated, either to separate X-sperm from Y-sperm completely, or to produce samples with a higher proportion of either sperm type. These methods are based upon varied assumptions about the electrical, morphological or DNA-content differences between the two types of sperm. Techniques currently under discussion in the clinical literature include electrophoresis, convection and centrifuge separation, flow cytometry, albumin gradient separation and Sephadex gel penetration. The most promising technique published to date involves separation of X- and Y-sperm by flow cytometry.⁵

Some published research reports by a technique's inventor(s) have been challenged for failing to conform

to standard research protocols, including conducting simultaneous control studies, performing sensitivity analyses, or having statistically significant sample sizes. In other instances, the initial positive results have not been sufficiently duplicated by other studies.^{6,7} Although these techniques arose following the demand of the agricultural industry for more direct control over livestock resources, no research has been published on the long-term effects of such techniques on domestic animals. Similarly, no research has been published on the short-term and long-term outcomes of these methods on either human embryos or, more importantly, on any resulting children.

These criticisms underscore the fact that preselection techniques must be considered as still in the exploratory, developmental phase of research. As such, they cannot be offered or provided as reliable, valid or safe means to prevent or to reduce the likelihood of the inheritance of serious sex chromosome-linked diseases. In the context of genetic counselling services for prospective parents, these methods must be explained as still evolving.

B) SEX PRESELECTION FOR NON-THERAPEUTIC REASONS

Many physicians and researchers support preselection techniques because they can meet the desires of parents to have a child of a particular sex. These desires can include: carrying on a family name, inheritance, having a more fulfilling parental experience, having a child who can have certain life plans open as possibilities, or balancing the sex ratios of the children in a family.

However, existing legal provisions in Canada and in many other countries allow sufficient latitude for retaining or modifying surnames, and for the private bequeathal of personal assets. A desire for a rewarding parental experience can misplace the appropriate and necessary focus of parenting. In accepting the responsibility to be a parent, the first priority should always be the child and his or her interests and needs, especially until the age of maturity and independence; any appeal to the benefits gained by the parent should be of much lower importance. Although the experience of parenthood should not be completely dismissed, and should indeed be as positive as possible for a parent, a presumption that a particular group of traits in a child will

result in a more satisfying parental experience is mistaken. Genetic makeup is only one of many factors that mould personality and character; a parent cannot predict what kind of relationship will arise with a child at any time, or with the adult the child will become. Similarly, it is unrealistic to assume that a child will ultimately pursue a particular goal or take advantage of any given opportunity. To predetermine a son or daughter's career or lifestyle is to impose unilaterally the parent's values on the child, thus ignoring the young adult's own interests, priorities, autonomy and agency. Claiming that some careers or opportunities are exclusively for males and others for females is evidence of traditional sexist thinking.

Many parents consider using some method of intervention to balance or equalize sex ratios in their families, an objective that reflects the idea of an "ideal" family. Such a notion is questionable because it presumes that there is some prescriptive standard for a "good" or "right" family unit, a perspective inappropriate to something as unique and deserving of respect as individuals and the families they constitute.

In general, preselection techniques may be viewed as increasing an individual or couple's reproductive choices; yet increasing technology may actually encroach on the decision process itself. The absence of data about the existing techniques' effectiveness, short- and long-term outcomes, and safety, means that a person's decision will be based on incomplete information. An assumed imperative to use any appropriate technology available could lead to the conclusion that not to avail oneself of an available method is to be judged irresponsible or irrational. Over time, these techniques may come to be perceived as no longer optional. In this way, opportunities for choice can be changed into burdens of choice. For this reason, pre-selection methods in themselves should not be presumed to be necessarily supportive of reproductive choice.

Individual desires do not in themselves impose duties or responsibilities on others. To create such obligations, a desire must involve an ethically legitimate and weighty claim. A parent's desire for a certain sexed child may be a considered desire from the parent's viewpoint, but such personal preferences do not place binding duties on the medical community to allocate scarce medical resources for the development and provision of



techniques to ensure a child of one sex rather than the other. Thus, none of these parental preferences can be considered as ethically important grounds for the provision of preselection services.

RECOMMENDATIONS

1. Sperm sorting for sex selection to avoid severe sex chromosome linked disorders is morally acceptable.
2. Sperm sorting for sex selection to have a child of a desired sex for non-medical reasons is morally unacceptable.
3. Sperm sorting for sex selection must only be offered to patients as a research technique (not a therapeutic intervention), until the safety and efficacy of a specific sperm sorting technique has been scientifically validated. Patients must provide an informed consent to this research participation.

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PRECONCEPTION ARRANGEMENTS

INTRODUCTION

In a preconception agreement, a gestational woman may allow her body to bear another's child. This agreement may be reached for any number of motives, including altruism or profit. As a living child is the product of this transaction, the parties involved cannot approach the transaction with detachment, being themselves involved physically and psychologically, as well as financially. The transaction does not usually remain between equals, even when it may have begun so. All of these factors, as well as the increasing frequency of this practice, compel us to examine the underlying issues and, consequently, the ethical validity of preconception arrangements.

TYPES OF PRECONCEPTION ARRANGEMENTS

A) GENETIC GESTATIONAL ARRANGEMENTS

The most common preconception arrangement involves the insemination of a fertile woman with the commissioning man's semen. Donor semen can be used, enabling an infertile man or a woman to be commissioner(s). The insemination can be done either with the help of health care professionals (the most common method) or through self-insemination. More rarely, the egg is fertilized through sexual intercourse. In all these cases, the child produced is genetically related to the gestational woman and the male commissioner or the sperm donor.

B) EXCLUSIVELY GESTATIONAL ARRANGEMENTS

These arrangements involve the implantation of a fertilized egg in the gestational woman's uterus, a highly technical process which always involves *in vitro* fertiliza-

tion (IVF). The child produced through the arrangement usually has no genetic link to the gestational woman. The child can be genetically related to the commissioning couple, or to the commissioning woman and another man, or to the commissioning man and another woman, or to two donors. Although initially rare, exclusively gestational arrangements are becoming increasingly common.

C) COMMERCIAL AND PAID ARRANGEMENTS

In commercial arrangements, a third party or broker helps to co-ordinate the preconception arrangement by linking a gestational woman with the commissioners for a fee, usually around \$15,000 to \$20,000. The broker is paid by the commissioners, as is the gestational woman, either directly or indirectly. Although there is an established commercial system in the United States, there appears to be no Canadian equivalent. Paid arrangements are those that involve the payment of money or other consideration to the gestational woman, on top of her expenses, but do not involve a commercial broker.

D) NON-COMMERCIAL ARRANGEMENTS

Non-commercial preconception arrangements usually imply that the gestational woman is a very close friend or family member of the commissioning person or couple. There is no fiscal profit for any of the participants, though in some cases there may be reimbursement for expenses associated with the pregnancy.

CANADIAN EXPERIENCE

What empirical data exist on the prevalence of preconception arrangements in Canada are scarce and outdated. The most recent examination, carried out in 1991 for the Royal Commission on New Reproductive

Technologies, focused on university-based infertility clinics, with only a limited sampling of independent practitioners.¹ Although only one child was found to have been born to a gestational mother within these parameters, three years earlier the Law Reform Commission of Canada found evidence of at least 118 preconception agreements which had involved one or more Canadian participants.¹ Canadians served as the gestational mother in 13 of the cases, as the commissioning couple in 62 cases, and in one case a single Canadian man received a child. At least 76 of the documented cases were arranged by a commercial agency in the United States. All figures are believed by the authors to be very conservative. Thus, it is likely that private units may be increasingly active in this area.

Quebec is the only province in Canada where preconception agreements are legally unenforceable;² legal analysts, however, have predicted that the result would be no different elsewhere in the country, although this has yet to be tested. Briefly, the prevailing legal opinion holds that although preconception agreements have been set up as contracts, the purported contract deals with the custody of a child, a subject clearly covered in existing family legislation. In keeping with the principles of family law, the determination of who should care for the child would not be based on the terms of the agreement, but on the child's best interests.

INTERNATIONAL EXPERIENCE

No uniform position on preconception arrangements exists, however, the general trend internationally has been to discourage the practice. To date, only Germany has completely banned the practice of all forms of commercial and non-commercial preconception arrangements.³ Most jurisdictions which have addressed the issue do oppose commercial arrangements, even criminalizing them in some places, while many have attempted to suppress non-commercial arrangements. Approximately two-thirds of the international guidelines and legislation examined demonstrate a preference for at least one of the commissioners to have a genetic relationship to the child. Where prohibitions and penalties are in place, most jurisdictions are careful not to penalize the gestational woman. In addition, the agreement between the parties is unenforceable in many jurisdictions, either because of spe-

cific legislation or because of court decisions which find such agreements to be invalid.

CRITICAL ANALYSIS

One of the most serious problems with commercial and paid preconception arrangements is the potential for exploitation of the gestational woman. On average, gestational women are much younger, less educated and less wealthy than commissioners. Although some brokers claim that money is not the main motivating factor for gestational women, most women would likely not participate if they were not paid. While it could be said that many jobs endured by disadvantaged women are oppressive and exploitative, carrying another couple's child cannot be compared to other, more traditional forms of employment. Gestational women are exposed to risk of physical and psychological harm. They experience one of the most intimate human relationships, that which forms between a mother and child, and are then forced to sever that tie. In addition, termination, a protection available in traditional employment, is not available to a gestational woman. She cannot terminate a pregnancy if it becomes unbearable, nor can she apply to the government for compensation if she suffers a physical injury or disability from the pregnancy. Although the pregnancy could be terminated by abortion, it is likely that the gestational arrangement will preclude this option, even where an individual woman's moral convictions might allow it; nor would a woman who chooses termination return to her pre-pregnancy state, either physically or psychologically.

As gestational women are generally less educated than other participants in the gestational arrangement, they may be at even greater risk of being manipulated. The primary concerns of the broker and the commissioner(s) are not those of the gestational woman, but focus instead on the completion of the exchange. Consequently, the broker or commissioner(s) may exert pressure on the gestational woman, coercing her into accepting risks or terms to which she may not wish to be exposed. For example, her activities while pregnant may be severely restricted, and she may be forced to take tests to monitor the development of the fetus. In these ways, gestational women are placed in a highly vulner-

able position, and financial need or lack of education may make it even more difficult for them to be adequate advocates on their own behalf.

A less obvious, but equally serious, problem with commercial and paid preconception agreements is that they are based on the law of contracts, a legal model designed to deal with the exchange of goods, not people. One of the principles at the heart of contract law is personal autonomy and the right to contract at will. In the context of preconception agreements, this means that women should have full control over their bodies and their reproductive capacities. Such control encompasses the right to enter a preconception agreement. By focusing exclusively on the contracting parties, however, this argument completely overlooks the subject of the contract: the exchange of a child for money. If a child is to be treated with the inherent respect and dignity afforded to all human beings, it cannot be treated as goods available for a price. Because of this turning of human life into a commodity and the potential for economic exploitation of the gestational woman, the existing contractual model of individual autonomy is found to be inadequate.

In contrast, unpaid preconception arrangements do not carry the threat of economic oppression of underprivileged women, nor do they bring the principles of the free market into the creation of human life. However, they do have the potential to be exploitative and oppressive. Given the depth of emotion involved, the arrangement has the potential to be extremely coercive. If a woman is upset by her inability to have a child, a close friend or family member may offer to act as a gestational woman, without adequately considering the risk for physical or psychological harm in the arrangement. Once she has agreed to participate, the gestational woman may feel trapped. If she changes her mind before the pregnancy, she may feel guilty for causing her friend more pain; while if she goes ahead with the pregnancy and then finds herself growing attached to the child, she may become reluctant to give it up. Instead of the joy and happiness which are supposed to greet a new life, feelings of betrayal, anger and jealousy may well result, regardless of whether or not she decides to give the child to the commissioner(s). Consequently, the commissioner(s) may attempt to reinforce their role as parents by minimizing contact with the gestational woman.

Unless the friendship is completely severed, the child's entire upbringing may be set against a backdrop of tension among the child's social, genetic and gestational parents.

Although the typical unpaid arrangement involves close friends or family, other agreements have the potential to be just as exploitative. In one case, the gestational woman agreed to carry the child of a male superior at work. Regardless of the precise type of potential coercion, the potent mix of expectations and needs among close family members, friends, co-workers and others directly and indirectly involved may make these "altruistic" private arrangements potentially even more coercive than commercial arrangements.

There is also a possibility that the female commissioner may be coerced into participating in a preconception arrangement. Because society places such a high value on woman's role as mother, many women who are unable to bear children feel inadequate. Thus, although the woman herself may not want to raise a child carried by another, she may be willing to go along with the arrangement to make up for her sense of perceived failure for her partner's sake.

Even in those cases where none of these individual concerns applies, there remain ramifications for society as a whole. In effect, each gestational arrangement constitutes a social experiment on the children who will be involved, and may lead society to view children as things which can be bartered or contracted for. With the increasing prevalence of exclusively gestational arrangements, more underprivileged women may find themselves carrying the children of wealthy couples.

Societal views of women may also be affected. Allocation of time, research and resources to the practice of preconception arrangements reinforces a perceived primary importance of women as mothers, yet simultaneously fragments that role; a child born through a preconception arrangement could have up to three "mothers." In this manner, motherhood could be turned into an assembly-line process with different women responsible for each segment, yet with each woman ultimately dependent on the medical practitioner to compile the segments into a complete child. This potential devaluation of motherhood could change the way society views the creation of a new human life. Although an "ideal" preconception arrangement may bring only

happiness to those parties directly involved, the individual rewards must be weighed carefully against the potential influences on society as a whole.

Thus, it appears that virtually all the possible dangers, as well as the pain of pregnancy and any reproductive technology used to achieve it, are suffered by the gestational woman, while the benefit is enjoyed by the commissioner(s). Along with the usual risks associated with pregnancy and delivery, the gestational woman may face the possible transmission of such sexually transmitted diseases as HIV. When IVF or other technology-based procedures are involved, there are additional, possibly unknown, dangers. These may be increased by the added stress of knowing the baby is to be given away at birth. Once the baby has been delivered, the gestational woman faces the psychological trauma of separating herself from the child she has nurtured for nine months.

Some justify this imbalance by comparing it to the altruistic donation of an organ by a living donor, noting that society condones such procedures, even though they involve harm to one person for the benefit of another. A woman should, therefore, be able to choose pregnancy, just as she might choose to donate a kidney. Although the analogy is initially attractive, it is clearly problematic. An organ is merely a body part, while a child is a human being with whom a woman develops a relationship during the nine months of gestation. Live organ transplants are performed to save lives, an important potential benefit that is commonly considered to justify the potential for harm to the donors. In contrast, the potential for harm in a preconception arrangement is incurred to alleviate the childlessness of the commissioner(s), and childlessness is not equivalent to a life-threatening condition. Finally, in most jurisdictions there is no commercial element to organ donation; the donor gives the organ freely to the recipient as an altruistic gesture. In contrast, most preconception arrangements involve some exchange of money, if only to cover the gestational woman's expenses, and many are overtly commercial. Without this exchange of money for a child, most preconception arrangements would fall apart.

RECOMMENDATIONS

1. Commercial preconception arrangements are morally unacceptable. The expected benefit to the com-

missioner(s) does not justify the possible physical and psychological harm to the gestational woman, the potential coercion and exploitation of women, and the explicit commodification of human life.

2. Non-commercial preconception arrangements may also be morally unacceptable, as they may result in more insidious forms of coercion. The potential for coercion of the gestational woman in these arrangements is extremely high, whether because of financial pressures or emotional ties to the commissioners. However, the committee was not unanimous in ruling out the potential that true altruism could exist in some cases of gestational arrangements.
3. The practice of preconception arrangements may influence society's view of children, replacing the inherent value of a child with legal notions of contracts and binding agreements for the exchange of goods, and may lead to further oppression of women, particularly disadvantaged women.

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OOCYTE TRANSFER: SOURCES OF OOCYTES AND THE NATURE OF THE EXCHANGE

INTRODUCTION

There are several actual and potential sources of oocytes for donation:

a. **IVF patients**

Oocytes retrieved from *in vitro* fertilization (IVF) patients are sometimes used to try to establish pregnancies for other women. A free or discounted IVF cycle may be offered in exchange for the oocytes.¹⁻⁴

b. **Surgical patients**

Women of reproductive age undergoing sterilization, laparoscopy to investigate their own infertility, or other similar therapeutic surgery, are another source of oocytes. These women may undergo ovarian stimulation prior to surgery to facilitate oocyte retrieval.

c. **Women not otherwise undergoing oocyte retrieval or relevant surgical procedures**

Women sometimes come forward to offer oocytes for transfer to others, sometimes with the potential donor anonymous, sometimes known to the recipient. Anonymous oocyte providers usually have one of two motivations: the desire to make a gift of their oocytes, or the desire to make money with their oocytes. Oocyte recipients frequently provide a friend or relative willing to undergo oocyte retrieval for the recipient's use.⁵ The shortage of oocytes available for transfer from other sources accounts for some of the use of women known to recipients; other reasons include the desirability of genetic relationship.

d. **Fetuses**

Fetal ovarian tissue has recently been proposed as a potential source of oocytes for therapeutic use. As immature fetal oocytes are essentially the same as immature oocytes found in the ovaries of women of reproductive age, it is reasonable to assume that they can be matured and used for pregnancy purposes.⁶ If any fetal

ovarian tissue is found to be morally and medically acceptable for therapeutic use in IVF treatment, it will come from electively aborted fetuses. The potential for genetic problems associated with spontaneously aborted fetuses is a sufficient reason to make these fetuses unacceptable as an oocyte source.

e. **Cadavers**

Another potential source of oocytes is the cadavers of women of reproductive age. As with fetal ovarian tissue, it is theoretically possible to retrieve immature oocytes from female cadavers, mature them in the laboratory and use them for pregnancy purposes.

NATURE OF THE EXCHANGE

There are three possible kinds of exchange for oocyte transfer:

a. **Donation**

No payment in money or kind is given in exchange for oocytes provided. Donation of oocytes does not exclude possible compensation for time, inconvenience, the costs of procedures performed, and so on.

b. **Sale**

Oocytes may be sold by providers to recipients or intermediary agents, including IVF programmes, who then sell the oocytes to recipients.⁷ In this case, a price is placed directly on oocytes.

c. **Trade or barter**

Oocytes may be traded for some other goods or service. For example, a free sterilization is sometimes offered in exchange for the provision of oocytes.^{2,3,8} Similarly, free IVF cycles are sometimes offered in exchange for half of the oocytes retrieved¹ or oocytes retrieved in excess of the IVF patients' own needs.^{2,3} Some IVF programmes offer IVF patients a discount on current⁴ or future¹ cycles if they provide some oocytes for other women's fertility treatments.

CANADIAN EXPERIENCE

Canada's medical community holds mixed opinions about using IVF patients as oocyte providers in exchange for IVF treatment.⁹ Some physicians, along with at least some of their patients, believe this practice provides financially needy patients with their only opportunity to achieve a pregnancy. That the pregnancy rate is suboptimal and involves some extra burdens is thought to be compensated for by the possibility that a birth may still result. Others in the medical community take an opposing view. They believe that this practice reduces human body parts to mere commodities and exploits women. Thus, other sources of oocytes must be found to increase the supply of oocytes for therapeutic use, and IVF treatment should be made available for financially needy women where it is medically appropriate.

INTERNATIONAL EXPERIENCE

In 1995, the Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) Standing Committee on Ethical Aspects of Human Reproduction issued a statement supporting altruistic donation of genetic material, allowing for reasonable compensation for legitimate expenses.¹⁰ Any payment for oocytes is unacceptable. Genetic material from a dead person is acceptable for transfer only when a written statement by the gamete provider exists; this point leaves open the possibility of using cadavers as oocyte sources. The committee also holds that the use of oocytes from an individual provider should be limited to prevent consanguinity.

In Australia, most European countries and Israel, where the local justice imperative in health care embraces reproductive medicine, financially needy women have access to IVF and, thus, are not in a position where they must consider allowing some of their oocytes to be made available for use by other women. In such countries as the United States, India and Argentina, where the government does not support IVF, IVF patients are commonly used as oocyte providers.⁹

In all countries where reproductive medicine is governed by legislation, the practice of using IVF patients as commercial donors is either prohibited by law (Austria, Germany, Norway, Sweden) or moral doctrine

(Islamic countries, Japan). Some countries (Australia, Belgium, France) permit non-commercial, altruistic donation. The practice of commercial oocyte transfer is found only in countries without national regulation (Argentina, India and the United States).⁹

Oocyte transfer involving oocyte providers known to the recipients is practised, advocated and/or preferred in many countries, including Australia,^{11,12} Belgium,¹³ the United Kingdom¹⁴ and the United States.^{5,15,16} Laws in the United Kingdom, Australia and many US states support the principle that the woman giving birth is the legal mother even if her own oocyte is not used.⁷ This and similar legislation may provide assurances to women considering undergoing oocyte retrieval for someone they know or for an anonymous recipient.

In 1994, British scientists proposed using fetal oocytes for oocyte transfer.¹⁷ In the same year, Britain's Human Fertilisation and Embryology Authority (HFEA) declared the use of fetal oocytes for transfer unacceptable,¹⁸ and the British House of Commons passed a bill banning the use of fetuses as oocyte sources for IVF treatments.¹⁹ Public opinion polls in various countries show fetal ovarian tissue to be the least supported source of oocytes.²⁰⁻²²

While researchers in Edinburgh propose research on techniques of cadaveric retrieval,²¹ cadaveric oocytes have already been used by some South Korean scientists to facilitate the conception and birth of a baby.^{21,23} Although the HFEA report holds no objection in principle to the use of cadavers as oocyte sources when the deceased woman gave prior informed consent, it does not give its sanction to such use.¹⁸

CRITICAL ANALYSIS

a) Sources of Oocytes for Oocyte Transfer

When women not otherwise undergoing oocyte retrieval or relevant surgical procedures become oocyte providers, they assume all the risks of oocyte retrieval, including ovarian hyperstimulation syndrome and the risks associated with surgery and anaesthesia. Surgical patients assume the risks of surgery and anaesthesia to meet their own surgical goals, but assume the risks of controlled ovarian hyperstimulation (COH) unless immature oocytes are cultured. There are no added physical risks for IVF patients who are oocyte providers for other women; as they assume the risks of oocyte

retrieval for their own sakes to facilitate their own pregnancies, allowing the transfer of extra oocytes retrieved is secondary. Electively aborted fetuses and cadavers cannot properly be said to incur risk of physical harm when used as oocyte sources. Practices that harm or potentially harm some participants for the sake of others should always be evaluated for their moral acceptability. Those practices where the physical harm is compounded by other serious moral concerns are especially suspect.

The potential for exploitation of some oocyte providers is great. Financially needy women seeking IVF treatments are most at risk for exploitation. Although they may not wish to share their genetic material, due to its intimate role in their self-identity or family-identity or for some other reason, poor women seeking IVF treatments often must choose between sharing their oocytes for a chance to reproduce or retaining their oocytes and foregoing reproduction.⁹ Although financially needy IVF patients are most at risk, all *in vitro* fertilization patients are vulnerable to social pressure and exploitation when they are asked to become oocyte providers for other women.¹¹ *In vitro* fertilization patients are aware of the shortage of oocytes available for transfer and the anxiety of those affected by infertility. Although they may not wish to provide oocytes for other women, they may feel obliged to share their oocytes when participation by these patients is suggested. Financially needy women who desire surgical procedures (other than IVF) that can only be obtained in exchange for making oocytes available for other women are another group at great risk for exploitation as oocyte providers.

In recent years, young financially needy university students have been targeted as an anonymous source of oocytes.^{24,25} These women are more easily persuaded to give up some oocytes at some personal risk for altruistic gains and financial compensation. Most programmes encourage these women to undergo oocyte retrieval several times,²⁴ thus compounding the risks of physical harm. The potential for exploitation in oocyte transfer is markedly reduced in countries where financially needy women have access to IVF treatments and relevant surgical procedures without giving up some of their oocytes in exchange.

Hopeful or desperate oocyte recipients may apply coercive pressure to friends and relatives to encourage

them to undergo the risks of oocyte retrieval, including genetic parenthood, for the benefit of the recipients.²⁶ Rejecting women known to recipients as a source of oocytes would prevent coercion of this kind. It may be argued that potential coercion in this context would not be greater than the potential coercion of known people to donate kidneys, bone marrow, liver sections and blood, when loved ones are at stake.⁷ This argument in itself does not show that the potential coercion involved with supplying known oocyte providers is morally acceptable. All coercive activities must be identified and minimized, if not eliminated. A rigorous informed consent procedure could help to accomplish this goal. Avoiding the use of this source of oocytes altogether might provide better assurance that participation is not coercive, but it would eliminate the possibility of genuine altruism.

As with all medical procedures, confidentiality and privacy must be respected and guaranteed. The release of information about oocyte providers, beyond those that have a legitimate need to know, infringes on their right to privacy and confidentiality. The guarantee of anonymity is shown to be an important factor for many women who undergo oocyte retrieval for the benefit of other women.^{27,28} People have interests in their own genetic material, in part due to its role in and effect on self identity and family identity, and its potential for reproduction. Respecting confidentiality and privacy protects those interests. It is possible that oocyte providers may prefer anonymity to protect themselves against possible legal liability for the maintenance of the child, inheritance claims, charges of negligence if the resulting child is defective in some way and invasion by the child or the child's family in the oocyte provider's future family life.^{2,3}

Legislation and thorough medical screening could reduce some of these concerns, but the oocyte provider's desire for privacy is realized best by anonymity. While total anonymity may favour oocyte providers' privacy interests over the interests of the children created with those oocytes,²⁷ there are compelling reasons to uphold some of the potential interests of the child created. Some information about the medical and genetic history of the oocyte provider may be important for medical reasons.^{2,3} In addition, it is widely held in the international community that people have a right to

know their biological origins,²³ and that such knowledge is important for developing self identity.²⁷ This information should be made available to oocyte recipients and/or their offspring as appropriate, while at the same time the privacy of oocyte providers should be protected by withholding their names and other identifiable information. Women who know the recipients of their oocytes are most at risk for infringement on their right to confidentiality and privacy. Steps should be taken as part of counselling throughout the IVF process to emphasize the importance of confidentiality and to minimize situations of unwanted disclosure.

As people have great interests in their own genetic material, obtaining voluntary, uncoerced and informed, written consent is crucial to the ethical acceptability of oocyte transfer between women. However, the potential for exploitation and coercion makes the establishment of informed consent very difficult.⁹ Still, the potential for exploitation and coercion are also reduced by ethical informed consent practices, including full disclosure about benefits and harm of participation, and assurances that refusal to consent to oocyte retrieval does not jeopardize access to health care. The chances of obtaining voluntary, uncoerced and informed, written consent from women of reproductive age is highest when oocytes are obtained from cadaveric sources. When consent is given before death, deliberation and participation decisions need not be made in times of stress, and such decisions are not subject to undue pressure or coercion by friends or families. Personal gain is similarly not a factor. By extension of accepted and acceptable reproductive freedom and cadaveric organ donation, it is morally acceptable for women to consent in cases of retrieval and transfer of their oocytes after death. The interests people have in their own genetic material would preclude using surrogate decision makers for the purposes of consent in cadaveric oocyte transfer.

Obtaining consent would be very complicated if fetuses were used as a source for oocytes.²⁹ Fetuses themselves are obviously in no position to enact informed choice, thus, this requirement falls jointly to both gamete providers. Although consent to have an abortion requires only the consent of the woman carrying the fetus, gamete providers must give joint consent to use fetal oocytes for pregnancy purposes, as each has an interest in possible

uses of their genetic material. Yet, as abortion decisions are often made in highly stressful, emotional conditions, informed choice when using fetuses as oocyte providers would be extremely difficult. Further complications occur when the gamete providers are not themselves in contact, or when one or both are minors, not infrequent circumstances in abortion decisions.

The potential for serious psychological harm to the children created using fetal oocytes from aborted fetuses provides the strongest argument against using such oocytes. A study in the United Kingdom shows that concern for children whose mothers never existed is the most common reason for objecting to the use of fetal oocytes to establish pregnancies.²⁰ It may be argued that there would be no important psychological harm incurred by children conceived using fetal oocytes as other children with a special conceptional status do not experience this condition. Analogies to other special conceptual practices, however, do not hold. That other IVF and adopted children lack knowledge about their genetic parents is not to suggest that they believe their genetic parents never existed as living people. It is assumed that they were alive, lived human lives, had thoughts, experiences and relationships with others. These assumptions, though general in nature, provide a framework for adopted children's sense of identity as individuals. Children of aborted fetuses would have no such framework for their sense of identity. Their conceptional status violates all accepted notions of motherhood and the history of people, for genetic mothers of these children have never lived basic human lives, and the children's biological history suffers the stigma of an unaccepted practice. The Human Fertility and Embryology Association believes that the widespread and fundamental objection to using fetal oocytes for IVF treatment would make it that much more difficult for children of aborted fetuses to come to terms with the means of their conception.²⁹

The psychological effects on children conceived using cadaveric oocytes are unknown. There is reason to believe that these effects would be less harmful than the effects caused by the use of fetal oocytes. Cadaveric oocyte providers were alive until shortly before their oocytes were used in IVF treatment. They chose to provide the means for these children's lives. Some medical and social information about the oocyte provider may

be made available to the recipients and their children to help the children develop a sense of identity. Donated cadaveric organs are widely accepted and appreciated as life-saving gifts. If the number of children created from a single oocyte provider are limited, then the resulting children should not feel that their conception involved a dehumanizing assembly line process using spare parts.

As with all oocyte transfer between women, the oocyte provider should consider the effects on her family of allowing another woman to use her oocytes to attempt conception. Genetic sons and daughters and half-brothers and half-sisters may be created. Some family members may wish to be a part of the lives of any children who are the genetic offspring of their relatives. This may be of greater concern for the families of some cadaveric oocyte providers. While some family members may be comforted by the simple possibility of new life formed because of a posthumous transfer of oocytes from a recently lost loved one, others may personally want to know the part of their loved one that lives on.

b) **Nature of the Exchange**

The flawed argument in favour of selling oocytes and the services that provide them is based on claims of ownership and the right to sell what belongs to oneself: that the oocytes of one's own body and one's own labour belong exclusively to one's own disposition; that no one has a greater property claim to one's own oocytes and labour than oneself; that the liberty exists to sell one's own oocytes and labour, just like other owned property. Rather, it is submitted that the liberty does not exist to use one's own oocytes, including their sale, in any way desired. One may not act to harm others without just cause. If the sale of oocytes and the services that provide them unjustly harms others, then their sale is morally wrong.

There are serious ethical concerns about women selling their oocytes and selling their services to provide oocytes. Such practices treat women, their bodies and human gametes as commodities, objects to be rented, bought and sold. Being party to the turning of humans and human parts into commodities violates basic norms of respect for human life, and sends a strong negative message against the specialness of human beings. Consequently, our self-identity may be harmed.

The selling of oocytes and the services that provide

oocytes also exploit those in financial need. The financial incentive will disproportionately entice poor women to undergo retrieval of oocytes³⁰ ultimately for the benefit of wealthy women. Not only do these financially needy women assume the serious risks associated with oocyte retrieval, they are also drawn to act in ways that devalue themselves as human beings and infringe on their interests in their own genetic material. As a group, the poor are exploited by a practice from which they have no chance of benefiting.

While some may think that to accept oocytes without payment is exploitative and unfair,³⁰ altruistic donation of human tissue and organs is highly regarded precisely because it does not benefit the donor, financially or otherwise.⁷ If ethical recruitment practices are followed, and voluntary, uncoerced and informed written consent is obtained, oocyte donation without payment may be considered altruistic. Although altruistic acts are appreciated, they are not normally considered exploitative or unfair, nor is it felt that they should be repaid.

While selling oocytes and the services that provide them is unduly harmful and morally unacceptable, compensating oocyte providers for their time, inconvenience and other direct expenses is reasonable. Women who willingly undergo the process of oocyte retrieval and make retrieved oocytes available to other needy women have, by these actions alone, made an important contribution for the sake of others. To compensate for other factors associated with oocyte retrieval demonstrates a willingness by those that benefit to share the burdens of oocyte retrieval. Compensation is distinguished from sale in that compensation does not exceed actual costs or costs in kind. It is a form of reimbursement, a refund for costs and burdens incurred.

The arguments about exploitation associated with the sale of oocytes also apply to some cases of reimbursing oocyte providers for services and expenses incurred during the oocyte retrieval process. For the financially needy, compensation for non-financial factors associated with oocyte retrieval, including their time, inconvenience and risk, may be essentially payment. The need for money may cause them to place a high value on the compensation offered and a low value on their other interests, or it may persuade them to give priority to the compensation over their other interests. To prevent

inducement to participate, the American Fertility Society guidelines recommend that payment should not be excessive.³¹ This recommendation is difficult to put into practice, as reimbursement that does not constitute payment for non-financial factors depends on one's personal circumstances. *In vitro* fertilization programmes can only be expected to use a reasonable personal standard to set the rate of compensation. Thus, appropriate compensation becomes whatever a reasonable person believes matches the financial and other costs associated with oocyte retrieval.

Women used as oocyte providers in IVF programmes are, at the same time, human subjects in oocyte transfer research. Thus, ethical guidelines for research involving human subjects are guidelines for ethical conduct involving oocyte providers. Each person's experience is relevant to an assessment of the practice of oocyte transfer. The Canadian Tri-Council Code for research involving humans supports compensation, but cautions against incentives for participation:

"While research subjects must not be induced by promise of reward to take risks in research that they would not otherwise undertake, neither must they be expected to subsidize research by suffering monetary or other losses. Costs incurred should be reimbursed... Payment may be calibrated to costs incurred, inconvenience, and alternative opportunities foregone by subjects, but should not be related to risk of injury in case subjects be improperly induced to take risks they would not volunteer in their usual lives."³²

Typically, less money is involved in compensation than in sale, so the risk and level of exploitation are reduced, though this remains an ethical problem. To keep exploitation of oocyte providers to a minimum, those at risk for exploitation should not be actively recruited by offering inducements to assume risks and burdens they would not otherwise assume.

Trading or bartering oocytes for goods or services may be considered either sale or compensation for donation, depending on the value of the offered commodity. If the value of the goods or services offered far exceeds appropriate compensation for oocyte retrieval, then the trade is not for goods of equal value and should, thus, be considered sale. If the value of goods or services offered matches the appropriate compensation, then the trade is compensation. However, to maximize the oocyte

providers' options and minimize undue pressure to participate, compensation should be made available as a financial refund to use as the oocyte provider wishes. Age limits for oocyte recipients remain controversial.

RECOMMENDATIONS

1. The transfer of oocytes is morally acceptable only in the context of donation. The sale of oocytes is morally unacceptable as is the trade of oocytes for adjunct services. The non-commercialization of oocyte transfer does not preclude compensation of the oocyte donor for reasonable expenses.
2. The transfer of oocytes from women (both live and cadavers) is morally acceptable, provided that technical, medical and regulatory safeguards are in place, and the informed consent of the oocyte donor and recipient have been obtained. The donor's informed consent must indicate whether any resulting embryos can be used for research as well as therapeutic purposes. The transfer of oocytes from fetuses is morally unacceptable.
3. To avoid the coercion of prospective donors and possible harm to offspring, oocytes donors should be anonymous. When coercion is not an issue, non-anonymous donation may be acceptable.
4. Donor oocytes should not be used in situations where pregnancy will endanger the health of the woman.
5. The number of children resulting from the oocytes of an individual donor must be limited so as to minimize the risk of consanguinity.

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DISPOSITION OF FROZEN EMBRYOS

INTRODUCTION

There are several reasons for freezing embryos. As the success rate for *in vitro* fertilization (IVF) is only 18.6 percent deliveries per retrieval,¹ more than one cycle of IVF is usually necessary to achieve pregnancy. A ready source of frozen embryos for later use improves the efficiency of IVF and embryo transfer (ET). Poor quality embryos are generally not preserved for therapeutic use.² Freezing embryos in addition to the maximum of three transferred to the uterus allows for the possibility of multiple embryo implantations for family completion without requiring additional ovulation stimulation for superovulation. Implantation can occur during a woman's normal cycle, thereby reducing the risk of ovarian hyperstimulation syndrome.^{3,5} Total costs, discomfort and inconvenience associated with ovulation stimulation are also reduced, as extra embryos obtained from one ovulation stimulation can be used for subsequent cycles.⁶ Finally, freezing embryos may permit some couples to store healthy embryos for later use when one gamete provider's future fertility is at risk, as is the case with some treatments for cancer.

Typically, most embryos are frozen up to the eight-cell stage of development. However, with improvements in technology, embryos up to the blastocyst stage of development may be frozen as well.⁷ "Disposition of frozen embryos" refers to what happens to embryos after they are cryopreserved. Voluntary, uncoerced and informed, written consent is integral to the ethical disposition of frozen embryos.

OPTIONS FOR DISPOSITION OF FROZEN EMBRYOS

1. PREGNANCY

Primarily, frozen embryos are used by the gamete

providers as part of the process that, for them, may facilitate pregnancy and the birth of one or more babies. If the gamete providers choose not to use existing frozen embryos themselves, they may choose to make them available to other women to allow them an opportunity to try to conceive. The frozen embryos may then be thawed and implanted in a woman who is herself infertile, or who is one party of a couple who are infertile.

2. RESEARCH PURPOSES

Frozen embryos may be donated for research purposes. Research may entail examination without manipulation, manipulation followed by discard, and manipulation followed by implantation.

3. DISCARD

Embryos may be discarded, if the couple desire.

CANADIAN EXPERIENCE

The final report of the Discussion Group on Embryo Research, submitted to Health Canada in 1995, affirms that decisions to donate frozen embryos for research are reasonable and ethically justified, with the informed consent of gamete providers, as an alternative to discard or donation to other women.⁸ Suggested limitations for acceptable research are mostly in agreement with the prohibitions cited in the 1995 voluntary moratorium on nine applications of reproductive and genetic technologies.⁹

INTERNATIONAL EXPERIENCE

The policies and practice of cryopreservation and the disposition of frozen embryos vary internationally from acceptance to prohibition.¹⁰ The National Health and Medical Research Council of Australia,¹¹ the Warnock Committee of England,¹² the American

Society for Reproductive Medicine of the United States (formerly the American Fertility Society)^{13,14} and the Board of Trustees of the American Medical Association of the United States¹⁵ all hold that cryopreservation is acceptable, and that gamete providers have joint decisional authority over disposition of frozen embryos created from their gametes. It is now common practice internationally for consent forms to provide couples with an opportunity to stipulate disposition decisions for at least some foreseeable circumstances including separation, divorce or death of gamete providers.¹⁶

There is general agreement in Australia, England and the United States that research on frozen embryos is permissible under certain conditions, and ET following research is permissible if it is reasonable to expect the embryo to develop normally.¹⁷ Donation of frozen embryos to other women for purposes of pregnancy tends to be supported internationally if appropriate counselling and consent procedures are taken.^{18,19} Embryo donation is prohibited in Austria, Denmark, Germany and Switzerland.¹⁶ Discard of frozen embryos at the will of those with decisional authority is accepted in England, Australia and most US states.²⁰

CRITICAL ANALYSIS

There are many factors to consider in determining the ethical disposition of frozen embryos. Each option must be discussed with the gamete donors to meet the requirements of voluntary, uncoerced and informed, written consent.²¹ Frozen embryos may not be donated to other women so that they may attempt pregnancies without the consent of the gamete providers, because the gamete providers have a strong genetic interest in what could happen to frozen embryos. Due to the complexity of relevant information and issues, counselling is an important component of giving consent for decisions about the disposition of frozen embryos. Although consent of those with decisional authority is emphasized, consent is also required by the recipients of frozen embryos when embryos are donated for research purposes or for their therapeutic use by others.⁶ Key information integral to consent decisions for ethical disposition is discussed in

the following eight categories:^{6,15, 22,23}

1. OPTIONS FOR DISPOSITION OF FROZEN EMBRYOS

Consent can be given only when detailed information has been provided about the options for disposition of frozen embryos (pregnancy, research, discard) and their subcategories (pregnancy for self or others, research for examination without manipulation, manipulation followed by implantation, implantation followed by discard and discard by various certain means). Consent may be given for one subcategory of disposition options, but not others (e.g. research involving examination only, but not research involving manipulation followed by implantation). The objectives, procedures and expected outcomes of each option should be explained, along with the expected or reasonably predicted benefits and harm for the embryo, the gamete providers and others. To the extent that the benefits and harm are not known, consent entails disclosure of this information as well. Information about which options are available at the freezing facility and which are available elsewhere must also be conveyed.

2. THE LIMITS OF DISPOSITION POSSIBILITIES

There are ethical, legal and practical limits to disposition possibilities. This information must be known by those making ethical disposition decisions. Designated donation must not be made on discriminatory grounds, for example, race, marital status or sexual orientation. Ethical limits also include observing the respect that frozen embryos deserve by refraining from uses that are an affront to human dignity (e.g. selling embryos). Efforts should be made to standardize the technology used at freezing facilities to maximize the availability of embryo donation for ET.

3. PERSONAL INFORMATION REQUIRED FROM GAMETE PROVIDERS

If they intend to donate frozen embryos for the therapeutic benefit of others, gamete providers must consent to testing for HIV, STD, genetic profile and other relevant assessments. They must agree to provide the freezing facility or appropriate parties with any relevant information obtained in the future.

They must also agree to inform the facility if they develop any reservations about donation.

4. COSTS

Those with decisional authority must have information about the costs of procedures, storage of embryos over time and insurance.

5. QUALITY AND SAFETY ASSURANCE

Information must be possessed about the extent to which the IVF programme and the freezing facility meet quality control and safety standards. The qualifications and experience of all personnel working with the frozen embryos should also be known. Quality assurance also includes quality of outcome. Accordingly, statistics about the success and/or failure of IVF and ET for live births, and in particular of ET following freeze-thaw, must be known.

6. CONSENT DOCUMENTS

Consent documents should remain flexible to protect the rights and freedoms of gamete providers, and to reflect their preferences and values.

7. PRIVACY AND CONFIDENTIALITY

Decision makers should know **how** privacy and confidentiality are guaranteed. If some circumstances threaten privacy and/or confidentiality, consent can only be given when decision makers understand these risks. To ensure that consent is both voluntary and uncoerced, it must be known that access to health care is not jeopardized when consent is refused or consent/refusal is evoked.

8. CHOICE

There are other important assurances that must be met. To ensure that consent is informed, those making decisions about how to use frozen embryos must be aware that they can ask questions, now and in the future, about these and other factors that may affect their decision.

Frozen embryos are not accorded the full rights and responsibilities of people.^{8,20} However, it is widely held that they should be afforded dignity and treated with respect.^{8,14,18,20,24} The Royal Commission on New Reproductive Technologies locates the justifica-

tion of respect in the embryos' connections to the human community, connections made by their past and present, as well as their potential future.¹⁸ It is wrong to use them to make cross-species hybrids, as this activity violates basic norms of respect for human life.¹⁸ Likewise, it is dehumanizing to sell frozen embryos^{23,25} or in any way treat them in a cavalier fashion. Disposition decisions must take into account the respect the embryo deserves, as well as the relative importance of different disposition options.²⁵

Possible parties who could have decisional authority over the disposition of frozen embryos include: each gamete provider separately; both gamete providers jointly; a designated official or committee of the freezing facility in possession of the frozen embryos; the transferees if other than the gamete providers.^{17,25} The gamete providers jointly have the strongest claim on this decisional authority, a moral claim based on the unique moral interests the gamete providers have in their own genetic material.^{6,11,13,15,17,18,21,25} Those interests do not allow one gamete provider to veto the wishes of the other gamete provider with regard to disposition. The joint consent of the gamete providers must be obtained prior to retrieval and fertilization of gametes, cryopreservation of subsequent embryos and disposition.¹⁸

However, circumstances do exist where other parties should have decisional authority. Other parties should have such authority when the gamete providers voluntarily transfer that authority, with the consent of affected parties, to another party. For example, the gamete providers may jointly transfer decisional authority to fertility researchers when they donate frozen embryos for the purpose of research, or to infertile women or couples when the embryos are donated for the purpose of ET to such women or couples. They may transfer decisional authority to an official or committee of the freezing facility when they judge that they no longer have an interest in the frozen embryos themselves and have no preference as to their disposition. Decisional authority can also be transferred to parties not connected with the freezing facility in possession of the embryos, or to the IVF programme in which the gamete providers participate (e.g. surrogate decision makers and estates).^{15,22}

If the gamete providers do waive their decisional authority, a designated official or committee of the

freezing facility in possession of the frozen embryos should assume decisional authority, according to mechanisms approved in a national forum. Unless the gamete providers consent to a disposition option other than disposal, the freezing facility should not use the embryos in any way.¹⁵

To this end, gamete providers should agree and consent, prior to gamete retrieval and creation and freezing of embryos, to a disposition plan, including voluntary transfer of decisional authority to come into effect in the event of certain possible future circumstances (e.g. death of one or both gamete providers, inability of one or both gamete providers to exercise control due to medical or other causes, divorce, disagreement or failure to maintain contact with the freezing facility). Recognizing that interests change over time, such prior agreements may be revised at any time by the mutual consent of the gamete providers.¹⁴ When gamete providers have joint decisional authority, their current joint agreement and consent to the transfer of decisional authority and the disposition of frozen embryos created from their gametes take precedence over past joint agreements and consent.

Although consent is required on each occasion when frozen embryos are used in some manner, consent must also be given in a joint disposition agreement prior to retrieval of gametes, their fertilization and the freezing of embryos created.¹⁸ Joint advanced directives represent the gamete providers' joint contingency plan for disposition of the frozen embryos in the event that they are not able to make joint disposition agreements in the future. Joint disposition agreements may be revised at any time with the consent of both gamete providers.¹⁴ In the absence of such revision, joint advanced directives should be considered binding.¹⁷

RECOMMENDATIONS

1. Informed consent to embryo freezing must be obtained from the woman, if single, or both members of the couple whose embryos are being frozen. If donor gametes are being used, the woman or the couple's decision is limited by the donor's prior consent.
2. Informed consent to embryo freezing must include advance planning for the use of thawed embryos in the event that: i) the embryos are not wanted for a subsequent embryo transfer cycle due to family com-

pletion; dissolution of the relationship (separation or divorce); death of the woman and/or her partner; or ii) the informed consent is not explicitly renewed by the woman, if single, or both members of the original couple in the time frame set by the clinic (to a maximum of 5 years). The options should be anonymous donation to another woman, donation for research approved by a research ethics board or disposal.

3. Informed consent regarding the disposition of frozen embryos may be revised at any time by the woman, if single, or the original couple whose embryos are frozen. If the couple are unable to agree on subsequent changes to their informed consent, they can renew their original informed consent or accept that the frozen embryos will be discarded.
4. Informed consent for the thawing and transfer of frozen embryos must be obtained from the woman, if single, or the original couple whose embryos are frozen.

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RESEARCH ON HUMAN EMBRYOS

INTRODUCTION

Four groups constitute the main stakeholders in the debate on embryo research:

A) MEN AND WOMEN AS A GROUP

As sources for the necessary gametes, both men and women as individual groups are involved.

B) IVF PATIENTS

Particular women and couples seeking medical assistance in procreation would be affected by the possibility and regulation of embryo research.

C) INDIVIDUALS AND GROUPS SUFFERING FROM OR AT INCREASED RISK OF GENETIC DISEASE

Because one important objective of embryo research is to identify genetic disease markers better, those individuals and groups who suffer from or who are at increased risk of genetic disease would have a strong interest in the permissibility of embryo research.

D) CANADIAN SOCIETY AT LARGE

The pluralist collection of citizens making up Canadian society at large has a shared interest in the nation's policies and regulations concerning human and communal well-being.

As stakeholders, each of these groups has special and valid interests and priorities pertinent to understanding this highly personal, yet socially significant issue.

CANADIAN EXPERIENCE

The final (1993) report of the Royal Commission on New Reproductive Technologies supported

embryo research when potentially important knowledge could not be obtained in any other way. Several restrictions were placed on the acquisition and subsequent use of human embryos.¹ In early 1995, a national moratorium on certain reproductive technologies, including most types of embryo research, was introduced.²

The 1995 report of Health Canada's Discussion Group on Embryo Research proffered twenty guidelines for the scientific, legal, social and moral issues of embryo research. Key among its recommendations were: no research to be allowed on human embryos unless approved and overseen on an ongoing basis by a national regulatory body (NRB); research to be allowed only after the exhaustion of useful inquiry using animal or other non-human models; research to be allowed only when demonstrably necessary for the improvement of the human condition; research involving developing human embryos not to be permitted later than 14 days after conception; medical procedures related to infertility treatment to be undertaken solely for the medical well-being of the woman undergoing the procedures and the resulting offspring.³

INTERNATIONAL EXPERIENCE

Although the 1997 Convention on Human Rights and Biomedicine examines most aspects of research on humans in great detail, it leaves specific regulation of research on human embryos *in vitro* to the individual member countries of the European Union, apart from a single general ban on the creation of human embryos for embryo research.⁴ Such regulations vary widely from country to country. France's three 1994 bioethics bills place a qualified ban on eugenics and genetic testing (except for research, medical or judicial purposes, or when parents risk bearing a child with a "particu-

larly serious" genetic disease), and highly restrict accessibility to IVF (to living, sterile couples of reproductive age only).⁵

Despite a 13-year *de facto* ban on federal funding of embryo research, caused by the dissolution of the ethics advisory board which had reviewed previous embryo research proposals, private sector embryo research in the United States continued to focus on improving IVF effectiveness. Only in 1994 did the NIH's Human Embryo Research Panel propose specific cautions and recommendations, most of which closely followed the Canadian 1993 model with respect to restrictions on permissible embryo research, albeit with slightly different donor paradigms.⁶ Perhaps its most controversial recommendation was that embryos be created specifically for the purpose of research. As of the time of writing, none of these recommendations has been adopted. Instead, a continuing resolution currently under review specifically prohibits the use of federal funds for embryo research.⁷

CRITICAL ANALYSIS

A) INDIVIDUAL VALUES

For a clinic or laboratory to obtain embryos, a woman usually undergoes pharmacological ovarian stimulation and subsequent surgery to retrieve oocytes. In addition to potential emotional and psychological burdens as well as the personal inconvenience of the necessary medical regimen for hyperstimulation, various physical risks, some of which can be serious, are involved in both procedures. Furthermore, by providing a portion of her oocytes for research, a woman's own fertility in that cycle is decreased because fewer oocytes remain for fertilization. Many of these risks may not apply should some of the alternate sources currently under consideration for oocytes, for example cadaveric or fetal sources, become accepted.

In contrast, when men provide sperm, the physical risks and burdens are generally not onerous. In many instances, sperm is donated anonymously to sperm banks, thereby reducing (although not eliminating) personal involvement in any future reproductive technology. Sperm banks in Canada only

reimburse men for directly related out-of-pocket costs, or offer a modest payment to help defray such costs. Thus, under the current system in Canada, any economic incentive to providing sperm may be considered compensation, and not sale, of gametes (Oocyte Transfer and the Nature of the Exchange). Consequently, any concerns about unethical coercion of sperm providers based on economic grounds are minimal.

Cryopreserved embryos in excess of family completion could also be used for research purposes, provided that all people holding decisional authority give their informed, written consent. Similarly, cryopreserved embryos might be donated for research purposes where joint disposition agreements prior to retrieval, fertilization, and freezing of created embryos allow for the disposition of created embryos for specified subcategories of research options (Disposition of Frozen Embryos).

B) SOCIETAL VALUES

While current national law and policies aim to promote individual well-being, protecting liberties and interests from unethical infringement by others, they also balance individual values against those of Canadian society as a whole. Given that the research under discussion is to be on a human entity, albeit one without the full rights and responsibilities of people, the embryo's connection to the human community must be balanced against the needs of society. Although both the Human Embryology Report and the Royal Commission Report found that there was no consensus among Canadians about the moral status of the human embryo, this lack of agreement does not necessitate ending all discussion on embryo research. Rather, preserving such balance should be a vital, moral concern.

Although medical research has been successful in developing many remedies and techniques to alleviate the suffering of human beings, many conditions still remain untreatable, with those remedies which are available being merely palliative. The ability to detect diseases as early as possible, and to understand the full aetiology of a disease, can greatly enhance the possibility of remedy and the options for treatment. To this end, it is hoped that experimentation

using human embryos will reveal critical knowledge about formative processes and development.

Comparisons with other forms of human existence can reveal a general delineation of the embryo's moral status. Because of its lack of sentience, autonomy or volition, an embryo may be viewed as of lesser moral significance than a person. However, because of its capacity for development into a person, it can also be viewed as of greater moral significance than human organs or tissues.

While Canada's economy is based on capitalism, it is also substantially influenced by various social and political priorities. In certain cases (e.g. organ transplantation), where buying and selling organs could create the potential for exploitation, particularly of vulnerable groups (e.g. economically disadvantaged women, visible minorities), these influences cause any economic advantage to be seen as unjustified.

Many aspects of assisted reproduction have evolved from research into clinical practice, including *in vitro* fertilization, donor insemination and controlled ovarian hyperstimulation with intra-uterine insemination. In the recommendations specific to intracytoplasmic sperm injection (ICSI), it is suggested that ICSI remain in the research context until longer follow-up of the children born of this procedure has occurred, and recommend that couples consenting to ICSI be advised of the potential for increased congenital anomalies until this further follow-up occurs (Intracytoplasmic Sperm Injection). In the section specific to pre-implantation genetic diagnosis, it is recommended that this technology be confined to research for the foreseeable future. (Pre-implantation Genetic Diagnosis). It is important to stress that to improve outcomes in such clinical practices as *in vitro* fertilization, research (e.g. testing of new culture media) is ongoing. Couples entering IVF programmes should be made aware of this ongoing research, but the need for review by research ethics boards of modifications to standard care should be monitored by national bodies which could waive the need for submission to research ethics boards.

RECOMMENDATIONS

1. It is morally acceptable to proceed with research on human gametes and potentially viable embryos to

improve human health, provided the research is approved by a research ethics board, technical, medical and regulatory safeguards are in place and the informed consent of the gamete donors has been obtained. If the gametes are from a cadaver, there must be prior informed consent.

2. Human gametes and potentially viable human embryos should only be used for research purposes if the anticipated knowledge cannot be reasonably obtained from non-viable human embryos, animal models or other research methods.
3. Because of the potential harm to women, it is morally unacceptable to initiate ovarian stimulation or undertake any surgical procedures strictly for the purpose of obtaining oocytes for research. Further, it is unacceptable to compromise a woman's chance of establishing a pregnancy in the hope of obtaining oocytes or embryos for research.
4. The sale or trade of gametes or embryos for research purposes is morally unacceptable. Reimbursement of reasonable expenses incurred by the donor, however, is not prohibited.
5. The mass creation of embryos strictly for research purposes is prohibited. This general prohibition excludes the creation of embryos in an experimental context to initiate a pregnancy. It also excludes the creation of a limited number of embryos for specific research projects where the research objectives are of exceptional importance, as determined by the appropriate regulatory body.
6. Consistent with the current international consensus, research involving potentially viable human embryos should be restricted to embryos which are no older than 14 days.
7. Further national exploration is required to determine the ethics of using fetal oocytes for research purposes.

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INTRACYTOPLASMIC SPERM INJECTION

INTRODUCTION

Intracytoplasmic sperm injection (ICSI) was developed to augment the pregnancy rates of IVF, especially in cases where there was poor sperm function or low sperm numbers. Three methods of micromanipulation had been developed previously: zona drilling (ZD), partial zona dissection (PZD) and subzonal injection (SUZI). Zona drilling and partial zona dissection involved "drilling" a corridor through the oocyte's surrounding zona pellucida to the oolemma (the membrane surrounding its cytoplasm) using a chemical compound. Dissection removed a small section of the zona to expose the oolemma by surgery or a laser. With either drilling or dissection, altered oocytes were then introduced into a spermatozoon-rich medium as in a normal IVF protocol. In SUZI, a later method, spermatozoa were injected past the zona directly into the perivitelline space between the zona and the oolemma. The newest technique, ICSI, involves injection of a single spermatozoon past the zona and oolemma into an oocyte's cytoplasm.

CANADIAN EXPERIENCE

At reproduction clinics in Canada, micromanipulation techniques have been used in cases where the cause of infertility appears to be poor semen quality and where repeated IVF procedures have failed to produce fertilized embryos for subsequent transfer to a woman's uterus. Canadian research on micromanipulation affirms that ICSI results in higher fertilization rates than those of standard IVF.¹ Also, ZD, PZD and SUZI have been found not to be as reliable nor as efficient as ICSI.²⁻⁴

INTERNATIONAL EXPERIENCE

Research on ZD, PSD and SUZI produced mixed results. In contrast, the first (1992) report of ICSI from a Belgian reproductive clinic demonstrated sig-

nificantly higher rates of fertilization and pregnancy than those typical of IVF. When healthy sperm were used, the same sizeable increment over IVF results was documented.⁵

Laboratory studies of ICSI and reports of clinical use of ICSI have come from Belgium, France, Spain, Portugal, the Netherlands, Germany, England, Scotland, Japan, Singapore, Australia and various American states, where ICSI is now offered in IVF units as the preferred therapy for couples with male-factor infertility.⁵⁻⁷ Common objectives for ICSI research include delineating and refining the essential steps for the technique, understanding its biological mechanics, producing predictable results and corroborating outcomes. Some reports suggest that ICSI should be included in all IVF cycles, irrespective of the nature and source of infertility.

In 1995, the European Society for Human Reproduction and Embryology (ESHRE),¹ formerly the European Society for Human Reproduction and Evaluation, reviewed 10,000 ICSI attempts from 65 centres. It found ICSI to be a promising technique, but recommended that the long-term health of ICSI children be studied to determine its full effects, and that multiple pregnancies be reduced because such pregnancies are usually detrimental to fetal development.⁵

An estimated 10,000 children worldwide have been born as a result of ICSI. Studies of possible congenital and chromosomal abnormalities have largely been limited to at-birth reports. Of these reports, some corroboration of abnormality rates has been found, but there have also been some wide variances.⁸ Three longitudinal studies of ICSI children have been published, based on evaluations in the first few months and at one year of age. Of these two reports, the sample size was very small, and abnormality rates differed significantly. The Van Steirteghem study, extrapolating from the Wisan-

to (1996) study, has followed children for four years. Confidence in the safety of ICSI will be closely tied to the results of this study.

Little information is available on the financial cost of ICSI in these other countries. In most instances, expenses for such reproductive assistance is not reimbursed by either private (i.e. commercial or employer) or public (i.e. governmental) health insurance. In the United States, the cost of ICSI cycles is approximately double that of IVF cycles, with more than one cycle sometimes needed to produce a newborn.

CRITICAL ANALYSIS

At the outset, it should be admitted that the biological process of reproduction in humans is still not fully understood in regard to the necessity, function, timing and sensitivity of each step bypassed by ICSI. For this reason, focus on ICSI must not deflect research from the physiological locus of malfunction.

Various forms of infertility in men may be heritable and have been linked to other genetic diseases, including cystic fibrosis. Couples must be counselled that ICSI may be assisting in the continuation of male infertility within a family, as well as increasing a child's risk of having other health impairments.¹²⁻¹⁷

To qualify as medical therapy or treatment, a procedure must not only be proven effective and have predictable outcomes, it must also be safe for those directly affected. In light of the preceding points, although ICSI is an appropriate therapy for male factor infertility or failed fertilization, further research is required to assess the long-term general health of resulting children, including the heritability of male infertility and of other potential diseases. Therefore, to make an informed decision about reproductive alternatives, a couple must not be frustrated by the absence of complete information.

RECOMMENDATIONS

1. Intracytoplasmic sperm injection (ICSI) is currently a recognized treatment for male factor infertility and fertilization failure. Because the long-term outcome of children born as a result of ICSI is unknown, the informed choice of the couple and careful monitoring of the children are essential.
2. Genetic counselling and complete andrological

investigation should be offered to couples considering ICSI. In case of congenital absence of the vas deferens, cystic fibrosis testing should be offered.

3. In order to detect any potential sex chromosome or autosomal aneuploidies in the offspring(s), prenatal genetic testing should be offered to all women who have become pregnant after ICSI.
4. Use of cells from earlier stages of spermatogenesis for ICSI into a site should be regarded as highly experimental, and offered only in the context of research, after approval from an appropriate research, ethics board and informed consent of the couple.

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PRE-IMPLANTATION GENETIC DIAGNOSIS

INTRODUCTION

Pre-implantation genetic diagnosis (PGD) has been developed to identify harmful genetic diseases in human embryos before the embryos are transferred to human uteri. As of August 1996, there have been over 100 babies born worldwide following PGD.¹ By transferring only those embryos not affected by the specific genetic disorder, PGD can be used to prevent mid-trimester abortion if the woman does not wish to give birth to a child with such a specific genetic disorder.^{2,3,4} This averts the stress of worrying about whether the child is affected by the genetic disorder as well.^{5,6} Women and couples can be committed to their pregnancies from the start. In this manner, PGD greatly increases reproductive choice for women who would otherwise avoid pregnancy so as not to have to choose between possible abortion and the risk of giving birth to an affected child.^{5,7}

In order for one or two embryos unaffected by genetic risk to be available for transfer after diagnosis, several embryos must be accessible for biopsy. The specimen is usually taken at the eight-cell stage. *In vitro* fertilization is a necessary prerequisite to PGD. Thus, all the risks of IVF and embryo transfer, including the risk of ovarian hyperstimulation and potential risk of ovarian cancer, also apply to PGD.^{5,6} Its cost is high⁸ and must typically be borne by those seeking the service. As with IVF treatments, the pregnancy rate following PGD is low, about 23 percent per cycle, with a wide variance between clinics.^{9,10} Pregnancy may be delayed for women who would otherwise conceive readily,⁶ and the risk of pregnancy loss remains unknown.⁵ There is a possibility of misdiagnosis. Three misdiagnoses have been reported,⁶ with the possibility of a precedent-setting malpractice suit currently developing in Maryland.¹¹

When used to diagnose X-linked disorders by sexing, PGD may result in the discarding of healthy male embryos and the birth of female carrier babies.⁵ Finally, the discard of genetically doubtful embryos necessarily limits the number of oocytes available for implantation and, thus, the couple's long-term prospects for successful genetic parenthood.⁹

CANADIAN EXPERIENCE

Based on a prediction that the use of PGD will increase public bias against disabled people, the National Action Committee on the Status of Women (NAC) recommended in 1991 that a moratorium be declared on human germ-cell genetic experimentation and intervention, including PGD.¹² The final (1993) report of the Royal Commission on New Reproductive Technologies recommends that PGD be considered experimental until its safety and efficacy are more fully established, adding that sex selection for non-medical reasons should not be offered. Also, it emphasizes the need to ensure privacy, confidentiality and informed consent for all PGD research practices.¹³

The final (1995) report of the Discussion Group on Embryo Research recommends limiting PGD to very serious genetic conditions, and that a list of appropriate conditions for PGD be developed and periodically reviewed by a national regulatory body. In agreement with the Royal Commission, the report indicates that PGD should be considered experimental and, thus, only be available in the context of structured clinical trials approved and monitored by the proposed national regulatory body, a position agreed with by the Canadian College of Medical Geneticists (CCMG).¹ The report does, however, acknowledge the benefit of PGD for women at high

risk for transmitting severe genetic disorders, including the option of avoiding late pregnancy abortions due to an unwanted genetic diagnosis.¹⁴ "Severe" is defined as those disorders which preclude a reasonable quality of life. In contrast, the CCMG maintains that those that make such decisions must reconcile many factors, including the cost and risk of the procedure, the burden (seriousness) of the disorder, the stress of the situation and the ethics of selective abortion. These factors are based not only on familial and societal effects, but also on the individual couple's perception of caring for a child with the disorder and on their economic and emotional ability to care for such a child. Given this latter, highly individual definition, the CCMG would consider it unwise to attempt a precise definition of the term, or to draw up a list of "serious" disorders. The 1997 Tri-Council Code confirms the importance of genetic research, while emphasizing that the aim of genetic research should be the advancement of knowledge or the amelioration of disease, not the "improvement or enhancement" of a population.¹⁵

INTERNATIONAL EXPERIENCE

First performed by Alan Handyside at Hammersmith Hospital in London, England, PGD research is now underway in more than twenty countries worldwide.^{6,9} Studies in both England and the United States indicate that women at high risk of transmitting genetic disorders to their offspring find this technology to be an accepted alternative to existing prenatal diagnostic technology.¹⁶

In the United States, the Council on Ethical and Judicial Affairs of the American Medical Association (AMA) and the American Society of Reproductive Medicine (ASRM),² formerly The American Fertility Society, both find a strong justification to prevent inherited disorders that severely reduce the quality of life or longevity of those affected, based on their suffering, the suffering of their families and the effects of their disorders on society. Consequently, the AMA and ASRM hold that both genetic selection (by embryo discard following PGD or by abortion following PND) and genetic manipulation are morally permissible in order to prevent, cure or treat genetic disorders. Selecting embryos for transfer based on

benign characteristics is not held to be acceptable.^{17,18} The Human Embryo Research Panel also finds PGD to be morally acceptable in certain cases, and specifically agrees to the use of federal funding to study PGD, a position opposed by the US governmental ban on such funding. However, researchers in many US clinics are using private funds to continue PGD research.¹⁹

Because embryos with handicapping genetic disorders are typically discarded following PGD, many European reports show concern that increased use of PGD will give rise to negative attitudes toward handicapped people. In France, the National Ethics Committee recommends that PGD be banned because its use could be based on convenience rather than medical necessity and could, thus, lead to eugenic practices.²⁰

CRITICAL ANALYSIS

For couples at high risk for transmitting severe genetic disorders, PGD allows avoidance of mid-trimester abortions, of the stress of uncertainty as to whether the unborn child is affected, and of the decision whether to attempt pregnancy when abortion is not an acceptable option. These are major benefits which will override the disadvantages of PGD for some women. This is especially true for those couples already undergoing IVF treatments as a solution to infertility. Under these circumstances, no further disadvantages peculiar to PGD will be experienced. Certainly even some of those IVF patients who are not at particularly high risk for genetic disorders might prefer PGD to conventional prenatal diagnostic testing in order to obtain these benefits.

Although there have been concerns that PGD could be used for selection of embryos based on such trivial traits as height or freedom from baldness, it should be remembered that such characteristics are multifactorial in nature, controlled by environment as well as by dozens, if not hundreds, of genes. At present, most of these genes have not yet been identified, nor does the technology currently exist to test for every gene in an eight-cell embryo.¹ However, the potential does exist for PGD to be used for detecting genetic traits beyond those that may cause severe genetic disorders and, thus, to be transformed from a useful reproductive technique into a tool for eugenic

purposes.^{7,17} As the use of PGD becomes more widespread, associated eugenic practices could occur in subtle as well as direct ways (e.g. in the withholding of social support to assist with the care of affected children). Such conditions might well dissuade parents who would otherwise choose the risk of having an affected child. Extensive, unacceptable eugenic use of PGD may also exacerbate differences between the wealthy and the poor, as well as between some cultural groups.¹⁷ However, this is no different from the current situation with prenatal genetic diagnosis. As the selection of sex as a readily identifiable, non-therapeutic trait has already been determined to be morally unacceptable by the joint CFAS/SOGC committee, a precedent has, thus, been created which could be extrapolated to a wider moratorium on the use of PGD to identify all non-therapeutic traits (Sperm Sorting for Medical and Non-Medical Reasons).

Even by preventing the birth of at least some children with inherited disabilities, the use of PGD may reinforce discriminatory attitudes against disabled people in general, attitudes which threaten equality for all human beings.¹⁷ For this reason, societal policies need to be in place to protect and enlarge the civil rights of disabled people and to reinforce the equality of respect that should be accorded to everyone.²¹ Thus, the goal of avoiding the birth of children with severe genetic disorders remains consistent with that of according equal respect to those with disabilities.^{3,4}

Privacy and confidentiality must be primary concerns in any use of PGD. By its very nature, genetic material contains information about a family, shared by all members of that family. Often the genetic information revealed by PGD is private and sensitive, and its release to those that do not have a legitimate need to know can cause detrimental or discriminatory effects even to those not directly involved as principal agents in the technique. In keeping with ethical research practices, confidentiality and privacy must be respected and guaranteed,^{13,15} and results of PGD should only be released to the gamete providers who gave informed consent for PGD, as well as to those judged by the appropriate regulatory body to have a legitimate need to know.¹⁵

As with participation in all research clinical trials and all medical procedures, informed, voluntary and

uncoerced written consent is required for all subjects in PGD clinical trials. In conformity with Tri-Council guidelines, prospective subjects should be informed of: eligibility criteria; nature and objectives of the research and existing alternatives; nature and probability of known and unknown possible consequences of research objectives and existing alternatives; qualifications of research team members; costs involved and any other information that could assist with making informed choices. Assurances that must also be conveyed include: participants' ability to ask questions now and in the future; respect of confidentiality; access to continued health care regardless of refusal to participate and revocable consent or refusal.⁵

RECOMMENDATIONS

1. Pre-implantation genetic diagnosis is morally acceptable to diagnose severe genetic disorders. It should not be used to diagnose benign disorders.
2. Sex determination by pre-implantation genetic diagnosis is morally acceptable for the diagnosis of sex-linked chromosome disorders, but not for the selection of a preferred sex for non-medical reasons.
3. Pre-implantation genetic diagnosis should only be available in the context of structured clinical trials approved and monitored by research ethics boards.
4. Discrimination against people living with disabilities, those choosing to have children with genetic disabilities and those carrying potentially harmful genes is morally unacceptable.
5. Pre-implantation genetic diagnosis should not be used to promote eugenic practices.

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SOCIAL SCREENING AND REPRODUCTIVE TECHNOLOGIES

INTRODUCTION

Whether there can be any ethically justified reasons, independent of any pertinent medical reasons, to exclude a defined group of individuals from participating in or using reproductive technologies is a highly controversial issue. The committee's exploration of social screening will consider both those seeking medical assistance for their infertility and those who donate their own reproductive materials, whether for research or directly to others.

CANADIAN EXPERIENCE

The 1990 SOGC and CFAS report *Ethical Issues of the New Reproductive Technologies* concludes that it is a physician's responsibility to restrict access to assisted reproductive technologies "where clinical circumstances present significant risks to potential offspring." While acknowledging that some unmarried couples, single women or lesbian couples could qualify for medical assistance in having children, the report did not elaborate as to specific factors to be considered, but left the decision up to each physician's personal conscience, with the proviso that the physician be required to inform any individuals not deemed suitable candidates of this decision, and then refer those patients to other qualified sources of assistance.

At present, no published statistics are available as to the socio-economic class and other classifiers of those who donate gametes and/or seek reproductive assistance, and who have been subsequently granted or refused access to reproductive technologies. This lack of statistics is likely due to the traditionally confidential nature of any data collection, so as to protect the privacy rights of the individual. Consequently, little evidence is available that any particular social group is pre-

sumptively precluded from donating gametes for non-medical reasons, although certain physical characteristics of a donor may be recorded to accommodate a possible request by an infertile individual or couple that the potential child bear a family resemblance.

Nor is any particular group targeted for donation. The lack of any financial inducement beyond direct personal expenses is likely to prevent exploitation of poor sperm donors. This is not the case for oocyte donation, where the motivation for the majority of "donations" is financial need, expressed either through an exchange of oocytes for IVF cycles or through direct sale of oocytes. However, the use of available medical services is greatly influenced by the proportion of financial coverage by third parties. At present, the federal government reimburses some costs of reproductive procedures for Canadians, although Ontario is the only province to cover the cost of any reproductive technology, and then only for initial cycles of IVF for women with blocked Fallopian tubes.

No legislation regarding reproductive assistance has been enacted which either stipulates those groups not qualifying for assistance, or prohibits the exclusion of any group based on socio-economic status.¹ Similarly, no definitive legal precedents have yet been established which could provide guidance as to what is or is not legally permitted in restricting participation in or access to reproductive services. Although it may be possible to invoke the Canadian Charter of Rights and Freedoms with respect to the presumed equality of all Canadians and their access to reproductive medicine, no test case has as yet occurred.

INTERNATIONAL EXPERIENCE

Substantial differences exist in the degree of implicit or explicit social screening of donors by reproductive

clinics in other countries. Some clinics offer large cash payments for gamete or embryo donations. While an age limit of 35 years seems to be fairly universal for oocyte donors, no comparable universal age limit exists for sperm donation. Routine recording of donor qualities may range from a simple physical description (e.g. hair and eye colour), to such personal information as history of alcohol or drug abuse, incidence of childhood or marital abuse and education.

Traditionally, reproductive technologies have only been offered to heterosexual married couples. Out of 14 industrialized countries, 13 stipulate that only heterosexual couples be given access to reproductive technologies, and two specifically require the couple to be married.² The British Warnock Report rejects the provision of reproductive services to homosexuals or single women, based on predicted harmful effects on the child due to the absence of a traditional family structure.³ Although none of these guidelines carries the force of binding law, their effectiveness is demonstrated in individual clinic policies. Still, it has been estimated that, since 1975, 25,000 children worldwide have been born to lesbians using artificial insemination (AI), a preferred procedure as it does not necessarily require the involvement of a medical practitioner or use of medical equipment.

Cost remains a limiting factor for low-income individuals and couples. Each IVF cycle costs at least 5,000 dollars, and usually several cycles are required to approach a 50 percent chance of pregnancy. In those countries where there is no public health insurance coverage, many low-income individuals and couples will be unable to obtain medical assistance for infertility.

CRITICAL ANALYSIS

A) DONORS

Four types of reproductive materials may be donated: sperm, oocytes, embryos and uteri. Each type of donation involves different burdens and different degrees of personal risk. Traditionally, donation of sperm has been anonymous, while the identity of a female donor may or may not be known to the recipients.

Social screening of donors may be either physical or environmental. Physical screening in this context refers

to the selection of donors based on various non-harmful criteria including hair colour, height or race. These criteria are usually recorded by clinics to ensure familial resemblance to the recipients. Further physical screening of donors could lead to eugenic practices and are, thus, unacceptable. Environmental screening could be based on a donor's education, sexual orientation, history of childhood or domestic abuse, or mental illness. The rationale for such screening is based on the possible genetic origin for such conditions. Where there is sound scientific basis for such beliefs, and where the condition is serious, such screening should be considered genetic rather than social; similarly, where the practice has been linked to an increased chance of birth anomalies, as with some prolonged substance abuse, such screening should be considered medical. Otherwise, any such screening is indicative of prejudice and elitism.

Generally, there is little financial incentive in Canada for a man to donate sperm, as there is currently in the United States for oocyte donors. Donation of oocytes, embryos, or use of the uterus may lead low income women to contribute their reproductive products for money to assist those in high income levels. To prevent such targeting, all donors of reproductive products should be reimbursed only for direct costs. (Oocyte Transfer; Sources of Oocytes and the Nature of the Exchange; Preconception Arrangements.)

B) RECIPIENTS

The practice of social screening has been more widespread among the recipients of reproductive assistance, having been based on factors as diverse as income level, sexual orientation, marital status, age, mental illness, violence in the family and substance abuse. Some of this screening is implicit, for example when high costs of reproductive technologies limit access for those of low income. Other bases for screening are explicit.

Screening for additional linked factors may also result. As there is a strong correlation between earning potential and education, ethnicity and family heritage, those who are denied access to reproductive technologies due to cost also tend to be those without university education, of non-Caucasian background and recent immigrants. Similarly, the heavy concentration of fertility clinics and specialists in urban centres implies that those living in rural areas are less able to use these facil-

ities than city dwellers. These covert forms of social screening cannot be ethically justified. If reproductive assistance is considered an important public or personal good, then access should not be hindered on the basis of irrelevant group attributes including race, education or residence.

Concern for the prospective child is central to claims that reproductive assistance should not be granted to homosexual individuals or couples, single heterosexual women, women over the age of 40, and those with mental illness or a history of violence or substance abuse. Each of these factors warrants specific consideration.

Although popular belief suggests that homosexual parents will negatively influence a child's development so as to cause harm to a child's mental well-being, repeated studies have found no evidence of such results. In fact, an even more positive development of the child's mental well-being, as compared to those raised by heterosexual parents, has been reported.

Single women may prefer the assistance of the medical community in having a child if they wish to take on the primary responsibilities of parenting alone, do not wish to "use" a man merely to obtain his sperm, or possibly because they wish to use sperm already screened for serious transmittable or genetic diseases. However, they are often discriminated against as being unable to sustain an adequate family structure and environment in which to raise a child, as comprehensive parenting is believed to require two people, one of whom should be a male role model. Yet even outside of assisted reproduction, increasing numbers of children are now being raised in households where there is only one parent, most commonly the mother. Examination of such households has determined that the absence of a father does not necessarily result in long-term harm to the child that could be attributed to the presence of only one parent. Because today's families are composed of diverse relationships and divisions of responsibilities often quite different from the traditional nuclear family roles, studies have found that single women will often extend the boundaries of her "family" so as to include other adults in the varied tasks of responsibly caring for and raising a child.

Public opinion is divided as to whether there should be an age limit to a woman bearing children. Recent medical advances have helped women over

50 years of age to deliver a healthy child, with relatively little risk to the woman. As there are no comparable, socially prescribed limits to the appropriate age for a man to be a father, some may argue it improper to deny women access to reproductive technologies beyond a certain age. Although age alone should not be a factor for screening out any group of potential recipients, it is possible that a man or woman of advanced age being a parent is not in the best interests of the child.

Although none of the above groups should be refused assistance for reproduction as a group, this proviso does not preclude refusal of treatment to any particular individual. If the person is believed to be a potentially incapable parent, ethically, access to reproductive technologies should be denied. This is also the basis on which those prospective parents who have a mental illness, or who have been abused as children or have themselves been domestic or child abusers, or who are substance abusers, should be screened. The primary concern should always be, not for the ability of a person to have a child, but for the prospective child to have a responsible parent(s). The fact of the new individual to be created demands consideration of his or her general well-being. Such evaluation must be made by appropriate medical practitioners, for example a physician who has had a long-standing relationship with the individual. The physician's opinion should be supplemented by the assessments of social workers and/or psychologists trained in the care of these types of behavioural problems. The standards for accepting or rejecting individuals for access to reproductive technologies should be comparable to what is publicly sanctioned in the general population. They need not be exactly the same, however, as the presence of any such behavioural factor is justified grounds for modifying the criteria so as to limit the likelihood of a dysfunctional family environment for the child.

A final caution remains. Health care in Canada has traditionally been viewed as a special public good. Accordingly, the institution of medicine must remain publicly focused and inclusive of all Canadians. However, particular reproductive technologies may be denied to certain groups if they erode the overall equity and universality of Canadian health care.



RECOMMENDATIONS

1. Non-medical, social factors should not impede participation in or use of any reproductive technology. This proscription applies both to the donation and to the use of sperm, oocytes or embryos. Accordingly, no group of individuals should be denied participation in, or access to, such technologies. However, individual participation or use of assisted reproduction could be denied for the welfare of the child.
2. If a physician cannot accept inclusion of a certain group of individuals based on social factors because of personal conscience, the physician is obligated so to inform the patient, and to refer him or her to other qualified medical professionals who will assist the patient in addressing the medical problem(s).

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MEDICAL AND GENETIC SCREENING OF SPERM, OOCYTE AND EMBRYO PROVIDERS

INTRODUCTION

Medical and genetic screening for the purpose of preventing or reducing transmission of infections and genetic disorders to gamete recipients and their offspring have become integral parts of in vitro fertilization (IVF) treatments. The extent of screening varies among IVF programmes. Typically, information will only be gathered about the gamete providers and their first, second and third degree relatives, with such information limited to potentially harmful medical or genetic conditions.

BACKGROUND

Some of the methods of assessing a person's medical and genetic status for the purpose of determining a perspective gamete provider's suitability are questionnaires, interviews, examinations and laboratory tests. These evaluative tools are capable of determining the presence or absence of a large number of conditions, disorders, and diseases, including:^{1,2}

MEDICAL SCREENING:

- major medical illness that has a genetic component;
- blood type, Rhesus factor;
- sexually transmitted diseases;
- basal follicular stimulating hormone level on Day Three of menstrual cycle for oocyte providers;
- sperm motility, concentration, morphology and cryo-survival for sperm providers;
- psychological stability;
- age.

GENETIC SCREENING:

- non-trivial Mendelian disorders;
- autosomal or X-linked disease or carrier status;
- chromosomal aneuploidy;

- chromosomal rearrangement that may result in unbalanced gametes;
- congenital malformations;
- multifactorial genetic disease;
- carrier detection in populations with increased risks.

CANADIAN EXPERIENCE

In the 1992 "Guidelines for Family History Screening for *In Vitro* Fertilization and Donor Insemination," the Canadian College of Medical Geneticists (CCMG) suggested some detailed genetic criteria which should be used to screen gamete providers for IVF, holding that, in cases where simple family history screening would have prevented transmission of a serious genetic defect or disease, the physician should be held liable.³ The 1993 Royal Commission on New Reproductive Technologies recommended that national guidelines specify infectious diseases to be screened in potential gamete donors, focusing on those diseases that could potentially affect the recipient or the child to be produced. To this end, the commission recommended a six-month cryopreservation quarantine of the donated gametes, followed by a second screening for the specified diseases, with negative results both times, prior to gametes being released for IVF.⁴

The two CFAS documents, "1996 Guidelines for Therapeutic Donor Insemination" and "1996 Guidelines for Ovum Donation,"^{1,2} recommend a number of conditions under which potential donors should be excluded from gamete donation, and detailed medical and genetic screening for those not otherwise excluded.

INTERNATIONAL EXPERIENCE

The United Kingdom's Warnock Report (1984) stipulates required medical and genetic screening measures for all IVF gamete providers, excepting only the

recipients' husbands.⁵ Similarly, the Centres D'Études et de Conservation du Spermé Humain (CECOS) Fédération in France established a set of guidelines for genetically and medically screening sperm providers, in keeping with advisory bodies in several other European countries, while at the same time rejecting selection on the basis of non potentially harmful criteria.⁶ Both sets of guidelines also specify an age limit for male donors, so as to avoid genetic mutations associated with paternal age. The British Andrology Society (BAS) endorses the minimum mandatory genetic and medical screening for gamete donors recommended in the American Fertility Society's "Guidelines for Gamete Donation: 1993," including most categories outlined by the CFAS.^{7,8} These guidelines are compatible with those of the Fédération Internationale de Gynécologie et d'Obstétrique (FIGO), which recommends that gamete providers should be healthy, of normal reproductive age, free of sexually transmitted diseases and free from hereditary disorders.⁹

CRITICAL ANALYSIS

Medical and genetic screening of gamete providers is most strongly justified by its preventing or reducing harm to others. By excluding prospective gamete providers who have a greater-than-average risk for transmitting harmful genetic disorders, significant harm is averted for these women and children. Similarly, the exclusion of prospective gamete providers who are at risk for transmitting HIV, hepatitis B, cytomegalovirus or other infectious agents to recipients and/or their offspring helps to prevent and reduce potential harm to recipients and offspring. Given this justification, screening for medical and genetic conditions that are not transmittable to recipients or offspring, or which do not result in any appreciable harm for those who acquire them, is not warranted.

It is difficult to predict which diseases and disorders should be considered significant. Factors of risks involved, potential of transmission, and severity of potential disorders should all be considered.¹⁰ Any risk that a child produced with a particular person's gametes might have a severe genetic or medical disorder should be avoided. However, justification becomes more difficult when the severity of the disorder wanes and the probability of its occurrence lessens. Medical and genet-

ic screening for conditions and disorders beyond those that could cause significant harm has the potential to transform reproductive techniques into eugenic practices and should, thus, be avoided.¹¹

International opinion on the need for psychological screening as part of the medical screening of gamete providers is mixed. While CECOS holds that such testing is not justified because the results could only be used for eugenic purposes,⁶ the American Society for Reproductive Medicine (ASRM) advocates psychological screening for oocyte providers, but remains silent about any such need among sperm providers, without giving any clear reasoning for such exclusion.^{8,12} It is possible that the increased risks of oocyte transfer make it more important to guard against coercion of oocyte providers.¹³ To the extent that psychological testing could have a positive effect on a solution to an infertility problem or on the goal of preventing or reducing harm to the offspring, in the absence of moral reasons to the contrary, such testing should be done.

Psychological screening can also be of direct benefit to the gamete providers, in that psychopathological motivations can be identified, for which treatment can then be offered. Such testing would identify those whose intended donation is psychopathologically motivated. Such people should be rejected from the IVF programme, as they are not in a position to give informed consent and may seek harmful contact with the offspring.^{11,14} Additionally, their psychopathology may have a major genetic component that should be avoided in the interests of the offspring. Finally, psychological screening may help to determine psychological stressors that will affect gamete providers during and following their participation in the IVF programme. This additional information might make counselling services for gamete providers more effective.

Because medical and genetic screening reveals personal and often sensitive information about the person being screened and possibly members of that family, confidentiality and privacy must be respected and guaranteed. The release of information about a gamete provider's medical condition and genetic make-up, beyond those who have a legitimate need to know, infringes on the right to privacy and confidentiality and could make that person the target of discriminatory behaviour. If made known to others, the results of med-

ical and genetic screening could interfere with an individual's ability to find employment and qualify for life insurance, detrimental effects which provide a further incentive to screen only for those medical and genetic conditions and disorders that are necessary ethically to meet the objectives of IVF programmes. For all these reasons, medical and genetic information obtained must be held in strictest confidence, with respect for the right to privacy and confidentiality.

Nevertheless, some medical and genetic information about gamete providers should be collected for inclusion in a registry.^{15,16} Consent of the gamete providers must be obtained for this purpose, and only non-identifying information should be obtained. Such a registry is essential in case gamete providers should later discover that they have a genetic condition, the knowledge of which could be vital to their offspring. Conversely, the registry could be of use to the gamete providers should a genetic condition be later discovered in the offspring. Apart from the benefit of access to important health information without personal identifiers, children conceived using donated gametes can identify more positively with their genetic heritage if they have some social, personal and medical knowledge of their origins,¹⁴ information which could be obtained from a registry to be passed on to the gamete recipient upon request. Providing such non-identifying, information is an extension of the fundamental objective to prevent or reduce harm for an offspring conceived with donated gametes.

Despite overall agreement in international statements and guidelines on genetic and medical screening, controversy remains over the recommended age of gamete providers. Restrictions are most often drawn on the upper age limits for gamete donors because the genetic quality of gametes deteriorates as men and women age, thus posing a greater risk of genetic disorders in offspring. However, precisely where those restrictions are to be drawn remains a subject of intense debate. While it is desirable to minimize the risk of new genetic mutations which increases with the father's age, allowing older men to be sperm providers minimizes the risk of those genetic disorders which only manifest at a later age (e.g. cadaveric "donation"). Greater unanimity exists among guidelines setting the upper age limit for oocyte providers at 35 years of age. Oocytes obtained from women beyond this age may be used so long as the

recipients are informed, have the option to refuse the older gametes, and have the option of prenatal diagnosis for chromosomal disorders.

RECOMMENDATIONS

1. Informed consent of gamete providers is required as part of medical and genetic screening practices.
2. Some medical or genetic screening of prospective gamete providers is morally required, but should be limited to those inquiries necessary to prevent or reduce the harm caused by transmission of infections or hereditary diseases to gamete recipients and/or their offspring.
3. Only those medical or genetic screening practices that could prevent or reduce the harm caused by transmission of infections or hereditary diseases to gamete recipients and/or their offspring should be performed.
4. Psychological screening is an acceptable part of medical screening in order to rule out pathology or coercion, and to anticipate stressors for the purpose of counselling. Psychological screening that exceeds these objectives should not be done.
5. A registry of medical and genetic screening results should be kept and updated.
6. The results of medical and genetic screening must be held in strict confidence.

GLOSSARY

COMMISSIONER(S)

The party(ies) who initiate a preconception arrangement and wish to have the resulting child.

CONSENT

The voluntary, uncoerced, and informed, written agreement of those with decisional authority over the issue in question.

EMBRYO

The human organism after the fertilized egg begins cell division.

GAMETE PROVIDERS

Those people whose oocytes or sperm are used to create an embryo.

GENETIC SCREENING

Those activities designed to ascertain genetic disorders that have an effect on health for the purpose of informing prospective parents of potential genetic risk, or excluding donors because of significant genetic risk.

GESTATIONAL WOMAN

The woman who carries and gives birth to the child in a surrogacy agreement.

IN VITRO FERTILIZATION (IVF)

Those practices where fertilization of oocytes by sperm takes place outside the woman's body, with at least some of the resulting embryos being transferred to women's bodies with the aim of establishing pregnancies and giving birth.

MEDICAL SCREENING

Those activities designed to ascertain a person's past and present state of physical health for the purpose of excluding donors or recipients who would constitute a significant risk to the potential child or to themselves.

PRECONCEPTION AGREEMENT

A written agreement setting out the terms of a surrogacy arrangement. Where such agreement is not set down in writing, **preconception arrangement** is used instead.

SOCIAL SCREENING

Those activities designed to ascertain a person's social or economic status for the purpose of restricting access to reproductive technologies.

SURROGACY, SURROGATE MOTHERHOOD

The process in which a woman is asked to bear a child to be turned over to the commissioning couple immediately after birth, either for financial compensation or for altruistic purposes.

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