

A Canadian Medical Association White Paper

Assisted Reproduction in Canada:

An overview of ethical and legal issues and recommendations for
the development of national standards

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Executive Summary

Ensuring equitable There is a growing need for the elaboration of national standards in the complex and rapidly evolving field of assisted reproductive technology (ART), particularly with respect to ethical and legal considerations. The purpose of this paper is not to set those standards, but to identify areas where they should be developed. The paper provides an overview of the current legislative landscape in Canada as well as an identification of the most important and relevant ethical considerations. It is the result of a collaborative process between the Canadian Medical Association (CMA), the Society of Obstetrics and Gynecology of Canada (SOGC) and the Canadian Fertility and Andrology Society (CFAS). It is hoped that this paper will lead to the development of these standards, and their adoption and incorporation by provincial governments and medical regulators.

We recommend the development of national ART standards in the following areas:

- Surrogacy and legal enforceability of agreements
- Pre-implantation genetic diagnosis, including a list of severe debilitating or fatal inherited monogenic diseases for which there is no known treatment, and for which PGD would be acceptable
- Those circumstances where it would be appropriate to undertake selective fetal reduction
- Donation of reproductive material and disclosure of medical and personal information to resultant offspring
- Informed consent to donation and treatment
- The number of embryos that can be transferred per cycle
- The number of offspring that can be born from the same gamete donor
- Embryo storage and the disposition of surplus or unclaimed embryos
- Information collection and results reporting from clinics and practitioners
- Funding and access to ART services
- Maternal age restrictions
- Fertility preservation in the context of acute life threatening illness or gonadotoxic therapies
- Moving scientific innovation to practice

Introduction

Assisted reproductive technologies (ART), that is to say methods used to achieve pregnancy with medical assistance, have been the focus of much research and debate in Canada and internationally. These technologies raise complex ethical, legal and regulatory issues which sometimes challenge the identity of individuals and society.

Conflicting values and competing interests can lead to opposing perspectives and barriers to obtaining consensus on ART practices. The purpose of this paper is to delineate the legal status of ART in Canada, and to identify and to discuss related ethical issues. Given the importance and increasing utilization of ART, it is strongly recommended that a national framework for both federal and provincial regulations is developed. Provincial governments and regulatory bodies such as Provincial and Territorial Colleges of Physicians and Surgeons are urged to take a leadership role in this area. Consistency from province to province will be critical to the success of this initiative, and to ensuring that all Canadian requiring access to ART services will receive the same standard of care and treatment. Currently, this is not the case.

This paper is intended to set the stage for these processes to take place. It can also be used as a guidance document for national and provincial health policy makers. It identifies ethical positions on key ART issues and, in so doing, can aid in the development of consistent ART regulations and standards across the country.

Canadian Legislation and ART

Introduction of National Legislation and Supreme Court of Canada Ruling

In 2004, the Government of Canada introduced the Assisted Human Reproduction Act (the AHR Act).¹ This comprehensive legislation concerning reproductive technologies arose from the recommendations made 20 years previously by the Royal Commission on New Reproductive Technologies. The AHR Act was intended to provide Canadians with a system of licensing, monitoring, and enforcing activities related to ART in order to protect Canadians' health and safety. The Act also clearly stated the values of the federal government in this field. The AHR Act identified several prohibited and controlled activities and created Assisted Human Reproduction Canada (AHRC), a federal agency with broad power to introduce and enforce regulations on matters governed by the Act.

The Government of Quebec sought judicial reference as to whether the AHR Act exceeded the legislative authority of the federal government, thereby rendering it unconstitutional.² The Quebec Court of Appeal ruled the AHR Act was unconstitutional and the Government of Canada appealed the issue to the Supreme Court of Canada. In 2010, the Court ruled that certain sections of the AHC Act were unconstitutional.³

The AHR Act's prohibitory provisions were accepted under the government's authority over criminal law and these remain in force. These prohibited activities include:

- human cloning;
- creating embryos for any purpose other than creating a human being or improving or providing instruction in assisted human reproduction (AHR) procedures;
- creating an embryo from any part of the cell of an embryo or fetus for the purpose of creating a human being;
- maintaining an embryo for more than 14 days outside the body of a female person;
- sex selection for any purpose other than preventing, diagnosing or treating sex-linked disorders or disease;
- germ-line genetic alteration; and,
- using or transplanting any reproductive material from a non-human being or creating a chimera or hybrid, in order to create a human being.

Most of the AHR Act's regulatory provisions were struck down. However, three of the controlled activities dealing with donor consent, age of consent, and reimbursement for donor and medical surrogacy expenses were sufficiently criminal in nature to be recognized as within the federal jurisdiction.

Quebec Legislation

The only province or territory in Canada to legislate on assisted reproduction is Quebec. In 2009, An Act respecting clinical and research activities relating to assisted procreation came into force.⁴ The Act regulates clinical and research activities relating to assisted procreation (AP) in order to ensure safe and ethical practices.⁵ The Minister of Health and Social Services is responsible for administering the Act.

The issuance, refusal and revocation of licenses to operate a centre for assisted procreation and to perform assisted procreation activities are regulated under this Act. Inspection of centres and penalties for violations of the Act are described. A centre must have its assisted procreation (AP) activities accredited by a recognized accreditation body and comply with standard operating procedures.

Additionally, persons carrying out AP activities must respect procedures covered by the Act. Two regulations produced by the Government of Quebec in 2010 specify the procedures covered by the Act.⁶ Revisions to the Act are currently before the Quebec National Assembly (Bill 20).

Implications and Recommendations

All areas of ART policy which the Supreme Court ruled unconstitutional cannot be regulated by the Government of Canada. A decentralized approach to ART policy may be adopted, either by legislating provincially, as Quebec has done, or by relying on professional regulatory bodies. Consistent practice standards and a national ethical framework for the conduct of ART are possible without national legislation and given the importance of this matter to those providing and using these services and to society at large, it is strongly recommended that such standards be developed. Organizations such as the Canadian Medical Association (CMA), the Society of Obstetricians and Gynecologists of Canada (SOGC) and the Canadian Fertility and Andrology Society (CFAS) can facilitate the creation of these standards by regulated health colleges and can also provide guidance to provincial and territorial regulatory authorities who wish to develop legislative policy in this area.

Table 1 - Summary of the Current Canadian Law on ART

Reproductive and Therapeutic Human Cloning	Prohibited
Hybrids	
Transplanting a sperm, ovum, embryo or fetus of a non-human into a human being	Prohibited
Using any human reproductive material or in vitro embryo previously grown in a non-human for the purpose of creating a human being	Prohibited
Creating a chimera or transplanting a chimera into either a human being or a non-human life form	Prohibited
Creating hybrids for the purpose of reproduction or transplanting hybrids into either a human being or non-human life form.	Prohibited
Genetic testing and screening	
Genetic testing and screening	Unregulated
Sex selection, except for preventing diagnosing or treating sex-linked disorders or diseases	Prohibited
SURROGACY	
Payment for surrogacy, inducing or counseling a female person to become a surrogate	Prohibited
Altruistic surrogacy	Undefined what constitutes reimbursable expenses or who can be a surrogate for whom
DONATION OF REPRODUCTIVE MATERIAL	
Purchase, sale or exchange of reproductive material (egg, sperm, embryo, gene, cells) for any consideration	Prohibited
Reproductive material for research	Tri-Council Policy Statement (2014) + Stem Cell Guidelines
Donation of Reproductive material (egg, sperm, embryo, gene, cells)	Unregulated
Reimbursing donor for expenditures in the course of donating	Regulated (but undefined what constitutes reimbursable expenses or who can be a donor for whom)
Restriction on donor age	Regulated (Canada) – 18 years old unless for the purpose of preserving the gametes to later create a child that will be raised by the donor
Restriction on recipient age	Regulated (only in Quebec) – no embryo may be transferred to a woman who is no longer

	of childbearing age
Gamete and embryo creation, use, manipulation	
Creating in vitro embryos for any purpose other than creating a human being or improving or providing instruction in AHR procedures	Prohibited
Creating an embryo from the cell or part of a cell of an embryo or fetus for the purpose of creating a human being, or transplanting an embryo so created into a human being	Prohibited
Maintaining an embryo for more than 14 days outside the body of a female person, minus any time during which its development is suspended	Prohibited
Altering the genome of a cell of human being or in vitro embryo such that the alteration is capable of being transmitted to descendants	Prohibited
CLINICAL ISSUES	
Use of reproductive material (including posthumous removal) for the purpose of creating an embryo without consent	Prohibited
Use of in vitro embryos for any purpose without consent	Prohibited
Restriction on number of embryos transferred in an IVF cycle	Unregulated
Restriction on number of offspring from the same sperm donor	Unregulated
Freezing of eggs and embryos	Regulated (only in Quebec)
Destruction of Surplus embryos	Regulated (only in Quebec)
Storing, transferring embryos	Unregulated
Creation and maintenance of records: Collect, analyze and manage donor information	Regulated (Quebec)
Disclosure of donor information	Regulated (Quebec)
Disclosure of medical errors	Provincial and Territorial Colleges of Physicians and Surgeons
Destruction of donor information	Unregulated
Selective Reduction	Unregulated
Introduction of new tests and procedures into clinical practice	Unregulated
LICENSING and access to services	
Issuance, revocation, suspension of license for use of embryo and ART activities; issuances of facility licenses; issuance of license for clinical trial	Regulated (Quebec) Also regulated by some Provincial Regulatory Colleges
Access for donors and recipients	Regulated (Quebec)

Ethics and ART

Cloning and Hybrids

Human and therapeutic cloning and the use of hybrids are prohibited in Canada since they have been found to be inconsistent with the values of Canadian society. This justification does not explain how these practices may violate human dignity, a term which varies in meaning for different people.⁷ However, many countries such as Australia, Germany, and the United Kingdom (UK) have also banned both types of cloning because it is a dramatic departure from natural or assisted conception and is viewed as a form of replication rather than reproduction.⁸ Therapeutic cloning is permissible in the UK with a special license. Therapeutic cloning is different from human cloning in that the former is used primarily to produce stem cells for research or therapeutic purposes while the latter is used to produce human offspring. However, in combination with stem cell research, therapeutic cloning has the potential to cure conditions such as diabetes, muscular dystrophy and Parkinson's disease.⁹ A consequence of its prohibition in Canada is that Canadian scientists may move to other countries to conduct this type of research. Although therapeutic cloning may challenge societal values because, among other concerns, it uses cloning technology, its prohibition raises the question of whether Canadians might be deprived of access to new and innovative therapies that may be developed as a result of using this technology.

Surrogacy

Surrogacy is a preconception arrangement where one woman bears and delivers a child or children for another person or couple (the commissioning person or couple). Traditional surrogacy involves inseminating the surrogate mother with sperm, whereas gestational surrogacy involves transferring one or more embryos, fertilized in vitro with the gametes of the commissioning couple or their selected donor(s) couple, into the surrogate mother's uterus.¹⁰

Payment for surrogacy, offering or advertising payment for a surrogacy, or inducing or counseling a female person to become a surrogate are all prohibited in Canada. The concern that human reproduction will become commoditized and the potential for exploitation of women form the basis for these prohibitions. Since money may be a greater incentive to some women, and this option would only be accessible to those who could afford it, the concern is that the risk of exploitation and inequality increases with procurement of surrogacy. The reality is that all of these activities take place covertly in Canada in an unregulated environment that offers neither support nor security for those who are surrogates.

Although the risk is less, coercion, oppression and exploitation may also be involved in altruistic surrogacy. A woman may feel pressure to act as a surrogate mother if a close friend or relative is making the request. In addition to the physical risks associated with reproductive technology and the pains of pregnancy, a surrogate mother may be coerced to change her lifestyle to accommodate the wishes of the potential recipient. Surrogacy can create alliances between women as well as hierarchies, especially if surrogates (whether traditional or gestational) are of a different ethnicity or socioeconomic status than the intended parents.¹¹

The psychological experience of being forced to sever ties with a child may be extremely difficult for the surrogate mother especially if she has a genetic link to the offspring, as is the case with traditional surrogacy. If the procedure is unsuccessful the surrogate mother may be the subject of blame or her relationship with the intended parents may deteriorate.¹² A genetic relationship with the offspring may also impact the family's relations and offspring's identity.¹³

The dichotomy between the surrogate mother and the fetus is highlighted when the interests of the intended parents do not coincide with the interests of the surrogate mother. The conflict between one woman's reproductive freedom to decide whether and how to have a child can consequently conflict with another woman's autonomy over her body. This distinction can potentially challenge some of our societal foundations underlying the right to abortion and the security and autonomy of women carrying a child.¹⁰

The prohibition of surrogacy in other countries such as Germany and France reflects the societal discomfort with the notion of maternal multiplicity and the concern about the risks of exploitation. In contrast, the United States (US) permits both altruistic and paid surrogacy since it places a high priority on individual autonomy within a more profit-driven system.⁷ Australia and the UK, like Canada, prohibit payment for surrogacy but permit altruistic surrogacy. Surrogacy arrangements are not legally enforceable in the UK and the surrogate mother maintains parental rights, even if she is not genetically related. In contrast, the majority of the states in Australia grant parental rights based on the preconception intent of the parents. In the US, both approaches exist depending on the state in which the surrogacy is undertaken.⁷

Altruistic surrogacy remains unregulated in Canada. Quebec is the only province to declare preconception agreements to be legally unenforceable. However, since these arrangements concern child custody, which is typically resolved according to the child's best interests under family law, it does not seem likely that a preconception agreement would be enforced in other provinces either.¹⁴ Consideration must be provided by both parties for an agreement to be legally enforceable, yet this raises the notion of commodification.

It is suggested here that surrogacy agreements should not be legally enforceable and that clear standards should be developed to ensure that all parties are informed of the risks involved. While we are concerned about the commodification of women in Canada, the lack of a reimbursement framework also

leaves those women who choose to be surrogates relatively unprotected. As well, by our actions, there is a risk that we may be encouraging commodification of disadvantaged women outside of Canada (for example in India, Cyprus, Panama, Eastern Europe or Spain) who act as paid surrogates for Canadians.

Genetic Testing and Screening Technologies

Screening of gamete donors

Medical or genetic screening of prospective gamete providers may prevent or reduce the harm caused by transmission of infections and hereditary diseases to gamete recipients and their offspring. For this reason it is morally acceptable and, some have argued, morally required. Although these techniques are permitted in Canada, they remain unregulated. Some have engendered considerable controversy (for example, screening for blindness, spina bifida, cerebral palsy) based on the concerns of those living with those conditions that screening out individuals like themselves diminishes their humanity and encourages bias and discrimination.

In some cases, donors may prefer that their gametes not be screened for fear that it will reveal their own risk of developing a disease or disorder, particularly in those instances where there is no treatment or cure for that condition. However, fairness to the recipients and priority for the health and wellbeing of the offspring would require that medical and genetic screening is conducted. In order to ensure that Canadians are equally afforded the benefit of this technique, it is recommended that national regulations specify conditions for which screening would be done, that the donor be advised of the results and that the results be kept confidentially in a registry.¹⁵ The potential transmission and severity of the condition should be considered in constructing the guidelines.¹⁶ Canadian Standards Association (CSA) standards require specific testing of gamete donors.

International opinion on the need for psychological assessment as part of the medical screening of gamete donors is mixed. However, the SOGC and CFAS agree that it is acceptable if it is used to provide the basis for informed consent, to rule out pathology or coercion. Screening for mental illness in gamete donors raises the risk that donors may be unjustifiably discriminated against. Standards from the CFAS psychology Special Interest Group and the CSA require counseling prior to consent signing, not to screen for mental illness but in order to inform and validate the consent process.

Informed consent is required as part of any medical and genetic testing and screening practices.

Screening of Embryos

Pre-implantation genetic diagnosis (PGD) is a method used to identify potentially harmful genetic diseases in human embryos before the embryos are transferred to a uterus. It identifies embryos that have inherited single gene defects in gametes from known carriers or affected individuals when using their own gametes, not donor gametes. PGD is currently used to identify all manner of genetic predispositions and conditions, not just diseases, which is one of the concerns regarding the use of this technology. There are communities deeply concerned about the implications and uses of PGD. PGD may provide the option to avoid late pregnancy termination due to lethal genetic conditions and hence IVF with PGD is a procedure considered by some patients who are known to carry a genetic disease. PGD does not provide an absolute guarantee against the future development of disease and it is recommended that parents are informed of this and that prenatal diagnosis (PND) is also offered.

PGD involves the same physical risks to a woman that are associated with IVF and additionally may cause damage to embryos when a blastomere is removed. The potential burdens of caring for a child who is certain to have a specific disorder and the economic ability to do so may outweigh these risks and costs.¹⁷

While most people regard PND as an important option for pregnant women that would inform them of the health of their fetus, some people consider PND a parental obligation to ensure the health and wellbeing of their offspring.¹⁸ Whether this view holds for PGD is unclear, but given that the procedure is expensive,

equity and justice issues regarding access to this technology also need to be considered. The ethical dilemma surrounding access poses an important consideration of whether it is fair to permit the use of this technology only to those who can afford it, or whether denying access to everyone because it is not financially accessible to some is a better solution. This also speaks, of course, to many of the equity issues surrounding the lack of public funding of ART services.

There is also a concern that screening for disorders may reinforce discriminatory attitudes towards those with the disorder.¹⁹ The possibility of avoiding the birth of children with disabilities who are genetically different from the norm and the promotion of universal screening programs may suggest that society is willing to invest resources to prevent the birth of people with a particular condition. This conflicts with the right to life for the genetically different.²⁰ Discrimination against people living with disabilities, those choosing to have children with genetic disabilities, and those carrying potentially harmful genes is considered to be morally unacceptable. However, ultimately it should be the right of the woman and her partner to have all of the relevant information.

PGD also has the potential to be associated with eugenic practices. This is a concern that has been particularly discussed in European countries. In France, the National Ethics Committee recommends banning PGD because of its potential use for convenience rather than medical necessity. It is currently banned in Germany, Austria, Italy and Switzerland.¹⁰

Questions also arise as to whether it is ethically acceptable to use PGD for selecting traits such as deafness in a child, which may be desired by parents who are also deaf. The principle of reproductive autonomy would support this use; however, this conflicts with the view that the birth of a child with a genetic disease or disability constitutes a harm to the child, who of course had no say in these decisions.

In the US, Belgium, Israel, and the UK, genetic selection and manipulation are permissible in order to prevent, cure, or treat genetic disorders.¹³ In Canada, PGD is permitted for medical reasons and viewed as morally acceptable by the SOGC and CFAS. However, it remains unregulated.¹⁴

In some countries PGD is being used to select genetically matching embryos with the potential of the resulting child to donate blood or bone marrow to save an older ailing sibling.²¹ This raises several ethical concerns, such as whether this constitutes a valid ethical and medical reason for using PGD, whether this is the creation of a human being as a means to an end rather than as an end unto himself/herself, as well as how it might impact the psychological wellbeing of the affected children or conflict with the 'saviour sibling's' autonomy.

Given the importance of this technology in preventing disease and the concerns regarding its use, it is recommended that national standards be developed in Canada to regulate its use. A list of severe debilitating or fatal inherited monogenic diseases for which there is no known treatment, and for which PGD would be acceptable, should be developed and reviewed periodically.²² It is recommended that PGD not be used to screen for susceptibility genes to multifactorial disease.¹⁰ Since counseling may be helpful in enabling persons to make a free and informed decision, standards on when and how PGD is to be offered should be developed as well. It is also recommended that IVF and PGD be funded in these circumstances.

Sex Selection and Selective Reduction

Sex selection for the purpose of preventing, diagnosing, or treating sex-linked disorders or diseases is permitted in Canada. Consideration for the child's potential suffering and the parent's freedom of individual reproductive behavior are reflected in this position.

Sex selection for any purpose other than to prevent a sex-linked disorder is prohibited in Canada because it contravenes the dignity of human beings. Concerns that sex selection may lead to gender discrimination and inequality also justify this view. Most countries consider sex selection unethical.²³ Sex selection for the purposes of family balancing is strictly prohibited in the UK but not in the US.²⁴ It is recommended that national guidelines and provincial regulations specify those medical conditions for which sex selection would be permitted.

Selective reduction is currently unregulated in Canada and there is evidence that it is actively practiced among some ethnic and religious communities.²⁵ Economic and cultural priorities can markedly influence the status and expectations for families and in some cases selective reduction may be appealing or appear necessary. Concerns for the health and safety of offspring can also necessitate selective reduction from more than two fetuses to twins. The psychological effect this can have for parents can be challenging since their interests in a successful pregnancy may conflict with religious or emotional resistance to selective reduction. It is recommended that national standards be developed to identify those circumstances where it would be considered appropriate to conduct selective reduction, and specify how physicians should counsel their patients in this regard.

Donation of Reproductive Material

Donation of reproductive material is a growing concern in Canada and is compounded by a donor shortage.¹⁸ Currently, most gamete donors for Canadians are anonymous and reside outside Canada. While the third party transfer of gametes is generally felt to be morally acceptable, in many cultures and religions people may be reluctant to accept or offer to donate their embryos for third party reproduction²⁶. All faiths have their own specific prohibitions and permissions around third party reproduction.²⁷ Gamete and embryo donors may donate for various reasons and thus have various interests in the process and outcome. Gamete donors may be motivated by generosity; however, some may also wish to play a role in the selection of recipients, or be informed of the outcome.²⁸ When the donor is a friend or family member, the donor may desire to play a greater role in the child's life and if the child is aware of his or her origins it may lead to confusion or conflict among the donor and the intended parents.

Embryo donation is most often considered after a person has undergone IVF and is determining the disposition of their spare embryos that they no longer wish to use for their own reproductive purposes. Some may prefer to donate their embryos for the purpose of creating a child instead of donating them for research or disposing of them.

Whether information about the outcome of the donation should be provided to the donor raises several considerations. It can be argued that donors deserve to know whether their gametes or embryos resulted in a pregnancy and this may provide needed psychological closure to their donation. Yet, it may cause the donor distress if either the pregnancy is successful or unsuccessful. This might also conflict with the privacy rights of the parents of the resultant offspring.

Anonymous donations raise additional ethical issues regarding the privacy of donors and the welfare of the offspring. Some donors, especially those who do not want contact with the offspring, prefer anonymity. Respect for privacy implies that donors can keep certain information confidential. However, this may conflict with Article 8 of the UN Convention on the Rights of the Child which stipulates that children should not be deprived of elements of their identity. Canada is a signatory to this Convention but does not constitutionally protect an individual's interest in knowing the identity of one's biological progenitors. In recognition of the importance of origins to identity, some countries such as the UK, Sweden and some states in Australia have mandated that donor anonymity be lifted when the child reaches the age of 18.²⁸ This issue has not yet been settled legally in Canada. Absence of donor anonymity without an aggressive national recruitment campaign can lead to a shortage of donors as was exemplified by Sweden.²⁹ France prioritizes donor anonymity but recommends that a child have access to non-identifiable information about the donor.²⁹ In Canada, prospective parents can purchase access to identifiable gamete donor information for their future children.

Given the importance of gamete donation in addressing infertility concerns, a compromise recommended by some has been to permit the child to know his or her medical history but maintain the anonymity of the donor. The US recognizes an obligation to consider authorizing disclosure of information, at a minimum the donor's medical history, if the offspring later requests this information. This information is important to recipients who desire to have healthy offspring and wish to know their family's medical history. It is reasonable to expect donors to be informed of their clinic's policies about information sharing and privacy prior to providing consent.

Another consideration is whether donors have an obligation to keep clinics informed of their health status.²⁸ In Canada, this is required under CSA standards. Although this may be of interest to recipients, it can be intrusive to some donors who prefer to view their donation as a single event. Counseling about the potential impact that their donation may have on their own children is also suggested so that donors grasp the significance of their decision. Counseling would also benefit recipients, yet making it mandatory in this area of healthcare where it is not in others may place an undue burden on those seeking these services. Therefore, it is recommended that any clinical regulations in this area be reasonably flexible.

The purchase, sale or exchange of reproductive material for any consideration, or advertising of such, is prohibited in Canada because it contravenes the dignity of the human person. Concerns of inducement and potential exploitation also support this position.³⁰ Reimbursement for expenditures incurred in the course of donating is permitted however.

Anonymous ovum and embryo donation is largely unregulated in Canada, with a few exceptions. Sperm donation is closely regulated by Health Canada under the Semen Regulations (Food and Drug Act). Under federal law, donors have to be at least 18 years old unless the intention is to preserve the gametes for the purpose of creating a child in the future that will be raised by the donor. There is no restriction on the age of the recipient in Canada, however in Quebec no embryo may be transferred to a woman who is over child-bearing age (which is not defined in the legislation).

The Government of Quebec recommends that gamete donors and recipients first undergo basic medical and psychological assessments and provide informed consent. Donors must be in good physical and mental health and know the identity of their biological parents so their medical history can be determined. A further requirement in Quebec is that donors have a stable sexual life with only one partner during the previous 6 months. These conditions reflect the political and cultural realities in Quebec and so may not be appropriate for other provinces. The SOGC and CFAS agree that donors must consent to any genetic profiling and other assessments and must provide relevant personal information in the future.

It is recommended that national regulations be developed from the current (2013) CSA standards for the donation of reproductive material in Canada, recognizing those provincial regulations in existence at the time.

Informed Consent

Informed consent is a requirement for all ART activities in Canada, and those receiving these services need to be made aware of the likelihood of success in a way that they can clearly understand. Consent to donate gametes and embryos is intended to protect the donors.³¹ It is recommended that informed consent is standardized for each ART procedure and each aspect of a procedure since patients may agree to some aspects but not others. Individuals may regret donating years later if a decision is made in haste or without proper knowledge of the risks, benefits, nature of the procedure and other options available.³² The donation of embryos raises additional issues since it involves the reproductive material of two persons. Whether ownership rights to the embryo are equal and how to determine the disposition of the embryo if the parties are in disagreement are issues that require consideration.

Since it is important that consent is informed and given freely, it is recommended that donors are also fully informed of the risks of the process, whether genetic tests will be carried out and the clinic's policy in evaluating the results.²⁸ Information about the quality and safety of the facility, the qualifications of the employees, statistics about the success and failure rates of IVF and embryo transfer (ET) for live births following freezing, and the latest evidence-informed information about the potential consequences on fetal health and child development of using these procedures must be made available to donors prior to obtaining their consent to donate.^{14,33} This information should be standardized for all clinics so that prospective patients are able to meaningfully compare one clinic to another, and one therapeutic intervention to another.

Donors must be made aware of the full implications of their donation and consent must be provided for the disposition of the gametes or embryos when they are donated. Advance planning and discussions of

ethical issues is recommended. Individual consent should be obtained for the freezing of gametes and embryos, storage, donation to a third party, donation for research purposes including specifics about the project, and disposal. In order to avoid undue influence, it is recommended that consent for research only be obtained after fertility needs are met and the decision is made to no longer store embryos.³²

It is recommended that donors be informed that consent to donate involves relinquishing their parental rights and that it is possible to change their minds without prejudice at any time until the intended research experiment begins or their reproductive material has been assigned to another individual.

Restriction on Number of Embryos

Imposing a restriction on the number of embryos transferred is ethically acceptable and arguably required in order to avoid multiple pregnancies and to protect the health of the mother and offspring. This remains unregulated in Canada outside Quebec. Quebec has regulated the maximum number of embryos that may be transferred in women depending on her age.⁶ Many countries also enforce a limit of 2-3 embryos per cycle to lower the risk of multiple pregnancies.¹⁸ In Germany it is an offense to transfer more than 3 embryos into the uterus.¹³ In contrast, the US imposes no limit.

Europe generally has lower success rates than the US, yet it is unclear if the difference in restrictions on the number of embryos transferred is a factor. This raises consideration of whether there is a tradeoff between pregnancy rates and more restrictive embryo transfer policies. Further, it demands a reflection on whether the gain in respect for embryos and precaution for reducing the chance of multiple gestations justifies the burden on women who may now go through additional transfer cycles,¹³ each of which entails variable risks and burdens to the woman, as well as additional costs.

Considerations regarding the optimal number of embryos needed to provide a reasonable chance of pregnancy, the health risks for mother and child of multiple pregnancies, and the financial, emotional and physical burdens of transfer at a later date are all important for determining a reasonable restriction on the number of embryos to be transferred. An additional consideration is the financial burden on the publicly funded healthcare system of providing very expensive neonatal and childhood care to prematurely-born infants that are common in multiple births resulting from multiple embryo transfers.³⁴ In this respect, a balance must be sought between the health goals of the individual and the publicly informed health priorities of society in general.

Restriction on Number of Offspring

It is recommended that restrictions be placed on the number of offspring that can be born from the same donor in order to lower the chances of consanguinity. The US recommends that each sperm donor be limited to 15 successful pregnancies, whereas South Africa imposes a limit of 5.^{18,35} National standards should be developed to reflect these considerations.

Disposition of Surplus Embryos

Research on embryos is guided in Canada by the Tri-Council Policy Statement on Research on Human Subjects (2014) and the Stem Cell Guidelines and is largely supported when potentially important knowledge cannot be obtained in any other way.¹⁴ The debate about whether research with embryos is ethically acceptable is framed around the moral status of the embryos and has largely been resolved.³²

There is currently no consensus among Canadians as to the moral status of human embryos. In the Christian literature, the embryo is variably ascribed the same moral status as a person from conception, or it acquires moral status at some time after conception and before birth, or it has no moral status until birth.³⁶ Those who view the embryo as deserving moral significance, do so based on its capacity for development into a person (or potentiality), its human individuality, and its species membership. Yet others view an embryo as being of lesser moral significance because of its lack of volition or sentience. Most ethics committees support the view of the embryo as a potential human worthy of special respect but not entitled to the same rights as a person.³² In Canadian law, an embryo is of human origin but is

not a human being with legal personhood and its attendant rights until it is born and outside of the uterus, although its potential to become a human being is recognized.³⁶

A balance between the embryo's moral significance and the needs of society must be met in determining appropriate standards for clinical research with embryos. Some religions strongly oppose allowing research to be carried out on embryos since research regards the embryo as a commodity and stem cells can potentially be derived from other sources. Since decisions to donate embryos generally occur after infertility needs have been met, these embryos would likely be discarded if not donated to a third party or to research. Given that research on embryos raises the potential for curing disease, some argue that this type of research is not just a morally acceptable option, but a societal obligation.³² There is not, however, consensus on this issue.

Approaches to cryopreservation and disposition of frozen embryos vary internationally from acceptance to prohibition. The storage of gametes and embryos in Canada is regulated only in Quebec. Clinical practices for storage are reported annually to the Government of Quebec for approval.

It is recommended that national guidelines be developed to define how long embryos should be stored and when an embryo may be declared abandoned. In the US and the UK, embryos are considered abandoned if 5 years have passed and the clinic has taken appropriate steps to contact the owners.³⁷ Standardizing the technology used at freezing facilities to maximize the availability of viable embryos is also recommended.

There is no national inventory of embryos available for research.

The destruction of surplus embryos is regulated in Quebec but remains unregulated elsewhere in Canada. Ownership of surplus embryos has yet to be resolved. The disposal of surplus embryos at the consent of the donors is accepted in England, Australia and most states in the US and parents must subsequently be notified of their disposal.³⁸

Information Collection and Results Reporting

Quebec is the only province to regulate standardized results reporting. The collection of both personal and non-personal information is regulated and facilities are required to report annually on assisted procreation activities.

National standards for maintaining a confidential, standardized registry of ART activities, and medical and genetic screening results of gamete and embryo donors, are strongly recommended. Updating registries as required is encouraged. Permitting access to clinic specific success rates will allow consumers to make informed decisions.⁹ There are currently some important initiatives underway in Canada in this regard, but there is resistance among the clinics for clinic specific outcome data.

The development of standards for the destruction of donor information and under which circumstances it is permitted is also recommended. How information is to be stored when a clinic is shut down or a physician retires must also be considered.

Disclosure

Since medical errors related to ART can have significant consequences, it is strongly recommended that medical errors continue to be provincially regulated and disclosed out of respect for patient autonomy and fairness. Written policy for reducing and disclosing errors is encouraged. Errors which diminish gamete or embryo reproductive opportunity or which lead to the birth of a child from an embryo intended for another parent or couple can have severe emotional, psychological and legal consequences.³⁹ The best ethical practice is to disclose such errors. Although harm to the family will likely result, disclosure enables the person affected to help decide remedial measures and avoid further harm.

Informing the offspring of their conception by gamete donation may involve conflicting interests of the donors, the recipient parents and the offspring. It is important for recipients and donors to agree about the

scope of information to be disclosed to recipients or offspring. Given the sensitivity of this issue and the role that clinics may play in disclosing information, it is recommended that national standards on how to respond to inquiries be developed.

There is a trend in favour of disclosing this information in the US, Australia and Europe.⁴⁰ The basis of this position is the argument that humans have a fundamental interest in knowing their biological origins. Studies show this information is central to individual identity but may also have adverse consequences^{41,42}

It is recommended that clinics should offer patients counseling to help them make decisions about the appropriateness of informing the child of the circumstances of their birth. There is little information on the age at which it is preferable to disclose this information. Concerns that children may experience social and psychological distress if the information is disclosed are valid. It is recommended that issues of disclosure are discussed with all parties involved.

Best Interests of the Child

The definition of the best interest of the child is statutorily enshrined in provincial legislation but the definition has not been modified to consider the children who might result from assisted conception⁴³. Children resulting from ART should of course be permitted the same opportunities for physical and psychological development as naturally conceived children. Physicians have a responsibility to protect the child from significant risks and to restrict access to ART where such risks exist. Priority should be given to the well-being of the future child, not the ability of a person to have a child if a physician has valid reason to believe that the prospective parent may be incapable of parenting. The American Society for Reproductive Medicine states that “offspring welfare is a valid consideration that fertility programs may take into account in selecting patients and providing services as long as they do not discriminate on the basis of disability or other impermissible factors. However, it does not follow that they are morally obligated to withhold such services, except when significant harm to future children is likely. Physician autonomy entitles physicians to provide medical services if they choose, but they are not usually obligated to do so.”⁴⁴

Predictions about how significant a risk exists to the child, however, are not easily made. It may be questioned whether a physician is capable of making an accurate assessment and to what extent their own normative views on childrearing influence that decision.⁴⁵

The possible effects on the psychological development of children born from surrogacy or IVF treatments with donated reproductive material should be discussed by a certified mental health professional with all parties who are considering these options.¹⁰ While anonymity respects the privacy of donors, this may conflict with a child’s access to information regarding their origins. Information surrounding the circumstances of a child’s birth can be important for the construction of identity, sense of belonging and well-being.

Some authors have also argued that children may feel a lack of connectedness with their parents and knowledge of their genetic origins might confuse their family relationships.^{18,12}

Funding and Access to Services

It would seem to be consistent with Canadian values that no group of individuals is denied access to ART. However, Canada is one of the few countries with universal health coverage that does not generally assist citizens with fertility treatments.⁹ Financial costs are an obvious constraint and will remain so, especially as technology advances. It is recognized that these are private clinics with expenses and overheads, but financial interests should not be the driver of best practices.

In Australia, Israel and most European countries, IVF treatment and relevant surgical procedures are available to women who are in financial need.¹⁴ One justification is that it reduces the attraction for other illegal means, such as exchanging oocytes for treatment, and the potential for exploitation. It is also

predicated on the principle of justice, whereby all prospective parents have equal access to reproductive services regardless of financial means.

The shortage of reproductive donors in Canada, which is related to the absence of regulations on how donors may be reimbursed, creates the conditions for reproductive tourism overseas. Some may resort to using donors (through questionable sources) who have not been thoroughly screened.⁹ This raises serious concerns for health risks to women and children.

Access to ART may reflect pronounced class and race based inequalities if low income ethnic minorities are unable to afford treatment.²⁰ If infertility treatment were recognized as medically necessary, it would likely be included as an insured service under the Canada Health Act.⁹ Currently, funding is provided in Ontario when both fallopian are obstructed. This discrimination against infertile men is being challenged and the matter is before the Ontario Human Rights Tribunal. Proposed new regulations in Quebec will withdraw funding and will limit tax credits based on taxable income, medical necessity and age.⁶ Quebec, Manitoba and New Brunswick provide tax credits for those who pay for their treatment. These circumstances and arrangements are in constant evolution.

Since resources are limited, the question arises as to who will get priority. Barriers to access include the heavy concentration of fertility clinics in urban centers and the potential for discrimination against homosexuals and single mothers. Neither concerns about the welfare of children, nor the desires to promote marriage, justify denying reproductive services to unmarried individuals, or couples who are gay or lesbian solely based on those individuals' sexual orientation or marital status.⁴⁶ In the United States, the courts have ruled that it is not possible for clinics to refuse to consider applications for reproductive technology for unmarried couples or single women.¹⁸ The absence of a father or being raised by a same-sex couple does not result in harm to the child, and the incidence of these family arrangements is increasing without the use of ART.¹⁴

Maternal Age

Another ethical issue is whether there should be an age limit to a woman bearing a child. The Government of Canada has prohibited females less than 18 years of age from donating their oocytes, although they are allowed to preserve them for the donor's later use. In Quebec no embryo may be transferred to a woman who is over the age of 42. Women aged 42 or older may not use their own oocytes in IVF.⁶ Although the safety of the child and the mother underscores these laws, it may also be argued that it is inappropriate to restrict women from having access to ART, given that there are no comparable laws restricting men from fathering a child using ART.

Whether it is appropriate and sensible to use ART on post-menopausal women is another consideration. Denying women an alternative for reproduction at an equivalent age to men potentially challenges gender equality. However, older women are at increased risk for complications which may threaten the safety of the offspring, in addition to the psychological or social discomfort the child may experience in having a mother who is old enough to be a grandmother (though of course similar age-based arguments could also be used for children of very young mothers).

Fertility preservation

People with cancer or chronic medical illnesses who undergo radiation, chemotherapy or other gonadotoxic therapies may want to store their eggs, sperm or embryos for subsequent use.⁴⁷ When these individuals are children, there are legitimate concerns about their capacity to understand the implications of undergoing the oocyte, sperm or gonadal extraction procedure and having their eggs, sperm or gonadal biopsies stored for later use. With adults, it is recommended that guidelines be developed to guide decisions about treating those with a futile or poor prognosis.

Much work needs to be done by governments to promote awareness and understanding of fertility preservation among patients, the medical community, and the Canadian public. Canadians need to receive timely information on fertility preservation options.

Currently fertility preservation is not an insured service outside of Quebec

Moving Innovation into Practice

“The introduction of new strategies, tests and procedures into clinical practice raises challenging ethical issues involving evaluation of evidence, balancing benefits and harms, supporting patient autonomy, avoiding conflict of interest, and promoting advances in health care.” (ASRM Ethics Committee, Draft Document, 2015). While innovation is a fundamental element in improving health care, well-designed clinical research is essential in developing new interventions. Evidence of safety and effectiveness must be demonstrated before dissemination into clinical practice. If new interventions are adopted into clinical practice, ongoing data collection is critical for complete understanding of benefits, harms, and optimal application of a new intervention until such time as safety and efficacy are established. The role of provincial and/or federal oversight needs further elaboration.

Suggested Approach to ART in Canada

The ultimate outcome of the Supreme Court of Canada’s ruling would appear to be an increasing reliance on provincial oversight to regulate ART. Some observers have concerns that the provinces will be incapable of protecting women and an inconsistent patchwork of clinical standards will give rise to inter-provincial reproductive tourism.⁴⁸ One potential benefit of provincial variation is the emergence of best practices through competition and the harmonization of policy through intergovernmental cooperation.

Canada might learn from Australia’s approach to regulating ART. Due to states modeling and copying each other’s legislation on ART, as well as intergovernmental arrangements such as the Standing Committee of the Attorney General (SCAG), Australia has achieved harmonization on all 5 areas covered by Canada’s Assisted Human Reproduction Act and also the effects on parentage, not covered in the Canadian Act. Half of the states there have mirrored the two Acts on prohibiting human cloning and another on regulating research involving human embryos. SCAG has also led initiatives regarding surrogacy bans. There is reason to believe that a similar approach might be successful in Canada. For example, provincial security commissions over time have achieved policy that is national in scope through provinces acting in cooperation.

A modification of the Australian approach may suit the needs of individual Canadians and provide a set of national standards which could be adopted by the provinces. A top-down approach of establishing national standards, while recognizing provincial constitutional authority, would address infertility concerns while ensuring that safe and ethical practices are in place to protect the health and integrity of Canadians. Specialists in the field, in addition to organizations such as the CMA, SOGC and CFAS, as well as provincial regulatory bodies should be involved in the development of national standards.

The development process should be free from political influence and open to consultation and debate. Provincial oversight on issues of licensing and monitoring of individual physicians is consistent with Canada’s approach to the regulation of health care practitioners as well as Quebec’s legislation on ART.

However, monitoring research related to ART, training physicians in ART, and guidelines for medical procedures and accreditation of facilities where ART is practiced, would be better addressed by national standards developed by the relevant bodies. Some of this is already happening on a provincial level, but not in a consistent or coordinated manner across the country. Thus, given the importance and increasing proliferation of ART, it is strongly recommended that national standards for regulation be developed with consideration for the important and complex ethical issues discussed in this paper.

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