

# BIOÉTHIQUE MEDICAL ETHICS BIOÉTHIQUE MEDICAL ETHICS BIOÉTHIQUE ETHICAL ISSUES IN ASSISTED REPRODUCTIVE TECHNOLOGIES

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About 10-15% of couples who want to have children are unable to have them, and popular culture calls them “infertile” [1]. Physicians have developed methods to overcome infertility, with the motive of helping such couples have their own child. In some countries the assisted reproductive technologies (ART) such as in vitro fertilization (IVF) and donor insemination (DI) are involved in 1-2% of all live births. The birth of children to infertile couples brings not only great human joy but a new human being. It is consistent in theory with the ethical principles of autonomy and beneficence, often argued to be the premier ethical principles. As a result, clinics providing ART services have sprung up all over the world, motivated by lucrative financial returns. Furthermore, we can see adverts for the services offered by commercial agencies promoting sale of gametes, adoption of embryos or surrogacy arrangements at competitive prices in countries around the world from the USA to India .

In the ethical evaluation of assisted reproduction questions of justice are raised regarding the eligibility or access to these techniques. Government funding is generally denied for ART services, because society has adopted different priorities in health expenditure. In many countries society prohibits access also to other persons including single parents or homosexual couples. This prohibition has been considered a violation of the human right to procreate and raise children according to individual preferences. Whereas personal autonomy or self-determination are prized moral values in health care decisions, when it comes to making choices about ART, society imposes regulations aimed at the well-being of the resulting child and the family.

Fertile people may have a need for fertility treatments also. People who undergo radiation treatment may want to store their gametes for later use. Similarly, young people who receive chemotherapy, especially women, may want to recover oocytes for future use. Sperm banks can also store sperms for future use. Generally ethical concerns have led most people to restrict posthumous use of gametes [2].

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In most countries, ART is supposed to be performed on heterosexual couples, either married or in a stable relationship. Other groups, such as single women and those in homosexual relationships have gained access to ART in limited areas. Unmarried individuals, including single people and partners in same-sex relationships, have been barred from ART by laws or by institutional or professional rules of practices. These have been based on or reinforced by claims that limits are compelled or justified to protect children against births into unstable or otherwise unconventional domestic settings.

These advances in biology and medicine, especially in reproductive health have moved faster than laws. Ethical dilemmas and controversies are encountered by the medical profession and society at large. It is important that every country should have a dynamic mechanism for dealing with ethical problems as well as regulating ethical norms in medical practice and research. This may involve the establishment of a national medical ethics commission and regional, local and institutional ethics committees. Such mechanisms must be responsive to changes within the country, and must take into consideration the views of the majority of the citizens. Recommendations of these various commissions were debated with politicians, religious authorities and lawmakers to help draft new legislation that would be culturally acceptable, and respectful of human dignity and consistent with recommendations of the international community.

In Lebanon, the National Consultative Committee on Ethics in Life Sciences and Health (CCNLE) was formed in 2001 by the Office of the Prime Minister as a consulting authority and charged with recommending national policies on ethics in medical practice and research. Within this mandate, the CCNLE reviewed the ART practices in the various centers in Lebanon and the ethical dilemmas emanating from these new technologies. The current Law on Medical Ethics which was promulgated in 1993 addresses only sperm donation and abortion issues. As of the 1990s, ART has developed fast to encompass a range of techniques to overcome infertility, increase fertility or influence or choose the genetic characteristics of offspring. Each technique brings with it a range of ethical issues. These issues have been brought squarely into the public arena, where they continue to provoke controversies involving the boundaries of governmental control, private choice, religious belief and parental wishes.

Initially these ART techniques sparked intense debate about their safe use, and the social and legal implications they were predicted to have.

In most developing countries like Lebanon, medical

ethics is not part of the mainstream thought, not even in the medical profession. It is alluded to whenever an instance of medical negligence or malpractice makes the headlines. Whereas discussions and debates on ethical matters can become passionate in Western countries, they are virtually absent in the developing world .

Biomedical ethical issues, guidelines, principles and regulations cut across national boundaries and often have universal implications. Though people and cultures differ, certain values are common to all. The most important is respect for human dignity and this should not be negotiable. Nevertheless, it would be naïve to expect guidelines to be quickly and effectively applicable in developing countries where poverty, severe underdevelopment and illiteracy are pervasive. In this setting, the greatest medical ethical need is justice and equity in allocation of resources and distribution of effective health care services.

To deal with the ethical challenges brought about by ART, some countries have set up ministerial committees – like National Ethics Committees on ART – to review ART proposals including health research, and treatments to determine whether they are ethical, whether the right of people is protected, and to develop for providers protocols and guidelines relating to the ethical issues involved with aspects of ART and advise the government authorities on ethical issues. Other countries responded by enacting legislations that are mandatory and statutory, others have set up guidelines intended to be followed voluntarily by those practicing ART and delegated the surveillance to professional bodies and the rest of the countries have neither guidelines nor legislations, like Lebanon. Of the countries with legislation, some have created specific licensing bodies, usually within health departments. Likewise, medical societies and professional organizations have drafted guidelines, policy opinions and consensus statements on acceptable professional practices.

Criteria for licensing vary from nation to nation, but in general it has to do with the quality of the program, the national distribution, health care needs and competence of the various personnel. The clinical surveillance is carried out either by a periodic report, or on-site inspection and some carry the surveillance only on request. Penalties for violations are imposed in some and they vary from withdrawal of license, either temporarily or permanently to fines or imprisonment. Surveillance of the embryologic laboratory sometimes differs from that of the general program. In order to regulate professional practice, audit of the use of these technologies should include not only the fertility success rate but also statistics on the incidence of multiple pregnancy, the use of fetal reduction, the maternal and perinatal morbidity and mortality, the incidence of pre-term delivery and low birth weight and the occurrence of long-term disabilities among the offspring.

The UK government set up, in 1982, the *Committee of Inquiry into Human Fertilization and Embryology* under the chairmanship of Lady Warnock – it is now commonly known as the *Warnock Committee*. This committee considered all aspects of assisted reproduction available at the

time and made some 63 recommendations. One of the most important of these was that the government *should* set up a new statutory licensing authority to regulate both research and those infertility services which the committee recommended should be subject to control. Certain activities were to be made a criminal offence, such as the placing of a human embryo in the uterus of another species. The UK government did not act until 1990 when the Human Fertilization and Embryology Act was passed. This Act set up the *Human Fertilization and Embryology Authority* (HFEA), and the main recommendations of the Warnock Committee were incorporated into the Act, which now regulates the use of assisted reproduction in the UK.

In the US, ART practice is regulated through several agencies. The Food and Drug Administration regulates drugs used in ART, and andrology laboratories providing ART services are regulated by federal clinical laboratory improvement law, state laws govern the practice of medicine and the hospital-based ART services. Each ART program is required annually to report pregnancy rates to the Center of Disease Control (CDC) and National Institutes of Health regulations govern aspects of research in reproductive medicine. In addition, standards set by professional bodies like Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine (ASRM), and the American College of Obstetricians and Gynecologists are observed voluntarily.

Currently, in Lebanon, there are no legal or credentialing requirements for physicians performing the ART, nor for any of the technical staff, the embryologist or the andrology laboratory. Those ART centers have no professional guidelines and the clinical outcomes are not audited, so the consumers are not provided factual information on the pregnancy rate, or on the hazards associated with ovarian hyper stimulation and the risks of multiple pregnancies to the mother and her newborns. The multiple ethical and legal issues emanating from ART are dealt with arbitrarily, often influenced by pharmaceutical manufacturers or medical supplies providers, and certainly by financial inducements.

A draft law on ART in Lebanon was prepared by CCNLE after extensive consultations with stakeholders, including ART providers, officers of the Lebanese Society of Obstetrics and Gynecology, and some religious and political leaders. The draft was submitted to the Ministry of Health (MOH), who forwarded it to Majlis Al-Shoura to make sure that the draft does not contravene constitutional rights. The Majlis asked for some explanations and clarifications. After approval of the Majlis Al-Shoura it was submitted to the Council of Ministers for approval prior to referral to the Parliament for final ratification.

The draft law defines ART technology as interventions aiming at achieving pregnancy without intercourse and includes DI, IVF, gamete and zygote intrafallopian tube transfer – (GIFT) and (ZIFT) – and intracytoplasmic sperm injection (ICSI), the latter accounting for the majority of ART interventions.

ARTICLE 2 states that ART is permissible only between

husband and wife (not permitted for single persons, homosexuals and cohabiting couples). Prior to resorting to ART, it should be explicitly stated that conventional investigations and treatment of the infertile couple has been exhausted and failed to achieve pregnancy. The same article also permits utilization of ART to avoid a genetically transmitted disease.

ARTICLE 3 prohibits the donation or sale of gametes (sperm and egg) or embryos, and surrogacy arrangements are prohibited and consequently any contractual agreements between individuals or agencies involving surrogacy or sale of gametes or embryos are null and void.

ARTICLE 4 states that all centers performing ART must be licensed by MOH.

ARTICLE 5 states that ART centers must provide for a multidisciplinary team of experts to study the medical and social history, concur with the indication to resort to ART, and inform couples of the factual success rate and of the inherent risks and morbidity of the intervention and the legal status of the particular ART in Lebanon.

ARTICLE 6 deals with the number of embryos to be transferred – no more than three embryos for women below 35 years of age and possibly four for older women. Supernumerary embryos are to be frozen for the explicit future use of the couple. The ART center is to keep a confidential log of the embryos in custody. Disposal of embryos requires the consent of the couple and MOH is to be notified. In case of death or divorce, also the embryos are discarded and if the divorcing couple disagree on the disposal, then the appropriate court will rule on the matter.

ARTICLE 7. The couple cannot authorize the ART laboratory to donate the embryos, sell them or have them adopted. Similarly, they cannot be used for research.

ARTICLE 8 permits preimplantation genetic diagnosis (PGD) only when medically indicated. Frivolous indications, like family balancing, or designer babies are not permitted.

The laws from other Arab countries, when available, were noted and the views of the religious communities in Lebanon on specific ART practices were observed and respected. The consensus statements and policy guidelines by credible international professional organizations were included.

#### DONOR GAMETES

One of the oldest and least controversial reproductive technologies is the use of donor sperm to overcome azospermia or low sperm counts or to avoid inheritance of some genetic condition that the male might pass on to his child. Donation is usually anonymous, but some characteristics of the donor are known. Ethical issues arising in sperm donation include the extent to which parents have the right to choose desirable characteristics in the genetic father of the child and the right of the child to eventually learn the identity of the father. The Lebanese Law on Medical Ethics clearly prohibits artificial insemination by donor spermatozoa, but allows the practice only between husband and

wife. The aforementioned law does not mention egg donation as the technology for retrieving eggs for IVF was not available at the time the law was passed by Parliament in 1993. Unlike sperm donation, egg donation is associated with physical inconvenience and poses risks to the donor. Reimbursements are much higher and can easily become coercive.

There are clear ethical parallels between sperm and egg donation. Like sperm, donor eggs can help infertile individuals achieve pregnancy and have a child who is genetically related to one parent, and again like donor sperm can be used to avoid passing on a hereditary condition to the future child. Donor embryos enabling a woman to go through pregnancy and childbirth are usually surplus cryopreserved embryos from couples who have completed their families, but can also be formed from separate egg and sperm donations.

Ethical issues are raised in relation to the social father or mother. They may feel less attached to a child that is not genetically his/hers – a problem that is compounded by the use of donor embryos. Another ethical question is related to whether a child conceived in this way should or should not be told of her or his origin and what would happen in each case. Traditionally, it was almost universal practice to keep the identity of both the sperm donor and the recipient confidential. This practice has been challenged on the grounds that the child has a “right to know the truth.” Several countries now allow children to access at least identifying information about their genetic parent(s). Donors may also request the right to information on their genetic offspring.

A related question is whether recipients of ART services can claim a right to choose specific gamete or embryo donors. With the exception, for instance of the wife of an infertile couple choosing her brother-in-law as a sperm donor, couples may claim a right of choice of donors who meet routine criteria, such as being HIV-negative. Ethicists and practitioners have raised the concern that family relationships may become blurred or confused by the use of spermatozoa from known donors, and issues of blame or regret may arise if donation is followed by an adverse outcome. Allowing ART patients to recruit donors also raises concerns of financial inducements, emotional coercion and exploitation of dependent relationships.

Physicians should attempt to determine whether known donors are motivated by undue pressure or coercion; in such cases, the physicians should decline to proceed with the donation. When applicable, the informed consent process should include a discussion of the psychological and social ramifications of egg donation within families.

Women who want to become egg donors must undergo super ovulation and egg retrieval procedures. These interventions involve risks and are not in the donor's best medical interests. Eggs donations are not, in principle, different from other widely accepted altruistic donations, involving tissues such as blood and bone marrow. When large amounts of money are offered to potential egg donors, women entering egg donation programmes are motivated

not so much by altruism but by monetary considerations. It could be argued that poor women in particular are coerced by the offer of monetary rewards. These issues have long been debated in the organ donation literature. Egg sharing is another way in which egg donations can be effected. In this case, the donor is herself undergoing IVF procedures and will share some of her eggs with another woman. In this case it may be possible that the donor will not succeed in having a baby, whereas the recipient of the donated egg might be successful. If this outcome is known to the donor, it may well be experienced as tragic.

Given the scarcity of donor eggs and the growing pool of potential recipients, scientists have looked into alternative sources of donor eggs. There are some indications that the maturation of eggs in vitro and the transplantation of ovarian tissues may soon become clinical possibilities. This could solve the problem of egg shortages and avoid the ethical burdens now resting on egg donors. Eggs and ovaries retrieved from aborted female fetuses have been proposed, but are perceived by some to be repugnant. It is argued that such procedure may entail social and psychological harm to children if they find out that one of their "parents" was a donated ovary, or an aborted "cadaver".

Egg donation opens up the possibility of pregnancy in postmenopausal women. Should older women who want to become mothers be barred from access to ART?

There is, of course, an increased possibility that older women do not live long enough to raise children to adulthood. But this argument against older women becoming pregnant will hold only if it is applied equally to older men fathering children and to younger women and men who have an increased risk of dying before their children reach adulthood. Barring ART technologies to older women is a form of medical paternalism, or individual or societal prejudice that amounts to unjust discrimination.

The review of the potential applications of ART by governments and the creation of regulatory bodies to accommodate, limit and regulate their use have nevertheless left some legal and ethical issues unresolved, and have caused other issues to arise. Issues that regulatory systems leave unresolved, or that systems have created, include disposal of embryos that remain after patient treatments are concluded, multiple implantations and pregnancy. This may result in risks to maternal, embryonic and neonatal life and health, and the contentious relief that may be achieved by selective reduction of multiple pregnancies.

Some reject ART as morally unacceptable in itself, irrespective of any of the good or bad consequences it might have; others have categorical objections to particular modes of assisted reproduction, such as use of donor gametes. Such objections are based on either religious belief or traditional assumptions about the nature of relationships and the role of the family. While it is true that ART has the capacity to alter traditional ways of forming families and of individuals relating to each other, it is not clear that this is an inherently bad thing. There is no reason to assume that the nuclear family and traditional relationships are the only and best way for human beings to relate to each other

and to provide a nurturing environment for children.

There are good reasons for rejecting the view that IVF embryos have a right to life. An early IVF human embryo, consisting of no more than few cells, lacks the capacities that could reasonably ground such a right or provide the basis for the attribution of any morally significant interests. Lacking a central nervous system, the embryo has no conscious experiences; it cannot feel either pain or suffering, exercise its autonomy, or have any sense of its own existence. It cannot be harmed or benefited by anything that is done to it. If an IVF embryo is destroyed, or simply discarded, no suffering has been inflicted on the embryo. The progenitors of the embryo have an interest or right to decide what should happen to it.

Hence it would be wrong to dispose of an embryo or conduct research on it without the progenitors consent. It might be said that an embryo is morally considerable, not because of what it currently is, but because of its potential to become a child and a person – that it is the potential which forms the basis of the embryo's interests or rights. This argument can be applied into a more controversial issue. Does a sperm and an egg, considered jointly, have a similar potential?

The legal status of the embryo – is it a person or a property? If a person, it cannot be bought or sold. Nor can the parents give it away. The law on abolishing slavery in US prohibits the ownership of one person by another. If however the embryo is deemed to be property, he may be contracted like goods or services. If the embryo is equated with human tissue, blood or organs, it may be donated but with no payment to the donor. The legal dilemma concerning the moral status of the human embryo is highlighted in the current controversy over "embryo adoption".

The issue of the commodification of people is a cloudier sub-issue for ART; it could be argued in two ways. First, from the very beginning, when a woman decides to donate her eggs or a man his sperm, some people can argue that we are buying and selling human beings or at the very least, the makeup of humans. Should this not be akin to slavery? Slavery is wrong in the sense that we are treating people like cattle, mere commodities, like something that can be assigned a monetary value, when, in fact, are humans not more valuable than money? On the other hand, others argue against this, saying that a human is not a human until conception, and some go even further to say a human becomes a human at birth.

The ethical debate hinges on the central underlying question: When does "personhood" begin, in the life of a fertilized ovum? The most conservative stance, opposing all interventions in natural procreation and therefore opposing most reproductive methodologies, is adopted by the Roman Catholic Church and a number of other conservative groups. This non-intervention stance grants full respect to the conceptus from the moment of conception, defined as when a sperm penetrates the ovum. Others, who assign the beginning of personhood to later stages of development, advocate a greater freedom to utilize ART, depending on the ethical merits of specific situations and

on the rights of other individuals who are involved. Within this group, a central question is where to draw the boundary between parental freedom to choose methods of procreation and to influence the characteristics of their child on the one hand, and on the other, societal interests in protecting the unborn child.

ART, from fairly simple artificial insemination to intracytoplasmic sperm injection (ICSI), involves the separation of sexual intercourse and reproduction. In addition in IVF and related techniques, fertilization takes place outside the body, making gametes and embryos available not only for research but also for testing and manipulation prior to transfer. Hence sex is no longer the only means of conceiving human beings. Possibilities of gamete donation has confused the genetic cohesion and integrity of traditional family identity, and initially triggered conservative responses. First reactions are often more instinctive or visceral than intellectual, and policy responses have tended to focus more on defense against perceived dangers to traditional values than on achieving potentials for human satisfaction and cultural enrichment through new applications of biotechnology.

The widespread condemnation of cloning as an option for human reproduction is being questioned by medical ethicists, lawyers and others [3-4]. This was observed with the early popularization of artificial insemination, when Kleegman and Kaufman [4] noted that: *“Any change in custom or practice in this emotionally charged area has always elicited a response from established custom and law of horrified negation at first; then negation without horror; then slow and gradual curiosity, study, evaluation, and finally a very slow but steady acceptance.”*

Societies progress through this transition at different paces, and establish and change their policies accordingly. Countries and societies that are most influenced by religious concepts are slowest to adopt change. More recent ART technologies such as pre-implantation genetic diagnosis (PGD) have created great controversy, with fears of sex selection and designer babies provoking much debate over its use. This essay will present the arguments for and against sex selection and designer babies.

## SEX SELECTION

PGD allows prospective parents to select the sex of their child by screening embryos prior to transfer to the uterus and discarding those embryos which are not of the selected sex. This procedure is often carried out for sound medical reasons, for example to prevent transmission of sex-linked genetic disorders. Debilitating diseases such as haemophilia, thalassaemia and muscular dystrophy can be avoided, which is of obvious benefit to both parents and their offspring. The only argument against such a use of PGD is from pro-life supporters who are against the use of PGD and IVF altogether on moral grounds. Debates about eugenics can also arise from the use of PGD to avoid diseases, but such a use of PGD is ethically justified in terms of the principle of non-maleficence.

Sex selection for social reasons is much more controversial. The main reason for its use is for “family balancing” purposes. However, some claim that it could lead to sex discrimination, because male children tend to be preferred, especially as the first child. This would serve to reinforce social and economic inequalities, and further devalue women, especially in male dominated cultures. There are also concerns that if such selection were permitted, sex ratio imbalances would result from the preferential selection of male children. This would challenge the ethical principle of equality.

Because of societal preference for a male offspring in the Arab culture, some ART centers in Lebanon have marketed, promoted and practiced PGD and sex selection strictly for financial gains. They ignore the health risks to the woman undergoing super ovulation and oocyte recovery and disregard the recommendations of professional organizations worldwide on the matter.

Many organizations have issued statements concerning the ethics of health care provider participation in sex selection. The Ethics Committee of the American Society for Reproductive Medicine maintains that the use of preconception sex selection by PGD for non medical reasons is ethically problematic and “should be discouraged” [6]. However, it issued a statement in 2001 that if prefertilization techniques, particularly flow cytometry for sperm sorting were demonstrated to be safe and efficacious, these techniques would be ethically permissible for family balancing. Because PGD is physically more burdensome, and necessarily involves the destruction and discarding of embryos, it was not considered similarly permissible for family balancing. Whereas sperm sorting does not require creating and discarding embryos.

The Program of Action adopted by the UN International Conference on Population and Development opposed the use of sex selection techniques for any non medical reason. The UN urges governments of all nations *“to take necessary measures to prevent prenatal sex selection.”*

The International Federation of Gynecology and Obstetrics (FIGO), rejects sex selection when it is used as a tool for sex discrimination. It supports preconception sex selection when it is used to avoid sex-linked genetic disorders. The United Kingdom’s Human Fertilization and Embryology Authority Code of Practice states *“Centers may not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for non medical reasons.”* Likewise, the Committee on Ethics of the American College of Obstetrics and Gynecology issued in Feb. 2007 the following: *“The Committee on Ethics supports the practice of offering patients procedures for the purpose of preventing serious sex-linked genetic diseases.”* However, the Committee opposes meeting requests for sex selection for personal and family reasons, including family balancing, because of the concern that such requests may ultimately support sexist practices: *“It violates the norm of equality between the sexes and encourages discrimination and has the potential for*

*creating an imbalance in the sex ratio that may lead to or perpetuate the oppression of individuals of a certain sex.” [7]*

#### CONCLUSIONS

Some of the key ethical questions that have been raised in this paper and included in the draft law proposal for Lebanon:

1. Should single parents have equal access to ART?
2. Should homosexual parents have equal access to ART?
3. Should we have age-based discrimination against old users?
4. Should an assessment of the stability of the relationship of the parents be a precondition to determine the family the child will enter into?
5. Should users be compensated by MOH or National Social Security Fund (NSSF), or other insurers for costs to make access independent of income?
6. Should the donors of gametes be unknown or known before and after to the users?
7. Should the gametes be selected or not selected, e.g. race, sex, intelligence?
8. Should the donors be paid or unpaid?
9. How long gametes and embryos should be stored in

- banks and what happens to left over embryos?
10. How long should embryos be stored in freezing?
11. What is the fate of unused frozen embryos? Research, donation or wastage?
12. Should PGD be utilized for medical indication only?

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