Ethical issues arising from the use of assisted reproductive technologies

BERNARD M. DICKENS

Introduction

The purpose of this paper is to address ethical issues arising from four aspects of the employment of assisted reproductive technology (ART), namely:

- the principle of equity;
- the establishment and change of social policies;
- commercialization of human gametes and embryos; and
- conflicts of interest.

Issues will be considered in this sequence, but they are not entirely separate from each other. There is unavoidable overlap among them, and some topics may fit as well under the headings of two or more issues. Similarly, there is some overlap among issues addressed in this and the other background papers on ethical and social concerns in this publication. Accordingly, for the sake of convenient analysis, topics will be presented under headings and subheadings, but they are not to be considered as discrete from each other. Some discussions will relate to others in different sections of the paper, and in other papers. Further, the thrust of some discussions may appear to vary from and even contradict that of others. This is because ethical analysis does not necessarily lead to a self-determined conclusion; rather, it exposes considerations that require or warrant attention, balance and prioritization. Balance and prioritization may be achieved in different ways, depending upon the ethical orientations, principles and levels of analysis that are brought to bear. For instance, deontological or principle-based orientations may produce different outcomes from utilitarian or consequentialist orientations, ethical principles such as beneficence and justice may be ordered in different priorities, and interpersonal or microethics may justify different results from public or macroethics *(1)*.

Different conclusions can be of equal ethical merit, related to the different factors that contribute to undertaking ethical reflection. For instance, much consideration of ART involves gamete and embryo donation, but in the Islamic tradition, where conceiving children and raising them in religious faith are particularly important values, so too is the integrity of a family's genetic lineage *(2)*. Accordingly, in this context, gamete and embryo donation from outside a married couple is ethically unacceptable, but within a marriage artificial techniques may be employed to achieve pregnancy. In contrast, the Roman Catholic branch of Christianity limits acceptable human reproduction to natural intercourse between a married couple *(3)*, but may tolerate transfer of a donated ovum to an infertile woman's reproductive system for natural insemination there by her husband. Artificial conception may therefore be ethically available to a

Muslim but not an observant Roman Catholic couple, and ovum donation may be ethically available to a Roman Catholic but not an observant Muslim couple.

Within some religious faiths, ethical pluralism is rejected, and divergence from authoritative doctrine may be deemed heresy. The modern practice of ethics or bioethics is secular and pluralistic, however *(4)*, recognizing that ethical reasoning on the same issue can justify different conclusions. This is not to say that every option is acceptable, but that adherents of one preferred outcome may well acknowledge that adherents of an alternative preferred outcome are applying approaches that result in different ethical, but not unethical, conclusions.

The principle of equity

Equity and equality

Equity is distinguishable from equality, although the two often coincide. Equality requires the identical treatment of all despite their differences, whereas equity requires equally fair treatment of individuals taking account of ethically significant differences among them. The ethical principle of justice requires that like cases be treated alike (hence the legal preoccupation with precedents) and that different cases be treated in ways that acknowledge the differences, raising ethical concerns of likeness and difference. For instance, the private insurance industry in the USA has long treated men and women as equals in covering contraceptive services for neither. However, women bear the consequences of, particularly unplanned, pregnancy more directly and oppressively than men. The inequity of this equality became clear when insurance companies speedily extended their cover to include the new male potency drug Viagra *(5)*, moving some state legislatures to require coverage of contraception *(6)*.

An initial issue of equity and equality concerning ART is whether people with impaired fertility, including those who turn to ART because their natural reproduction would expose their children to unacceptable risks of harmful genetic inheritance, should be as free to reproduce as people of usual fertility. In many countries and cultures, particularly of the western world, the latter are not subject to legal prohibitions, requirements of marriage or, for instance, medical screening on genetic or other grounds, although they are subject to the regular law on their partners' capable consent and the prohibition of incest. The mature and responsible are not privileged over the immature and irresponsible, nor the wealthy over the poor or the healthy over the infected, but all rank equally as individuals able to exercise choice of reproductive behaviour according to their own preferences and instincts.

In contrast to the capacity of usually fertile individuals to undertake consensual reproductive behaviour in private, is the public attention and regulation to which reproductively impaired individuals are increasingly subject when they propose resort to ART. Particularly in developed countries where ART techniques have been pioneered, such as Australia and the UK, state and national commissions with distinguished memberships have proposed criteria by which ART may become restrictively available to reproductively impaired people. Proposals of many commissions have been enacted into laws or adopted as professional or clinical practices. These may limit access to ART to legally married or cohabiting heterosexual couples in relationships of specific duration, require or facilitate their scrutiny according to medical, genetic and perhaps psychological standards, or screen them by reference to other criteria such as age, personality and criminal or childcare history.

An ethical concern is the extent, if any, to which different approaches towards reproductively impaired and unimpaired people, established in law or practice, can be justified. An important human rights provision is nondiscrimination on grounds of physical and mental disability, according to which reproductively disabled people should be placed at no disadvantage in contrast to people of usual fertility. Another provision is to ensure due protection of children, however, which allows, for instance, lawful removal from their parents' care of children exposed to or at serious risk of abuse or neglect. This provision may afford an ethical justification of laws and practices that bar or scrutinize access to ART of people whose circumstances or histories furnish credible apprehension that, even unintentionally and despite their good will, any children for whose care they became responsible would be at risk of serious disadvantage or neglect. The ethical principle of respect for persons balances rights of autonomy against rights to protection of vulnerable persons, of whom young, dependent children are obvious examples.

The goal of serving the best interests of prospective children is sometimes invoked to justify limiting people's access to ART, even though the consequence

may be that the prospective children whose interests are claimed to be protected are never conceived. The inequality or inequity of controlling the reproduction of infertile people who are dependent on ART, when that of usually fertile people is not and perhaps cannot be controlled, is sometimes explained on pragmatic or utilitarian grounds, and by recognition that, in many countries, fertile people whose parenthood exposes their children to undue risks will be subject to child protective intervention that denies them childrearing opportunities. However, the children of fertile couples are not legally removable from their care on the ground only that public agencies believe that they can better serve the children's "best interests" by placing them elsewhere, and it appears inequitable to invoke a "best interests" criterion legally to deny ART to infertile couples when there is little risk of their future children being abused or neglected.

Disability and pathology

Impairment of fertility may be due to a pathological cause, but it is ethically contentious to describe people seeking access to ART generically as unhealthy or diseased people, or, indeed, apart from their impaired reproductive capacity, as disabled. Infertility itself is not a disease, and alone it does not impair medical health, although among those who want to have their own genetically related children it may impair their health in so far as the World Health Organization recognizes "health" as a state not only of physical well-being but also of mental and social well-being. On this basis, UN conferences have endorsed the definition that: "Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have … the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are the right of men and women to be informed and to have … the right of access to appropriate health-care services that will … provide couples with the best chance of having a healthy infant" *(7)*.

Infertility can deny mental or social well-being and be a cause of acute affliction and anguish, evidenced by the extent of physical and financial cost individuals are willing to bear for its relief. However, many countries that provide publicly funded health care for medically necessary services do not fund ART. They usually fund diagnostic services, and may fund drug and surgical treatments, such as of diseased fallopian tubes, that restore fertility, but not ART that does not reverse the medical condition of infertility but overcomes it by artificial means of conception.

The ethical and related human rights principle of nondiscrimination on grounds of disability raises the question of whether states should ethically do more than to permit those with the personal means to avail themselves of accessible ART services to do so; that is, whether ART should be allowed as luxury medicine, like, for instance, cosmetic surgery, available with minimum screening on social or moral grounds to those with the means of purchase, or whether the principle of equity requires some measure of public funding or subsidy of ART services, such as by taxation relief for its cost. States that provide publicly funded health care services to restore natural capacities, including reproductive capacities, may claim that they satisfy their duties of equity in treating all eligible recipients of state medical services alike, and that they have no further ethical responsibilities to those that ordinary care cannot assist. It may be that medical treatment of pathological conditions that cause infertility, such as premature menopause and fallopian tube blockage, discharges the duty of health care equity, and that there is no such duty to relieve remaining disability by provision of costly ART services. Nevertheless, limited access to ART services due to their high cost remains a major equity issue raising questions about reproductive rights of people with limited financial means.

Negative rights and positive rights

Considering impaired fertility as a reproductive disability raises the concern of the appropriate public or macroethical response to the rights of such disabled persons to equitable treatment. Rights are often contrasted by reference to negative and positive rights. Negative rights amount to rights to be left alone, whereas positive rights require that holders be provided, often by state agencies, with means to exercise such rights. Rights to luxury goods and services are usually considered only as negative rights. By analogy to transportation, governments may provide low-cost or subsidized public transit services by road and rail to take people to and from work and between major population centres, but not maintain rural transit networks, provide subsidized airline services, or provide motorized vehicles for private use. Similarly, they may provide routine, low-cost treatment for

pathological causes of infertility and limited higher-cost care for more resistant conditions, but not the more expensive forms of ART. They may explain this in terms of health care economy, and also by reference to cost-effectiveness considerations in the budgeting of public services.

The negative right to ART, meaning individuals' right to acquire access by their own resources, requires that state and other agencies forbear or restrain themselves, or be restrained by judicial or other lawful means, from undue intervention by their creation of barriers or obstacles to equitable access. Many of these barriers have been of a moral nature, prohibiting individuals from unfettered resort to both publicly funded and privately available ART services. Some initial reactions to novel means of conception have exhibited what has been described as "moral panic", meaning an unreasoning fear of subversion of the moral order. It was noted in 1991 that "While the past 40 years has seen the meltdown of the nuclear family and its surrounding myths and ideologies—in less than ten years half of all children born in the United Kingdom will be brought up outside the 'conventional' family—new demons, chimeras and spirits have been summoned to haunt the new families which technological and personal upheavals have introduced" *(8)*.

For instance, unmarried individuals, including single people and partners in same-sex relationships, have been barred from ART by laws or by institutional or professional rules or 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 speculative claims may be unsupported by empirical data, however, such as is available of the harms suffered by children that live in violent homes. Comparable claims that have denied rights to adoption of children are now yielding in many countries to recognition that children are as well reared in less conventional as in more conventional home environments. It is increasingly recognized that more than conservative orthodoxy and negative speculation based on generic bias are required to deny a right of privately funded access to ART.

Preconceptions about the unsuitability and ineligibility for access to ART of those affected by mental disorders may also require reconsideration on grounds of equity. Mental disorder of a severe nature, although not requiring institutionalization, may justify ineligibility for a childrearing role, whether children result from natural or medically assisted procreation, but many mental disorders are transient, of different levels of severity and amenable to treatment. It has been observed that "The stigma suffered by the mentally ill dates back to antiquity and has its origins in fear, lack of knowledge and ingrained moralistic views. Though erroneous, these associations remain pervasive.... At times, the unusual and even unfounded nature of psychiatric theories and the practitioners who uphold them has compounded the problem" *(9)*. Equity requires that particular applicants for ART be clinically assessed on their individual merits, and not be denied rights of access on grounds of impersonal, collective stigmatization and discrimination.

ART applicants' liability to exclusion on grounds of their physical health should similarly be clinically assessed. Their vulnerability to premature death or disability, leaving young children at risk of orphanage, destitution or neglect, may properly weigh negatively in the balance, but rights of access should not be denied on the basis of negative stereotyping. The *British Medical Journal* has recently observed, for instance, that in view of the prolonged life expectancy of people who are HIV-positive and receiving treatment now available, particularly in developed countries, there is no justification for denying infertility treatment to patients who bear the infection. It reported that "Judicious use of combination antiretroviral therapy during pregnancy and labour, delivery by caesarean section, and avoidance of breastfeeding are proved measures which have reduced the risk of vertical transmission to less than 2%" *(10)*. Exclusion of HIV-positive applicants from ART programmes may be explained not by their incapacities to be suitable parents, but by health care practitioners' inequitable reluctance to treat them as patients *(11)*.

Although potential donors of gametes and surplus embryos may be liable to comparable negative stigmatization, for instance when gay men are rejected as sperm donors, it is doubtful that they have an ethical or equitable right of donation. The question is sometimes posed of, whether human tissue donors, for instance, of blood for transfusion or creation of plasma products, have a general right or only a selective privilege of donation. Egalitarians tend to favour the former in light of the humiliation and loss of self-esteem those whose altruistic offers of donation are rejected may suffer. The right/ privilege distinction may be a false dichotomy, however, since

donation may be neither a right nor a privilege, but only a qualified opportunity; that is, an opportunity to offer to satisfy objectively, scientifically justified criteria of eligibility. For instance, a couple may be admitted to an ART programme as suitable, informed recipients of the service, but not be eligible on genetic or other grounds to donate their gametes or surplus embryos to others. They have no ethical rights of donation, but only the right to offer to donate (see the chapter on "Gamete and embryo donation" for details on the criteria of acceptability).

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 as a sperm donor, couples may claim a right of choice of donors who meet routine criteria, such as being HIV-negative. It has been reported regarding ovum donation, for instance, that "90 percent considered using a sister, 76 percent decided that a sister would be the preferred donor, 70 percent asked a sister to donate, and 60 percent found a sister to be willing" *(12)*. Ethicists and practitioners have raised the concern that family relationships may become blurred or confused by the use of such known donors *(13)*, 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. The New York State Task Force on Life and the Law recommended that: "When known egg donors are used, informed consent to donation should take place outside the presence of the recipient. Physicians should attempt to determine whether known donors are motivated by undue pressure or coercion; in such cases, the physician 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" *(14)*.

Establishing and changing social policies

Policy evolution

The ethical conduct of a "social policy" suggests pursuit of a principled, deliberative public programme of action designed to serve the interests of a given organized population or society, according to the science of politics or statecraft. However, the conception and birth of children has customarily been regarded as a private or family matter, regulated by the unpredictable chance of nature or as a divine mystery outside decisive human control. The principles of family law within a community reflect its most historical and customary or intuitive values, often embedded in religious beliefs regarding private intimacy, associated with the transition between generations of family traditions, identity and property.

The emergence of ART including gamete donation has confused the genetic cohesion and integrity of traditional family identity *(15)*, and initially triggered conservative responses. First reactions to what reproductive technology shows to have become possible are often more instinctive or visceral than intellectual, and policy responses have tended to focus more on defence against perceived dangers to traditional values than on achieving potentials for human satisfaction and cultural enrichment through new applications of biotechnology. This was observed with the early popularization of artificial insemination, when Kleegman and Kaufman noted in 1966 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 *(16)*.

Societies progress through this transition at different paces, and establish and change their policies accordingly. Those most influenced by religious concepts are in some ways slowest to progress. For instance, since the Roman Catholic Church adopted the concept of papal infallibility in 1870, its teachings cannot contradict earlier papal pronouncements made *ex cathedra*, and much of its scholarship is devoted to assertion of the authority of conclusions reached in earlier times. Doctrinal reassessment within the church is severely compromised, because it has to be shown consistent with existing authority. Social policies that reflect any variation from church doctrine, such as the doctrine that artificial or "unnatural" means of achieving human conception are illicit, are considered a scandal or heresy, and strongly opposed. Indeed, it has been explained that the modern emergence of secular, pluralistic western bioethics was strongly influenced by the Vatican's intransigence in 1968 on doctrinal

reform regarding artificial contraception *(17)*. In contrast, although Islamic prohibition of gamete and embryo donation is firm, the use of ART to overcome infertility within marriage is accepted, often welcome and even considered necessary *(18)*.

Different popular religious attitudes to relations between human beings and their perceived divine creator can influence policy responses to ART. In many Christian communities, for instance, it is considered offensive and a condemnation that one should assume to "play God" with human conception and birth, as an impertinent human arrogation of divine power and authority. Accordingly, social policy treats the practice of ART conservatively as bordering on impropriety, and detracting from or tampering with the awe and humility with which to face divine authority. In other religious traditions, however, such as Judaism, there is a perceived partnership between humans and their divine creator, so that individuals' "God-given gifts" of skill and initiative are properly employed in scientific advance and in the cure or overcoming of medical impairments, including by ART. In this tradition, the divine creator is described as acting in ways of beneficence, mercy and compassion, and "the human being is required to imitate God in this respect" *(19)*. Social policy in Israel, for instance, is strongly pro-natalist *(20)*, and encourages ART within marriage, provided that ovum donors to Jewish couples are Jewish, in accordance with the first direction given to Adam and Eve in the biblical *Book of Genesis*, chapter 1, verse 28, to "be fruitful and multiply, and fill the earth," reinforced perhaps by demographic and geopolitical incentives.

Problematic and constricting though religiously conditioned social policy may be, it has the ethical advantage over purely secular policy development of invoking profound and enduring principles. In contrast, secular policy-making is more pluralistic but may seem to defy the ethical principle of justice in producing quite different responses to the same circumstance, influenced by idiosyncratic values and priorities and introduced as a consequence of political power rather than of any transcending ethical principle or even conscious tolerance of ethical pluralism. When surrogate motherhood rose to public visibility, for instance, and women were recognized as potentially willing to gestate and surrender children to serve other families, diametrically opposed responses appeared. Some urged and enacted policies that prohibited any woman from undertaking surrogate gestation who had not previously delivered a child, on the principle that truly informed consent to gestation and childbirth could not be given by a woman lacking this experience. Others were fearful of the psychological harm a young child might suffer from recognizing that its mother is willing to give away her child to others, and urged that women with dependent children be prohibited from surrogate gestation *(21)*.

Policy (reform) commissions

Nevertheless, the advent of surrogate motherhood illustrated an ethically defensible process to establish social policy, to evaluate whether existing policy is dysfunctional or inadequate to address new technical possibilities, such as arise from ART, and to change it if necessary. From the late 1970s, many countries and states and provinces such as those of Australia, Canada and the USA, established governmental or other official enquiries into ART, to propose social policy responses to limit, accommodate and/or monitor effects of these new biotechnological capacities on human reproduction and the founding of genetically diverse families *(12,21–29)*. They tended to be composed of members of mixed social, academic, philosophical, religious and other backgrounds who were experienced in development of social policy. They received representations from community groups and individuals, solicited information and opinions they considered necessary or appropriate to fulfil their mandates, and consulted with specialists in technical areas and on social and ethical implications of policy options. They tended not explicitly to invoke the language or categories of ethical discussion, speaking instead of the social values and pragmatic considerations they considered significant, but their discussions and conclusions were amenable to ethical analysis.

The conclusions and array of recommendations that these commissions produced did not always win favour with ethical analysts, and were often greeted with dismay both by libertarians and by many who assessed them from conservative religious perspectives. This was because they tended to recommend acceptance of some practices, such as unpaid gamete and surplus embryo donations, prohibition of others, such as commercial transactions including surrogate motherhood agreements, and, for instance, setting of conditions and time limits by which preserved gametes and embryos had to be let perish.

The commissions contributed to ethical social policy development, in that they opened issues to

public debate, either through their own processes or through generation of public discussion of their conclusions, and sometimes both. They were respectful of those who made oral or written representations to them, although at that time organized religious institutions were better equipped to advance their views than bodies claiming to represent infertile people, they beneficially added to public understanding of the issues and response options raised by ART, and they attempted to justify their balancing of the competing principles and pragmatic considerations that conditioned their conclusions and recommendations. They had different levels of success in having their recommendations enacted in law, but tended to be well respected by medical and related professional associations whose members were practitioners of ART.

The ethical character of these commissions was based more on the transparency and integrity of their processes than on the substance of their conclusions and recommendations, many of which were contentious among ethical analysts and commentators. Many received information and opinions, and formed their own conclusions, before the present emphasis on evidence-based medicine arose. In light of this newer perspective, some of the information they were given and the scientific conclusions they reached might now appear questionable. Further, and perhaps more significantly, they made no approach to advance or consider founding the social policies they explicitly or implicitly adopted on empirical evidence. They almost invariably accepted as true, for instance, that children are better reared in legally married unions than in unmarried unions, and that heterosexual parenthood provides a superior rearing environment to stable same-sex unions. Many uncritically accepted conventional stereotypes of family life and functioning, without seeking or reviewing evidence, for instance, of the incidence and nature of marriage breakdown and family dysfunction within their societies, and the effects on children's well-being. This deficit in these studies raises ethical concerns about the adequacy of this method of establishing, changing or declining to reconsider social policy.

The burden of proof

Commissions of enquiry often include members from the legal profession or judiciary, sometimes as their leaders, and some indeed have been conducted within law reform commissions *(21,26)*. This may provide means to address, though not necessarily to resolve to uniform satisfaction, a key ethical issue of where the burden of proof lies to preserve or change prevailing social policies. The evidence and policy implications arising from individuals' access to ART services and from operation of ART programmes are rarely unequivocably favourable or unfavourable. It is uncertain, for instance, whether treatment that results in an infertile couple having a new family of two or three prematurely born children that suffer respiratory and/or neurological impairments is to be considered successful or unsuccessful, or whether treatment that provides an infertile couple with one or two healthy children following a multiple pregnancy that was "selectively reduced" by ending the lives *in utero* of several embryos or fetuses is to be celebrated or deplored. When a country's social policy is unaccommodating of equivocal new technology, the ethical question is whether potential users can claim an ethical right to policy change to accommodate it, so that opponents have to make the case to preserve the status quo, or whether the burden lies on supporters of the new technology to make the case for policy change. Similarly, when a government proposes a new law to restrict access to a newly developed service, the question is whether the government has to make an ethical case *(30)*, or whether the ethical burden of resistance is on political opponents; the policy is not ethical simply because a government can implement it in law.

When the need for, or desirability of, policy reform is equivocal, and there is as much to be said against policy change as for, and vice versa, the question of whether supporters or opponents of policy change bear the burden of making their case is decisive. Neither case may be made persuasively, and the side bearing the burden will fail to discharge it. Conservative or risk-averse forces will claim that a long-standing and adequate social policy should be changed only when advocates of innovation present a convincing argument in favour, and those of a reformist or socially experimental disposition will claim that prima facie evidence of advantage from innovation should be sufficient to propel policy reform, and that those resistant to reform bear the burden of establishing the case against it. In contrast, however, when a new practice appears to threaten conventional values, such as surrogate motherhood or human cloning, conservative forces want to speed restrictive provisions, and reformists urge caution and time for balanced reflection against precipitate prohibitions *(31)*.

Both conservative and reformist preferences may be based on ethical principles, and often on variants or counterpoints to the same principles. The principle of beneficence may support reform to accommodate the advantages attributable to a new technology, but the duty to do no harm, nonmaleficence, may support its rejection. Supporters of reform may claim that denying a policy that would accommodate the new technology does harm to those it may benefit, and that reform is required by the principle of justice, since the new but excluded practice is like one already accommodated. However, opponents may identify a feature or consequence of the new practice that renders it distinguishable. For instance, advocates of cloning by embryo-splitting may claim that it only simulates natural or spontaneous identical twinning, and so should be allowed, while opponents may claim that it accommodates multiplication by successive twinning of an embryo twinned *in vitro* and, unlike natural twinning, allows identical twins to be gestated and born years apart. A social policy compromise may be to limit induced twinning to a single occasion, and require concurrent implantation of successfully divided embryos. Ethics may provide no self-evident or clear outcome on the merits of a particular case, but provide protagonists of different outcomes with the language and concepts of their advocacy.

Commercialization of gametes/embryos

Ethical arguments against commercialization

Ethical arguments against commercialization include reference to dangers of exploitation of vulnerable people, such as those who are impoverished, and to the more abstract concept of human dignity *(32)*. A principal argument against allowing human gametes and embryos to be the subject of commercial or profit-earning exchange stems from the ethical principle of respect for persons, which is sometimes considered analogous to the concept of human dignity as applied in Europe. Neither gametes nor embryos are persons, but both may be considered potential persons and what philosophers describe as "the argument from potential" *(33)* requires that they be treated with the respect and dignity due to the persons they have the potential to become. Since abolition of slavery, the concept advanced by the German secular philosopher Immanuel Kant (1724–1804) has prevailed, that people, and by implication potential people, should not be treated as objects, nor only as means to ends. As ends in themselves, individuals have inherent worth and value, not simply the instrumental or utilitarian value ascribed to objects, which are valued only for what can be done with them. Accordingly, it is inconsistent with their inherent worth that human gametes and embryos should become the subject of commercial value, barter and trade.

This ethical reasoning is supported from a variety of extraneous perspectives. A religious view, adopted by the Roman Catholic Church in 1869, displacing earlier concepts of ensoulment that determined when the soul enters the body, is that human life begins at conception or fertilization *(34)*. This view requires that an embryo be afforded the same respect and protection as a born person, although the application of this view to sperm and ova appears more difficult to establish *(35)*. A view from philosophy and political science is that some interests, objects and functions, such as motherhood, should not be amenable to market transactions because of the damage that would result to human values, community and dignity. Margaret Radin, for example, condemns paid surrogate motherhood as devaluing women in general, mothers in particular, and children universally by making them "completely monetizable and fungible objects of exchange", meaning that any one may be replaced by any other and has no individual value in itself, so leading to "an inferior conception of human flourishing" *(36)*.

The ethical argument against commercialization of gametes and embryos is not simply the pragmatic harm this may do to the spirit and practice of altruism. Nor is it the inducement payment affords sellers to conceal and misrepresent reasons why the material they propose to sell may be tainted and harmful to recipients, advanced in a modern classic text opposing paid donation of blood for transfusion *(37)*, and indirectly advocating the moral and practical superiority of (UK) socialized medicine over (USA) market-directed health care. Rather, the argument is that commercialization through commodification damages important ethical values in that it raises functional utility over inherent human worth, invites competitive bidding for superior over inferior products, in the case of gametes and embryos, perhaps because of offensive distinctions in genetic pedigree and racial or ethnic properties, and imposes a monetary tariff on all means by which children are conceived and born. That is, a man's loving act by which his wife conceives their child becomes reduced to his transfer of sperm of a given

market value, and her gestation becomes a service, even when unpaid, that is known to be commercially marketable at an employment rate per month or lesser period.

This impoverishes the quality of human and family life, because it devalues and impersonalizes a profound act of personal commitment and dedication. The social fracture in relationships is comparable to that done by a guest invited to a friend's home for dinner who strips the invitation of its personal character by equating enjoyment of the company and the meal to a restaurant service, and expresses appreciation by placing the assessed money value on the table in cash. A more obvious analogy may be in equating reproduction to prostitution. This description is now often redeemed or mitigated, acknowledging the vulnerability and oppression that direct young persons into this occupation, by being termed "commercial sex work", but its original description implies shameful and immoral debasement, or sacrifice of self-respect for financial gain.

This analogy contributes to another pragmatic reason to oppose commerce in human gametes and embryos; that it would be liable to be exploitive of those vulnerable through poverty who have no other means of earning. Gamete selling is more oppressive of women than is sperm selling of men, since ova recovery, perhaps following superovulation induced by hormonal or other drug treatment, would be considerably more physically invasive and uncomfortable or risk-laden. Similarly, experience shows that infertile couples may be induced to trade a number of their cryopreserved embryos created *in vitro* in exchange for a further treatment cycle, when they cannot afford its financial costs. This payment in kind, in exchange for services rendered, would not be asked or invited of couples that request further treatment on a regular fee-for-service basis.

Ethical arguments allowing commercialization

Few arguments urge commerce or trafficking in human gametes or embryos as positively desirable in itself *(38,39)*, and some who find payments defensible recognize that there is something unsavoury in individuals selling their gametes *(40)*. However, many find that exchange for value may be tolerable, and analogous to practices societies have already accepted. Invoking the ethical principle of justice, that like cases be treated alike, they equate giving and receiving commercial rewards for rendering the service of donation with other payments for products and services that are reputable and tolerated in materialistic and capitalistic or market-based economies. They find contradiction and even hypocrisy in social tolerance and sometimes admiration of some forms of commerce in the overcoming of infertility that accompanies condemnation of giving and receiving commercial rewards for supply of the gametes and embryos that may make treatment possible. For instance, medical practitioners earn professional fees or salaries for their services *(41)*, infertility clinics organize diagnosis and treatment on a for-profit basis, particularly since publicly-funded health services tend not to cover ART services adequately or at all, in some countries sperm banks provide samples for payment, laboratories charge for testing gametes, genetic and other counsellors earn livelihoods by their availability and, for instance, drug companies and equipment manufacturers sell their products for care of infertile patients. The demand or expectation that only those who supply their own sperm, ova or embryos for the same purpose should be altruistic, appears unjust.

Even where the admonition of Richard Titmuss against commercial purchase of blood for transfusion *(37)* is taken seriously, laws often allow payment for whole blood or plasma donation, as an exception from their general prohibition of commerce in human tissues, on pragmatic grounds. The social need for an adequate supply of transfusible blood and blood products overwhelms objections of principle to commercial transactions. The physical dangers to which people are exposed from infertility are less than those posed by loss of blood and by anaemia, but where the claims of infertile patients to have children are respected, commercial incentives to donation, where necessary, may be ethically tolerable. Accordingly, the UK Human Fertilisation and Embryology Authority (HFEA) has suspended its plan to prohibit payment to sperm and ova donors of a modest fee and reasonable expenses *(42)*. Allowance may serve the ethical goal of beneficence, and the burden may fall on those who argue that, on the contrary, commercialization violates the ethic of nonmaleficence, that is the ethic to do no harm, to make their case persuasively. In utilitarian terms, they must show that the harm of society enduring relievable childlessness, and imposing it on those who seek to have children, is less than the harms that would arise from commercial transactions in human gametes and embryos.

The case that would-be sellers might suppress information that would expose their genetic material

and embryos as unsuitable for use is considerably weakened where modern means of genetic diagnosis are available, since they make reliance on the proposed seller's disclosure of personal and family history less necessary. More persuasive may be the claim that payment would induce poor people to undertake what people of means refrain from doing, that is, to make their genetic material and embryos available to strangers. The special emotional burden of donation of extra embryos created in infertility treatment is that the gamete donors may remain childless, while knowing or suspecting that a strange couple have borne and are rearing their child. The risk that impoverished people will become liable to exploitation arises from many sources. These include experience in tissue donation, for instance, when four poor Turkish workers were paid to fly to a London hospital for removal of kidneys for transplantation into wealthy recipients, in documentation of eye and kidney sales in the Republic of Korea under recession *(43)*, and in surrogate motherhood transactions when there are significant wealth differences between commissioning couples and gestational mothers, raising concerns about "how such practices might further oppress poor and disadvantaged women" *(44)*.

Against this, however, it is argued that in order to sustain prohibitions of apparently exploitive practices on ethical grounds, "we need better reasons than our own feelings of disgust" *(45)*. "Protecting" willing, intellectually competent vendors of their gametes and embryos against "exploitation" may disrespectfully deny them their ethical claim to autonomy, and hold them within a paternalistic confine that is itself an oppressive exercise of power over less powerful members of society. They may consider such a sale to be the best option open to them, so that their position is worsened when the option is removed.

The argument that poor people cannot exercise intelligent choice, such as the choice of a healthy, fertile woman to donate ova or of a healthy, athletic man to undertake professional high-risk contact sport such as boxing, is patronizing and insulting. The argument that their choice is not freely made because of the pressure of poverty scarcely provides an ethical justification for further denying their choice. The claim that their choice may not be adequately informed, for instance, because they have not been able to consider or gain access to feasible options, provides a basis for affording them additional, realistic information or opportunities rather than denying them the choice of acting on the information they possess. The objection that ovum sales may involve women in medically unnecessary, invasive and risk-bearing treatments has substance, but the procedures are the same for commercial as for altruistic donors, and although the latter may be willing so to serve only for family members and friends rather than for strangers, the exchange of money does not itself affect the nature of the procedures, and should not affect the care offered by those who counsel or conduct them.

The objection that commercialization of donation unfairly attracts poor people to serve as vendors, and unfairly privileges rich people as purchasers, may be factually correct. However, this does not distinguish gamete and embryo sales from the attraction poor people may feel to sell their labour in low-paying, unpleasant or above-average risk employment, or from the capacity of rich people to purchase superior consumer products and services, including private health care. Where legal prohibitions exclude the capacity of affluent people to purchase the products and services they desire in their jurisdictions of residence, they are allowed to seek them elsewhere, including as "reproductive tourists". In any event, the unjust privileges available to people of means do not provide ethical grounds to deny poor people the opportunity to obtain benefits as they perceive them.

An ethical middle ground regulation

Even where gametes themselves cannot legally be sold or purchased, donors often receive payments that may not be unlawful. Prohibition of commercial commodification of gametes has not prevented payments from being made to donors, not for their genetic material itself but for the service of making it available. That is, they receive payment not in a commodity transaction but under a service transaction. Men are not paid, for instance, for the genetic properties or volume of their ejaculate, but for the service of offering its availability. In principle, they should receive the scheduled payment even if their sperm are found on analysis to be unsuitable for use in reproduction due, for instance, to a genetic deficiency or viral infection. In the same way that health care professionals are ethically entitled to charge conscionable fees for their services, gamete and embryo donors may claim that it is not unlawful or unethical that they should receive payments that are proportionate to their inconvenience in donation. For instance, in the UK, the Human Organ Transplants Act 1989 provides in section 1 *(1)* that a person commits an offence if (s)he "makes or

receives any payment for the supply of, or for an offer to supply, an organ", but section 1 *(3)* states that "payment" means "payment in money or money's worth but does not include any payment for defraying or reimbursing … (b) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying an organ from his body" *(46)*. Organs cannot be traded, but those supplying them can recover the reasonable costs of that service. Ethical concern that it is inconsistent to allow payment for the service of donation but not for the donated product may be addressed, in part, by recognition that service costs are more measurable in equitable market terms, and less open to the charge of people turning their bodies into "things".

Rates for the supply of gametes and embryos could be independently set or approved under regulations of an appropriate public or publicly accountable agency. This would unlink buying from selling, preclude private barter, and prevent wealthier patients from outbidding less wealthy applicants for infertility treatment. Payments could be made by an independent agency rather than by, for instance, a for-profit clinic, and donations be allocated among clinics according to an equitable formula. This would address an ethical objection to commodification of gametes and embryos, namely, that it unfairly privileges the wealthy through their superior means of purchase.

Both banning commerce in gametes and embryos and permitting their availability according to market principles are ethically problematic. Bans risk exclusion of legitimate benefits, and injustice in light of what else societies permit to be traded, and free operation of market forces risks indignity and indefensible exploitation. In principle, markets may be believed to solve problems of inadequate and surplus supply and, for instance, of quality control, but these concepts seem inappropriate and offensive to common sentiment where human reproduction is concerned. Even in the USA, where supply of health services is widely believed best undertaken through private agencies, there are legal prohibitions of commerce in organs, children and, for instance, surrogate motherhood services *(47)*. The logical virtues of market discipline are subordinated to moral repugnance *(48)*. Nevertheless, the ethics committee of the American Society for Reproductive Medicine has recommended limiting payment to the last few years' "marketplace norm" of US$ 5000 per completed cycle for donated ova *(49)*.

Between the ethical hazards of a prohibited market and an entirely free market is the ethical preference of a regulated market. This is shown in the UK, where the HFEA monitors ART developments, licenses ART centres according to their capacities of equipment and personnel, enforces a Code of Practice, gathers relevant data and informs the public in general and prospective users of services in particular of where they may receive treatment and how successfully particular treatments, and treatment centres, work. The HFEA monitors research initiatives, storage and disposal of embryos, and compliance with legal requirements. The Authority also determines which payments are acceptable and which are not, deciding in 1998, for instance, that it is tolerable for a patient's *in vitro* fertilization (IVF) treatment to be subsidized in return for the donation of some of her ova *(50)*.

The HFEA's observance of the law has also cast illumination on "reproductive tourism". This is often discredited by association with sex tourism, the condemned practice of people, overwhelmingly men, going to usually poor foreign countries to have sexual encounters with local residents that are unlawful in their own countries, such as with legal minors. In 1997, the English Court of Appeal ruled that the HFEA correctly applied legislation of 1990 in denying a widow permission to be inseminated with sperm recovered without his consent from her comatose dying husband *(51)*. The Court noted, however, that the widow was entitled to seek lawful services in countries of the European Community that were unlawful in the UK, and she subsequently was successfully inseminated in Belgium. Accordingly, so-called reproductive tourism need not be regarded only as a devious way to avoid the restrictions of national laws, but may be an ethical means to achieve personal reproductive goals compatibly with the different standards of one's own country and of another where services are lawfully available. Instead of using the pejorative description of "reproductive tourism", with its implications of flawed morality or leisure-time triviality, it may pay ethical respect to those who seek to have children to employ a description such as resort to "transnational services".

Conflicts of interest

Conflict in reality or in appearance

In ethics as in law, conflicts of interest clearly arise when those who induce others to depend on their

integrity and good faith place their own interests above those of such dependants. Accountability for conflict of interest goes far beyond this, however, because it also arises when those in whom others are encouraged to trust are in a position to favour their own interests, whether or not they actually succumb to the temptation of self-interest. Practitioners in health care professions, on whose specialized knowledge and training lay people must necessarily depend for the services they feel they need, are almost invariably enmeshed in multiple functions and commitments that require an exercise of choice among options, some of which might appear more favourable to themselves than others, and some of which might appear less favourable to the interests of patients to whom they have conscientious duties. Conflict of interest arises not just from the actual prioritization of self-interest, but also from an appearance that self-interest might be indulged at the cost of a reliant patient. For many reproductive health care practitioners, in publicly funded facilities as well as in private, for-profit centres, conflict of interest created by the appearance of conflict of interest, is inescapable.

Conflict is more obvious in some cases, of course, than in others. Professional fee-splitting is considered conflictual because it risks dissipation of the practitioner's allegiance to the patient *(52)*. Practitioners who are also owners or financial shareholders in for-profit clinics, who advise clinic patients to take more costly or prolonged treatments than appear indicated, are vulnerable to the suspicion of conflict. So equally, however, are practitioners on fixed salaries in publicly funded services, who advise patients whose care would be costly of material resources and/or care-givers' time that their prospects of successful treatment are poor, and that they should reconcile themselves to clinical failure and perhaps pursue an alternative such as adoption. When practitioners serving fee-paying patients with the same medical characteristics advise them that further treatment is worthwhile because it may succeed, it may appear that the former practitioners are unethically serving goals of institutional economy, contrary to their patients' interests, that the latter practitioners are unethically profiteering or serving futile extravagance, at their patients' cost, or both.

Practitioners therefore need not be employed in for-profit clinics to fall under suspicion of being in a conflict of interest. Private clinics that genuinely can present themselves as non-profit institutions, for instance, may pay staff members, who may also be proprietors, inflated salaries, and function to cover their costs, which are boosted by paying such salaries. Although these clinics may accordingly be non-profit, they may be sources of considerable personal enrichment to their practitioners.

Conflicts may appear in the options and advice that practitioners offer patients on preservation and disposal of their gametes and embryos. If clinics make profits from storage, or storage fees contribute to pay the costs of storage facilities, clinic personnel may have an apparent interest to recommend or offer preservation, reinforced by the incentive this may give donors to remain in treatment programmes. It has been reported, for instance, that a facility in New York charges $ 500 for three months' storage of embryos *(53)*. As against this, however, patients' compliance with requests or recommendations that patients should make surplus ova and/or embryos available for donation to other patients, may provide clinics with access to scarce materials through which treatments can be offered to additional patients, and with incentives to super-ovulate women patients in ways that may be contrary to their health interests and reproductive options. The HFEA in the UK accepted transfer of ova for fees or as part-payment in kind for infertility treatment late in 1998 *(50)*, and has now allowed similar donation of embryos *(42)*. Practitioners' interests in preserving and employing patients' gametes and embryos in these ways are not necessarily contrary to patients' interests, but opportunities for clinics' and practitioners' own advantage exist from which conflict may appear.

The definition of infertility and genetic risk

Particular difficulty arises from different, legitimate definitions of what constitutes infertility, and from what outcomes of natural reproduction present prospective children with genetic risks. In Canada, for instance, the Royal Commission on New Reproductive Technologies, following the practice of the World Health Organization, conservatively defined infertility as a failure to conceive following 24 months of normally frequent unprotected sexual intercourse *(29)*, whereas clinics often admit applicants on the basis of 12 months' failure. Clearly, more couples are infertile by a 12-month test than by a 24-month test. This raises the concern of whether clinics are being aggressively entrepreneurial and self-serving in admitting applicants of normal fertility or slight subfertility, claiming

credit for pregnancies during the following 12 months that occurred or would have occurred naturally, or even applying procedures that obstruct pregnancies that would have happened without their interventions.

Clinics may justify a 12-month test, however, on rational and compassionate grounds. Their clients, or patients, tend not to be young, newly married couples, but couples in which the female partners are approaching, at or a little beyond so-described advanced maternal age, meaning about 35 years of age or above. They may be in second or later marriages, perhaps having had children in earlier relationships but wanting to have families in their new marriages. When women's capacity to achieve pregnancy is in natural decline, clinics are reluctant to require that they wait a further year or more to become eligible for treatment. Further, with a rising risk of abnormality in a later-conceived child, particularly Down syndrome, delay in access to ART may be clinically contraindicated. Accordingly, clinics' apparent haste in admitting applicants to treatment on an assessment of their infertility may not be clinically suspect or unethical.

Assessments of genetic or dysgenic risks to future children that may induce couples to forgo natural reproduction and turn to gamete or embryo donation, or to IVF with their own gametes and preimplantation genetic diagnosis (PGD), may become more refined with advances in genetic understanding. However, questions are likely to remain of calculations of genetic risk, how prospective children's predispositions or susceptibilities to illness or injury due to genetic inheritance are explained to prospective parents, and what inherited conditions or abnormalities render a child's nonexistence preferable to its existence, in its own interests, those of its prospective parents or those of others such as existing children of the family. A background concern is the qualification a practitioner or counsellor has to undertake genetic counselling of ill-informed and perhaps apprehensive applicants for ART. Considerable room exists, by choice of language, emphasis, nuance, contrast or analogy, which may be deliberate or unconscious, to control or influence patients' decisions. Eugenic and aesthetic themes may infiltrate discussions, on practitioners' or counsellors' initiatives. Their preferences for children of particular stature, appearance and propensity can distort prospective parents' exercise of the choices that, ethically, they should be informed and empowered to make. Practitioners and genetic counsellors must show that they can be relied upon to be self-conscious of their own values and biases, and to exercise the self-restraint to suppress any tendencies to impose their own preferences that may be in conflict with those of their patients.

Resolution of conflicts of interest

In an idealized clinical setting for ART, conflicts of interest would be avoided. Although real settings are frequently far from ideal, the ethical principles of beneficence, nonmaleficence and perhaps justice compel practitioners' efforts to minimize the incidence and extent of conflicts. For instance, clinicians should not ask their patients to volunteer to be subjects of research studies of which they are the principal investigators, lest they unethically abuse their patients' dependency on them for their own interests *(54)*. Similarly, clinicians should not accept or be required to be gatekeepers of departmental or other collective resources on which treatment of their individual patients must draw, lest they may favour their patients to the disadvantage of colleagues' patients, or violate their ethical duty of allegiance by sacrificing their patients' interests to a perception of departmental, institutional or other extraneous priorities. As departmental or institutional gatekeepers, they are unethically compromised in discharge of duties owed to individual patients who rely on their disinterested judgment, clinical integrity and capacity for supportive advocacy of their interests. In many legal systems, these ethical responsibilities to patients are reinforced by the law.

Because conflicts of interest consist in appearance as well as reality, they are frequently inescapable. They may then be ethically resolved by due disclosure. Disclosures should be to those at risk of suffering disadvantage from a conflicted exercise of choice, or at least to a superior officer whose duty is to ensure ethical management of conflicts, and that those that consist in appearance do not evolve to consist in reality too; that is, that an apparent conflict is confined to the superficial level of mere appearance. In the doctor–patient setting, the doctor's conflict should in principle be disclosed to the patient. For instance, doctors with financial interests in the profits of drug companies whose products they are inclined to prescribe, or for instance, in clinical laboratories to which they propose to refer their patients for the testing of their biological samples, should so inform the patients, and provide them with alternative drug or laboratory options in which they are disinterested.

Physicians' interests in these regards are not necessarily unethical. They may be based on a genuine conviction that these companies or laboratories provide superior products and services or, for instance, on the conviction that, as interest-holders, the physicians can ensure maintenance or improvement of their products or standards. If these convictions are sincerely held, indeed, it may be unethical for a physician to seek to avoid the appearance of conflict of interest by prescribing inferior products or referring patients to inferior services; disclosure may be the ethical ideal for patients' informed choice.

It has been seen that a conflict arises when a person who wants therapeutic care from a clinician is asked by that clinician, or by a colleague on his or her behalf, to consider entering a study that the clinician is proposing to conduct. The proposal requires that the person be clearly informed that treatment under the study is not intended primarily as therapy, and that, if the study design includes randomization between an unproven intervention and a placebo, it may include no proven medical treatment at all. Disclosure to the person seeking care is ethically necessary, but not sufficient, because those asking physicians for care often accept the so-called "therapeutic fallacy" that the medical treatment they are offered in research studies is intended for their personal well-being. Accordingly, proposed investigators must also submit their study designs, including details of how subjects are to be recruited and informed, to independent ethics review committees. These committees will address how adequately prospective subjects are informed that the studies are primarily intended to advance scientific knowledge rather than their personal therapy, and how capable such subjects are to decline involvement in studies and instead to obtain the therapy they seek.

A modern classic of unethically resolved conflict of interest arose in the much-discussed legal case of *Moore versus Regents of the University of California (55)*. A patient whose cells were found to have unusually valuable genetic properties was asked to provide additional tissues so that investigators, presenting themselves only as his therapists, could patent and trade in a cell line they biotechnologically developed from them. The Supreme Court of California dismissed his claims based on his property interest in his cells or the cell-line, but allowed it to proceed for his lack of informed consent and the investigators' breach of the fiduciary duty they owed him. This is the way courts may reinforce the ethical duty of more powerful parties not to benefit themselves at the cost of those they induce to depend on their superior knowledge *(56)*.

A particular conflict that may affect ART clinics is how they report and advertise their treatment outcome data. Independent monitoring systems, such as in Sweden, may provide the public with reliable data. Similarly, governmental agencies in, for instance, the UK and USA, require clinics to submit annual reports of their practices, including numbers of patients and conditions treated, procedures undertaken and results. The Centers for Disease Control and Prevention (CDC) in the USA *(57)*, and the HFEA in the UK *(58,59)* publish quite detailed aggregated annual data reports, and include warning that the data do not allow reliable comparisons among clinics, for instance, because they will have treated different types of patients with different severities of reproductive disorders. Nevertheless, the news media have at times publicized the data in the form of a table that ranks clinics in order of their performance, or, as the CDC report is entitled, their "success rates".

The conflict of interest, arising at both micro-ethical and macroethical levels, is that clinics can influence their success rates by the choice of patients they accept and how they treat them. They can achieve higher success rates by accepting only patients below certain age levels, who are more subfertile than infertile, and whose conditions afford greatest prospects of successful treatment. Clinics that, as a matter of social justice and commitment, or of research interest to advance care, accept patients who have less promise of success and who are more difficult to treat, are liable to appear lower in rankings of success. Clinics operated for profit, that promote their services by commercial advertisement, have an incentive to boost their competitive status by screening out applicants with poorer prospects of reproductive success, and admitting those of borderline infertility. Clinic success rates may be achieved at a loss of social equity in access to services.

A more immediate ethical concern is whether clinics recommend more traditional infertility treatments before recourse to ART, even when their use might compromise later ART, or whether ART will be first recommended when more traditional, less expensive procedures might succeed. Recommended care should be based on practitioners' clinical judgement directed to each patient's conscientiously assessed best interests. An incentive to achieve a clinic's financial success or an impressive publishable

success rate may present a practitioner with an unethical conflict of interest. Disclosure of the profit-seeking status and preferred practice of clinics to regulatory authorities, and indirectly or directly to prospective patients, may afford such patients desperate for reproductive success only limited means to exercise independent choice. Professional ethics and self-regulation have a significant role in monitoring the integrity of clinical practice and guarding the public and prospective patients against unethical practice.

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