

Evidence-based ethics and the regulation of reproduction*

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Getting pregnant and having children has rarely been a wholly personal matter. The institutions of society—from the elders of the village, through the churches, to elected governments (and the interest groups that lobby them today)—have always had much to say on the subject of who can get married, how they should behave sexually, and what they are free or not free to do with their pregnancies and offspring. Over the last several hundred years, these institutions (themselves evolving) have had to come to terms with at least four revolutionary changes in the technicalities of human reproduction and their social consequences (Jansen, 1997): the predictable survival of children into adulthood; the re-invention of divorce; the development of efficient contraception and safe pregnancy termination; and, lately, effective (if still expensive) treatment of infertility.

In this article I examine how governments, commissions of inquiry and statutory authorities are continuing to set moral standards for the community on reproductive behaviour when conception is assisted medically. Using illustrations from fiction and from recently developed national rules in several countries for the practice of modern reproductive medicine, I make a case for governments and their agencies to ascertain outcomes of harm or good done to determine ethics-based policy and to use time clauses to require review of morality-based restrictive laws and regulations.

'Peace, order and good government power' and 'community, identity and stability'

'The Supreme Court has decided that the peace, order, and good government power can be invoked in support of federal legislative action. We are firmly of the belief that new reproductive technologies, as defined in our mandate, meet [these] criteria established by the Supreme Court, so that federal intervention ... is constitutionally justified.' (Royal Commission, 1993, p. 19)

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'More than any other aspect of health-related technology or service, the research and application of new reproductive technologies have significance beyond the individuals directly involved.' (Royal Commission, 1993, p. 19)

'Given rapidly expanding knowledge and rapid dissemination of technologies, immediate intervention and concerted leadership are required at the national level (Royal Commission, 1993, p. 19) ... citizens in provinces with insufficient regulation may suffer harm.' (Royal Commission, 1993, p. 21)

'The Royal Commission on New Reproductive Technologies recommends that the federal government establish an independent National Reproductive Technologies Commission charged with the primary responsibility of ensuring that new reproductive technologies are developed and applied in the national public interest.' (Royal Commission, 1993, p. 112)

Royal Commission on New Reproductive Technologies, Ottawa, November 1993

'A squat grey building of only thirty-four stories. Over the main entrance the words, CENTRAL LONDON HATCHERY AND CONDITIONING CENTRE, and, in a shield, the World State's motto, COMMUNITY, IDENTITY, STABILITY.' (Huxley, 1946, p. 1) *Aldous Huxley, Brave New World, first edition 1932 (from which, 'test-tube baby')*

'The people who govern the Brave New World ... are not madmen, and their aim is not anarchy but social stability.' (Huxley, 1946, p. x).

Aldous Huxley, in a new foreword to Brave New World, 1946

'There was old sex in the room.' (Atwood, 1987, p. 13)

'We still had our bodies. That was our fantasy.' (Atwood, 1987, p. 14)

'In the days of anarchy it was freedom to. Now you are being given freedom from.' (Atwood, 1987, p. 34)

Margaret Atwood, The Handmaid's Tale (on the Republic of Gilead, set in the near future)

Differences and similarities

The Canadian *National Reproductive Technologies Commission* (proposed in 1993 and now proceeding to legislation) (Kondro, 1996) shares with the world government of Aldous Huxley's *Brave New World* (published in 1932) a particular emphasis—for the Canadians it is explicitly their *raison d'être*—on reproductive technology. Specifically it is in-vitro fertilization (IVF) that is the target of the Canadian Government's attention and it is for the concept of 'test-tube babies' that (at least in this context) Huxley is best remembered. The government of Gilead in Canadian author Margaret Atwood's *The Handmaid's Tale* (published in 1986) does without IVF, invoking reproductive technology only to react against it and

to justify the state's turning to a sort of neo-Old Testament dependence on classic, but enforced, sexual intercourse. In the book, nuclear war has wreaked havoc with sperm counts and precipitated totalitarian political upheaval in this North American republic; the conservative revulsion against artificial procreation has led to the recruiting of young women to be surrogate mothers, impregnation of whom is at conventional coitus, delivered by patriarchs well-connected in more ways than one.

It is the fictional accounts here, the two novels, that extend to the whole reproducing population what Canada's Royal Commissioners on New Reproductive Technologies want for infertile people. The commissioners claim that, unlike in other areas of medicine, the application of technology to reproductive medicine is unique—distinct from non-technological help—and that this is reason enough to separate off for special state intrusion those people who require medical technology to conceive. Specifically, the commissioners have proposed that the powers of the National Reproductive Technologies Commission will include:

- (1) deciding who shall be eligible for artificial insemination (recommendation 83, Royal Commission, 1993) and other reproductive services (r.131) (but note that being without a male partner is not to be considered as necessarily detrimental to receiving reproductive technology to become pregnant [rr.94,99,121,145] and nor are the wishes of sperm donors to be taken into account in deciding who can receive their sperm [rr.87,92]);
- (2) determining who will be licensed to practise reproductive medicine that involves technology (and a doctor who decides to exclude a single woman from receiving reproductive medicine on grounds that contravene Canada's bill of rights will presumably lead to the revoking of his or her—or their clinic's—licence [rr.86,103,159]);
- (3) determining which reproductive technology shall be appropriate to exactly what clinical condition (rr.126,129,135) (excluding all clinical applications that have not been proven valid by a randomized, controlled clinical trial [r.124]—a stipulation inconsistent with the Helsinki Declaration of 1975, of which more below); and
- (4) legislating against provision of reproductive services outside the national system [r.154 and Royal Commission (1993, pp. 21, 27)] (a second, private tier of IVF services is acknowledged to be available to Canadians—but for how long?—across Canada's border in the laissez-faire United States).

The similarities in these three social settings are, however, as striking as they are simple. In each there is a central, regulated approach to human reproduction that above all else eschews social disorder. There is a monopoly of supply: other technology or sourcing of the technology is not to be tolerated in these three societies. There is a monopoly of consumer or purchasing power—a monopsony. Not just is the price paid to doctors for their reproductive services set by the respective governments; non-approved women or couples are not eligible for these services whether they pay for them themselves or not. Most importantly, in each of the three scenes, members of society are dissuaded by threat of substantial punishment

from seeking a path to reproduction outside the government system (Jansen, 1994).

Government and personal professional relationships ...

The three printed works brought to example in this article each shun two important professional distinctions. The first distinction to be lost is that between medical infertility and the social state of childlessness. Whereas all infertility means childlessness, not all childless states constitute infertility. Society's agents, including physicians, are compelled either to consider these circumstances equally important in the production of children (in the case of the Canadian Royal Commission) or equally compulsory to mangle (the two novels put an end to natural procreation)—but in each case to disregard the personal needs and suffering of couples or the personal discretion of the physician, however experienced the physician might be. (This is part of an apparent move in Canada—a move ahead of other Western countries—to define both the profession of medicine and to prescribe the detailed practice of doctors in both the public and the private sector.)

The second distinction to be lost is that between medically aided reproduction (in a personal, private sense) and 'for-the-public-good' reproduction; in other words, private needs, whatever the personal suffering behind them (Cassell, 1991), are subordinated to an imagined public good. In a personal professional relationship between reproductive physician and infertile patient can have no meaning that has not been foreseen and embraced by regulations developed by the particular Canadian commissioners and their successors (who might or might not consult widely, but who generally will make up their own minds); however, special a personal set of circumstances might be that if it is not approved in advance it will not be available to Canadians unless they travel abroad. Perhaps predicting the need to free Canada's citizens from this expensive temptation—referred to critically as 'reproductive tourism'—the commissioners want 'harmonization of national regulations' (Royal Commission, 1993, pp. 21, 27), so a stop can be put to international as well as national ethical and regulatory experimentation. I make the case later in this article that it is this premature setting in stone of ethical and regulatory truth that, far from being the solution, is a serious problem that has got in the way of employing experience in the development of best ethical and regulatory practice.

The national health system in Canada effectively considers total population spending on health to be a publically financed zero-sum game (Royal Commission, 1993, pp. 78–82). Doctors are either in the system (no private practice) or out of it (private practice only—an onerous existence few can manage). The commissioners wanted private practice in reproductive medicine to be banned, so that there is no private expenditure on it (r.154) that might push control of it out of their reach. [The curious justification is a notion that medicine for profit (Jansen, 1986) somehow cannot be professional: that it is commercial and bad (Royal Commission, 1993, pp. 707, 716–718). William Osler, the celebrated physician from Canada who distinguished himself early this century both in academic and private medical practice (Fye, 1989), must be turning in his grave. It is not payment that turns a medical service into

a commodity; a service, like a manufactured product, becomes a commodity if it can take only one form—which is exactly what Canada seems bent on.] What role is this for government? We have the nonsense that discretionary spending by citizens on effective, scientifically based, private reproductive medical practice is illegal, whereas their spending on non-evidence-based hypnotism, herbalism, acupuncture, astrology and so on can continue without government taboo.

In each of the three works, a government agency takes away the freedom *to* reproduce and replaces it with a freedom *from* being burdened by having to make a complicated personal decision. Atwood has much to say on the difference between the two kinds of freedom in her book. Governments generally—and public servants and intellectual leaders individually—ought to be criticized publically when they attempt to portray a restriction on an individual's liberty to be to that individual's gain, when what is a closing of an aspect of society is painted as if society were being opened up. By embracing an illiberal approach to the application of reproductive technology in their country, the six Canadian commissioners have acted in a paternalistic manner, patronizing the people of brave new Canada.

... *the Helsinki Declaration* ...

'In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.'

Section II of the Declaration of Helsinki, 1964, revised 1975 [Medical Research Combined with Professional Care (Clinical Research)]

The foundation of most Western countries' ethical practice of medicine is generally, and often explicitly, the World Medical Association's Declaration of Helsinki (World Medical Association, 1997). The report by Canada's royal commissioners on reproductive technology, in contrast to, for example, an Australian report (National Health and Medical Research Council, 1983), does not base its moral position on the Helsinki Declaration, and in some respects the Declaration is implicitly contradicted. Recommendations 130 to 136 of the Report would punish ('an offence subject to prosecution' [r.130]) the use of IVF by a doctor for 'any indication other than complete tubal obstruction' (r.135) outside the context of a multicentred trial on effectiveness (rr.132,136), funding for which would be recommended to provincial/territorial ministries of health as having 'highest priority' (r.136) (in Canada the disbursement of funds for health is a provincial not national responsibility—and such funds are notoriously tight). Whatever a physician might think, whatever his or her professional training and experience might have been in Canada or abroad, he or she will be compelled by legislation and regulation to treat a woman with blocked Fallopian tubes and no male partner, and will be prevented from treating a married couple with, say, 10 years' infertility resulting from oligozoospermia and endometriosis (r.145), irrespective of the nature and the depth of the suffering of one patient compared with the other. There is no room for medical discretion in the matter.

The Report emphasizes that no reproductive technology or

manoeuvre is to be made available that has not been subjected to a properly controlled clinical trial. On the face of it this is a good principle (the Helsinki Declaration supports the use of clinical trials), but it does put a layer of bureaucracy between doctor and patient, the costs for which must be squeezed from cash-strapped provincial health budgets rather than from what would be a second tier of discretionary expenditure should private reproductive medical practice be permitted (r.154); it also pushes the medically regressive notion that there are disease states to be treated, rather than suffering people to be helped (Cassell, 1991).

... *and a type 2 error in evidence-based medicine*

In the field of statistics, a 'type 1 error' is the incorrect rejection of the null hypothesis: accepting an experimentally obtained difference as real when there is a reasonable possibility that the difference could have occurred because of chance alone. A 'type 2 error' is the incorrect non-rejection of the null hypothesis: regarding an experimentally obtained difference as insubstantial on the grounds that a statistically significant difference has not been reached. Type 2 errors are likely when the observations have been too few to have had the power to show with reasonable probability what would have been the minimum difference in outcomes to be regarded as important when the study was designed.

Evidence-based medicine is the use of medical treatments for indications for which there is compelling evidence of efficacy, meaning (at least to its more explicit advocates—see Grahame-Smith, 1996; Wagner, 1996) that there has been a statistically significant positive result from a properly conducted prospective randomized controlled clinical trial. Its newly popular reputation in medical practice is aimed at stopping the making of what might by analogy be called a type 1 error in evidence-based medicine: the use of medical treatment based on an unverified, thus possibly incorrect, assumption that the treatment works.

On the other hand, by stopping the use of IVF as part of the medical treatment of infertility for all reasons other than blocked Fallopian tubes—on the grounds that its use for any other indication is unproven (Royal Commission, 1993, pp. 517–522)—the Canadian commissioners and others (e.g. Wagner, 1966) are committing what we might call a type 2 error in evidence-based medicine. They draw the conclusion that several other likely indications (e.g. oligozoospermia) are not to be accepted into clinical practice because such prospective trials as have been published showing benefit (compared with continuing to attempt pregnancy naturally) have not reached a statistically significant level of difference. (The trials do show a difference—and the difference would be of a clinically important magnitude if it had been shown with greater certainty not to be a chance finding—but the trials were not designed to define such a difference.)

Let us leave aside the calculation that the monthly probability of pregnancy in a population with 5 years infertility due to oligozoospermia theoretically cannot be higher than ~3% (Jansen, 1993, 1995; Leridon and Spira, 1984). Leave aside how strange it is to ignore the empirical data—generated a decade ago in Canada—that the actual monthly probability of

conception among couples with mixed male-factor, endometriosis-related or unexplained infertility of more than >3 years infertility has been shown to average <2% (Collins *et al.*, 1983, 1984). Leave aside the abundant data that the chance of becoming pregnant after gamete intraFallopian transfer under the age of 40 is well over 30% per treatment-month (Craft *et al.*, 1988; Yovich *et al.*, 1988; Jansen *et al.*, 1990).

At this point there are two good reasons to pause in systematically invoking evidence-based medicine so narrowly. They lie, first, with the general danger of committing such type 2 errors, were Canada's commissioners to set the example they seem to intend. Second, they lie with how discrepant such a habit would be with the proper role of government in regulating the practice of medicine as defined by the nations of the West in 1975.

Government and moral autonomy

'Only a large scale movement toward decentralization and self-help can arrest the present tendency toward statism. Unless we choose to decentralize and to use applied science ... the social chaos resulting from rapid technological progress under the need for efficiency and stability (will develop) into the welfare-tyranny of Utopia.'

Aldous Huxley, in a new foreword to Brave New World, 1946

Embryo research

A gulf still separates those of our society's citizens who regard research on fertilized eggs to be, in principle, a moral thing to do and those (rather fewer) citizens who regard research on pre-embryos as fundamentally immoral (Annas *et al.*, 1996). The latter define human life, with all its needs for protection, as starting with fertilization. A study of the leverage exerted by minority fundamental moral viewpoints on central government power in plural societies is instructive, especially by those moral positions that are not almost universal.

'Thou shalt not kill (people)' is an example of a moral position that requires no evidence-based ethics for its force and universality throughout society. We all agree that this is an intuitive moral principle for which no explanation or justification is needed. Some might say it is 'hard-wired' into our cerebral circuitry. But for most people, 'Thou shall not kill fertilized eggs', does not mean the same thing. Among the world's formal religions, only the Roman Catholic Church officially promotes equivalence between the rights of a fertilized egg and the rights of a formed human being (Walton, 1990), and even among its members the Catholic Church's uncompromising stance on the matter is seriously and thoughtfully questioned (McCormick, 1989).

The quandary faced by societies as to whether or not to carry out research upon fertilized eggs (loosely called 'embryos') is an example of how hopeless it is to seek consensus or compromise on such matters of personal morality or immorality. Even in a modern plural society this type of deadlock rests on faith. For as long as there has been IVF in Britain, for example, the production of embryos that will not be transferred to a uterus in receptive circumstances has been morally unacceptable to Cardinal Basil Hume, Archbishop of

Westminster and a Roman Catholic (Walton, 1990); on the other hand John Habgood, the Archbishop of York, and some other moral theologians of the Church of England (Dunstan, 1986) believe that humanness develops not instantly but in a sequence, albeit a rapid one, over the first weeks of pregnancy—which results in a moral position that accords increasing duties to the protection of these stages, but which allows both IVF and infertility-related research on human embryos created in special circumstances for this purpose without equating it to homicide or infanticide.

For a secular government to take one side in such a moral debate—and to push one (generally conservative) moral view upon the other side in the absence of overwhelming support—risks gratuitously oppressing an important part of society. The British parliament admirably resisted such pressure in permitting embryo research in the United Kingdom. However, research on fertilized eggs is banned in Germany (Tuffs, 1990), Austria (Goldbeck-Wood, 1996), Norway (Goldbeck-Wood, 1996), France (Lansac, 1996) and now Canada (Kondro, 1996)—and might soon be banned in Italy (Biggin, 1996). With one exception there has been no evidence to bring to bear on this particular moral debate that advantages one or other position. The exception—and it is an important observation regarding outcome of which everyone should be more aware—is that the people who work in IVF laboratories are not brutalized by their encounter with it: in my experience their respect for human life and human values is expanded by their IVF experience, not diminished.

The undesirable way of attempting to deal with such personal moral conundrums is to impose, from a politically privileged position, one view at the expense of the other. The desirable way is to leave practical decisions that hinge on these moral conundrums to the people most directly affected by them. Such personal moral questions can and should be debated publically, but surely the decision itself ought to be a private matter, made by those who will carry with them the direct consequences of their actions—in this case the infertile couple whose eggs and sperm produced the embryos. Aldous Huxley, quoted above, would have called it an area of applied science for moral approval or disapproval—an area of ethics that is best taken out of the hands of governments and devolved to 'local communities'.

Huxley lived before the information revolution made the village global, and before local communities became family units hooked up to the Internet, but his fears for the community in a technological age are timeless. It is important to remember that Huxley had no problem with technology: it was not the test-tubes or the babies in them that was the problem. Huxley wrote *Brave New World* to personify the hazards of bureaucratic control over private matters in a technological age. His problem was what we see today in Canada and the UK—the way social, personal decisions are taken out of the hands of the people who are most affected by the decisions and placed with the authorities on the excuse that technology is involved. Any discretion that local communities (or ethics committees) might have lies in one direction only: to tighten, ratchet-like, the restrictions, not to loosen them.

Gender selection

Another question that arouses public passions in reproductive medicine today, and upon which a questionably general moral imperative has supplanted observation or experiment for ethical resolution, is whether couples should be allowed to try to influence the sex of their next child. *The Economist* (the liberal but hardly radical London weekly newspaper) opines: 'People are generally free to choose how to bring up their children. If they want to choose their child's sex as well, why not?' (Anonymous, 1993). But the decision, in Britain at least, has this year been pre-empted by the country's embryo regulators, The Human Fertilisation and Embryo Authority (HFEA; what would this body's title have prompted from Aldous Huxley?). The Authority has decided, 'no.' An analysis of this judgement is important.

Couples intending to influence the sex of their next child might try to do so in various ways. Most presently available manoeuvres—such as a rooster on the end of the bed during a full moon (well, 'available' with a bit of planning)—probably don't work. The one method of separating sperm cells that has been shown by molecular DNA studies to meaningfully influence the proportion of X- and Y-chromosome-bearing spermatozoa in a sample is an expensive fluorochrome-determined cell-sorting technique patented by the US Department of Agriculture and licensed for humans to a Fairfax, Virginia, clinic (Johnson *et al.*, 1993). In Britain, as a result of the HFEA taking a moral decision centrally, this particular technique may be used by licensed clinics only for 'medical indications'—which is generally interpreted as meaning the intention to decrease the chance of male offspring in families affected by X-linked inherited diseases such as haemophilia, muscular dystrophy and Tay-Sachs disease, in contrast with the presumably non-medical intention of wanting a child of the opposite sex for the good of a particular family.

Leave aside the practical issues a particular clinic in Britain might face in having enough patients referred with genetic indications to justify investing in the cell-sorting equipment, technical knowledge and, presumably, licence fees needed to offer this genetic service. The critical point (and a point on which the Authority ought substantially to justify itself) is that the British are still at liberty to spend their money on ineffective sex selection methods—whether they be laboratory-based, astrological, or whatever. Why pick out responsible, competent professionals for sanction and, ultimately, threaten them with disgrace, a fine or imprisonment when they are responding to what some of their patients are asking for? How can it be imagined that somehow patients who undergo sex selection abroad—or the children who result—should be discriminated against upon return to Britain?

Meanwhile, the HFEA seems to have lost sight of a side-benefit of fluorochrome-stained, DNA-content-based sperm sorting that might soon make this particular procedure indispensable for all IVF programmes engaged in the treatment of male infertility. This benefit consists of its ability to filter out sperm with any hypohaploidy, hyperhaploidy, diploidy or polyploidy that gives a DNA mass not exactly that of either 46,XY or 46,XX. [Such chromosome abnormalities affect 10%

of sperm cells from normal men (Pellestor *et al.*, 1996) and, probably, a greater proportion in some cases of male infertility.] In other words, the HFEA's decision stands in the way of a promising technical development that would make sure that eggs *in vitro* are fertilized only by chromosomally normal sperm—a position from which it is almost certainly going to have to retreat. To add further interest, the cell sorting equipment for carrying out such sperm filtering will have to be set either for X-bearing sperm or for Y-bearing sperm—they cannot be set for both at once. Who will make that decision? Will the authority insist that two sorting runs be made in every case—one for each sex—and then compel the tipping of the two lots of sperm together? Is policing such practices really what anyone wants government authorities to do? Modifying sperm cell sorting for less mature sperm or spermatids and selecting for X-bearing male gametes will also enable families with genetically-based male infertility to have just daughters, if they so choose, thus fulfilling at once (and responsibly) their desire for children while not perpetuating a genetic disability carried by males. (I predict that sooner or later we will at least see an administrative backdown in the form of permitting an X-based sort for any significant degree of oligozoospermia.)

Sex selection for personal, family reasons has now been criminalized in Canada (Kondro, 1996) as well as in Britain. But where is the evidence that it is harmful to families or to society? An argument for stopping parents selecting the sex of a child for their own reasons has been made by some feminists, who have claimed that boys might systematically be preferred at the expense of girls (e.g. Corea, 1986; Rowland, 1992). Let us overlook the free-marketers' retort that 'if women became rarer they would become more valuable' (Anonymous, 1990). The fact is that sex selection clinics already exist in Britain and other Western countries to test this hypothesis. Whether the albumin column-based methods used at these clinics work or not is immaterial here. The information we have from the clinics is that more couples visit them trying for a girl after a series of boys than for the reverse (Liu and Rose, 1996). Faced with such evidence, feminists whose concern is based on the supposition that boys will be favoured over girls must rethink their proposition (if not their objection).

The likelihood is that a few years' experience with the probably-rare (Statham *et al.*, 1993) families who might be prepared now to buy the service of effective sex selection for their children will furnish the data to answer the question of who, if anyone, suffers from the exercise of such a personal option. The gathering of such data and its presentation and discussion in scientific forums would hardly be novel. Coverage of the issues by innumerable magazines, television programmes and talk-back radio programmes will no doubt ensure less formal evaluation as well. In these ways we can get to know how sex selection actually affects the families concerned (including the circumstance where the wanted sex is not obtained) long before the technique becomes cheap enough to be widely available. But in the meantime Britain and Canada have taken sex selection for non-strictly-medical reasons out of the hands of the doctors, nurses and counsellors who are most likely to exercise family gender balancing effectively

and responsibly. Britain and Canada have done so not just in the absence of evidence of harm, they have acted in a virtual absence of public debate and without even a polling of opinion. As in France (Butler, 1996), the mere existence of bioethics consultative committees in a quick position to advise government means that ethical questions are prone to be hijacked, to the detriment of debate and determination of facts.

Government and evidence-based ethics

For people who wish to be objective whenever it is feasible to be so, the logic of examining the validity of ethical considerations on the basis of evidence, experience and cautious ethical experiment should be attractive both in theory and in practice. The ethical hypothesis that is involved—that sex selection, more often than expected, leads to some index of family dysfunction—ought in principle to be as testable as any hypothesis generated in medicine. It is a hypothesis to be tested. It is not a self-evident moral truth. It is not even a truth that can be reached by a poll of opinion after public debate.

In Canada it is ironic that the vigorous evidence-based approach being insisted on for medical services is absent from the social restrictions on reproductive medicine proposed by the Report of the Royal Commission on the New Reproductive Technologies and which are now being enacted. For example, a woman will be prohibited (i) from voluntarily donating her eggs or zygotes to another woman she knows (rr.167,172), (ii) from voluntarily undergoing an egg retrieval procedure for her sister or best friend (rr.166,174), and (iii) from making use of her remaining frozen embryos should her husband die before she considers her family complete (rr.171,180) (though she can, instead, then qualify for new embryos produced from anonymously donated semen) (rr.121,141,145). There is no empirical or experience-based evidence to support these prohibitions. Nor is the gathering of relevant data proposed. There is not a hint of recognition that different communities within Canada's society might have different values. There will be no trials carried out on the social, personal assumptions in which outcomes of good or harm done would be ascertained among the women concerned. They are simply to become law: law based on what the commissioners believe at this moment to be these women's true interests (Royal Commission, 1993, p. 1020)—or if not their own true interest then the Commissioners' idea of the national interest (Royal Commission, 1993, pp. 63–65).

In Britain, the HFEA (constrained, it says, by the law) unsympathetically forced Mrs Diane Blood to the high court and a technical loophole to gain access to her dying husband's sperm (Edwards and Beard, 1997). The possibly admirable but ultimately abstract principle invoked—that no written consent had been obtained from Mr Blood (he was by then unconscious) was so important to the HFEA that the needs and plans of the few people to be affected by Mrs Blood's action were forcefully and publically extinguished. The HFEA dismissed as irrelevant the evidence that he married to have children, that there was no indication from those close to him that his wishes might have been otherwise, and that general experience has revealed that most people faced with death are anxious to procreate (Jansen, 1985). In a more general action

in 1996, the HFEA also threatened clinics with loss of license to practise reproductive medicine if they did not obey a directive that embryos stored for 5 years be destroyed, even though evidence was becoming available that many couples responsible for the embryos would not consider such destruction to be in anyone's best interest. The HFEA's continuing and defiant justification of these two actions (Deech, 1997) illustrates how little the members of the HFEA are prepared to use evidence on ethical matters in individual situations. Thoughtful observers have concluded that the Authority relinquished two important opportunities to respond to individual and evidence-based needs among citizens and exert leverage on government to come to its collective senses (Black, 1996).

We should be explicit about what is happening in Britain, in Canada and in other countries where ethical decisions affecting individuals' reproductive behaviour are taken by a small group of people and given the imprimatur of government on the excuse of guessed-at harm. The enforcement of ethical principles developed this way—resting on nothing firmer than a philosophical construction—is analogous in medical practice to the ancient Greeks deducing from hypothetical premises and logic alone how the body works and how to fix it when it is diseased. Beware also of a manoeuvre that falls short of constructing moral danger in the abstract: I refer to the polling of the public's opinion on moral and ethical matters as justification for regulation and legislation. The enforcement of ethical rules after polling people's moral opinions when those opinions are based on faith and intuition and not on direct experience is analogous in medical practice to sanctioning medical procedures favourably on the grounds of popularity rather than evidence (which, we know, is just the fallacy evidence-based medicine sets out to avoid).

A libertarian society is not a laissez-faire one

An open society, in the mould of Karl Popper, is a society that allows or enables the greatest number of individuals to reach their fullest potential—a society, to paraphrase Atwood (1987), that creates the greatest number of 'freedoms to' and the fewest 'freedoms from'. Such a liberal, open society is not fostered by the extreme opposite to government intervention, namely the predominantly commercial, competitive approach often thought to be typified by the United States today. I argue elsewhere that the US-style laissez-faire approach to commercial 'third party reproduction'—the purchase of anonymously donated sperm, eggs, embryos and gestating uteri (in the case of commercial surrogacy contracts)—carries serious risks for an open society (Jansen, 1997). Today we see a conservative and paternalistic reaction to US practices in Canada. In the US itself, a moral backlash to reproductive technology has not yet been averted: a morals-based suspension of federal funding for research into human IVF has been in place since 1980 (Annas *et al.*, 1996) and has recently been renewed (Wadman, 1997a).

The harms that might come from commerce in human reproductive tissues need to be systematically explored and defined, and precedents developed for such evidence then to alter clinical practice. For evidence-based ethics to work—in defining the safe limits of third party reproduction, as in other

areas of reproductive medicine—it is important for us to ensure that ethical questions and hypotheses are stated explicitly. If they cannot be explicit then it is likely that we are dealing not with true consequences of harm or good done but with matters of faith. (Faith-based considerations are important within groups of multireligious communities but they are irrelevant between groups in a plural society unless shared extremely widely.) It is important to recognize when untestable, faith-based considerations are rephrased in a consequential manner, as in ‘this is unethical because it would cause God to be displeased’, or ‘this is unethical because I find it offensive’.

A practical limit for morally cautious legislation

Gestational surrogacy among friends and relations for altruistic reasons (as opposed, possibly, to non-related, commercial surrogacy) is an example of an area in which experience is showing that ethical damage is uncommon. Yet this is an area into which many governments have rushed to enact prohibitory legislation, justified by concern about the imagined harmful effects altruistic surrogacy is meant to have on society, and curtailing freedoms and reasonable aspirations among citizens that risk bitterness, resentment and diminished respect for authority. In theory such restrictions buy time for a conservative society to study an issue and to research the potential for harm before permitting a medically-based social innovation to be established in the community. This can be warranted if, as in evidence-based medicine, the experience of others—preferably with use of the new techniques in controlled circumstances—is being awaited. In the case of gestational surrogacy the experience in more liberal societies has been that there are personal situations where each party to the surrogacy arrangement gains. In practice, however, the prohibitions enacted by conservative governments will, if other experience with legislation associated with IVF is any guide, be depressingly difficult to reverse.

A more responsive yet still cautious regulatory option to consider in such cases first favours those who oppose change but then confers on them the burden of proving the need for a continuing prohibition. ‘Sunset clauses’ can be attached to legislation that force regulations to become inoperative at a specified future time unless there has been explicit review of the regulations’ effects. Such time clauses are beginning to be found in some countries among regulations that affect, for example, the conduct of commerce and business, as well as exemptions granted to anti-discrimination legislation. Contentious legislation restricting the application of reproductive knowledge and practices, debated with heat in an absence of data, is well suited for such an administrative caveat.

I know of no countries that have added sunset clauses to prohibitions involving reproductive medicine and the application of reproductive technology. Indeed few if any governments have purposefully taken an evidence-based approach to social legislation involving reproduction. On the contrary, we see from the kind of freedom-restricting legislation and regulation that has been all too prevalent (Statham *et al.*, 1993) the confidence with which centrally positioned moral authorities typically and quickly assume that they are uniquely perceptive and correct (Edwards and Beard, 1997). They act in a preemp-

tory way that would have disturbed Aldous Huxley. They are acting in a way that ought to disturb all of us.

Conclusion

Infertile couples—those who are poised to benefit from what we might call ‘the fourth reproductive revolution’ (Jansen, 1997)—deserve the fruits of evidence-based medicine free of type 1 and type 2 methodological errors. When they make their personal decisions on what treatment to attempt in forming their families, infertile couples also deserve to benefit from ethical principles established from evidence—from knowledge of advantageous and disadvantageous outcomes that have been observed in controlled circumstances.

When concern for public order leads governments to suspend or to prohibit forms of medical care for which a demand is demonstrable in the community (in this case reproductive assistance), our societies should insist on time clauses to the regulations and legislation that suspend those activities. Such sunset provisions will encourage the gathering of evidence, by the authorities or pressure groups behind the regulations and laws, that the proposed harm they are protecting us all from is both real and general before we are locked in by legislation that (for as long as it directly affects only a minority of a country’s citizens) can prove impractical to overturn.

For governments to do other than this will perpetrate wasteful expenditure of public money on reproductive regulation and legislation, the point of which is in doubt; it will perpetrate needless friction within the community between those affected and those unaffected by the reproductive disability of infertility; and it will perpetrate further suffering among infertile people, who already feel isolated and who will feel doubly trapped. As Huxley would have wished, knowledgeable decisions on reproducing and having children, whether technology is involved or not, can and should be made by the people and the families immediately affected by such decisions. And that’s a long way from a central government committee or authority.

Note added at proof

In the USA, President Clinton has attached a 5 year sunset clause to a bill banning anyone in the public or private sector from using somatic cell nuclear transfer (‘cloning’) to create children (Wadman, 1997b). The admirable aim of having the legislation expire in 5 years is to force a review at that time. Conservative Republicans, however, have complained that the President’s bill is ‘morally inadequate’ and are seeking a permanent ban (Wadman, 1997c).

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