
BIOETHICS OUTLOOK

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New Ethical Guidelines for Reproductive Technology

Gerald Gleeson

In this issue

We begin with Gerald Gleeson's assessment of the NHMRC's Draft Ethical Guidelines on the use of reproductive technologies in clinical practice and research. Dr Gleeson asks readers to begin by thinking about what they would hope to find in such guidelines. He argues that what is lacking is any principled account of the proper use of such technologies in relation to the creation of human beings.

We then present an interview with John Quilter of the School of Philosophy at Australian Catholic University which was published in the *Catholic Weekly*: in it, Mr. Quilter indicates something of the character of the teaching of philosophical ethics in the University's Master of Arts in Applied Ethics (Health Care).

Finally, Bernadette Tobin sets out her view of some current preoccupations - both strengths and weaknesses - in the field of enquiry known as 'bioethics'.

The NHMRC has just issued, for a one-month period of public consultation, Draft *Ethical guidelines on the use of reproductive technology in clinical practice and research*. The guidelines have been prepared by the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC. They will impact on all clinical and research activity in Australia that involves human embryos and gametes, and will have legal force as part of "the new legislative framework to regulate research involving excess assisted reproductive technology embryos" under the *Commonwealth Research Involving Human Embryos Act 2002*. Given their importance, the brief consultation period being allowed is clearly inadequate.

Matters of principle

Before I comment on what is actually contained in these guidelines, I invite readers to stop for a moment, and to ask themselves what they would hope to find in such a document. My own answer to this question is that I would hope that *ethical* guidelines for the use of reproductive technologies would first clarify the "proper" or ethically appropriate use of technology in relation to the creation of new human beings. To this

end, two issues in particular would need to be addressed: the *context* for the use of reproductive technologies (should they be confined to married couples?), and the *role* of technology in relation to *human* reproduction (should technology merely assist, or may it replace, the human-sexual acts by which human life has until recently been transmitted?).

In Australian society as a whole there is little agreement on these two fundamental issues. On the one hand, as many readers will know, Catholic moral teaching affirms the use of reproductive technologies only when they assist sexual intercourse between husband and wife (see *Code of Ethics for Catholic Health and Aged Care Services in Australia*, Part II, 2.7-2.14). On the other hand, many people accept that reproductive technologies such as IVF should not be limited to husbands and wives, though how widely available they should be is disputed. Moreover, it is likely that few people agree with the Catholic teaching that reproductive technologies, even in the case of married couples, should only assist, rather than replace, intercourse. Finally, there is widespread support for research that involves human embryos, though less agreement about just what kind of research is ethically justified.

Given the lack of ethical consensus in our society, it is instructive to examine the way AHEC presents its new *Guidelines*. Although they lack the kind of explicit and controlling ethical principle found in Catholic moral teaching, it is possible to discern the implicit ethical framework employed in the *Guidelines*. First, there is a general "consideration" – "a respect for human life at all stages of development" (p. 2). (One wonders: how much respect is "a respect"? Indeed, given that these guidelines go on to permit the destruction of human embryos for research purposes, it seems dishonest to claim that this is one of the ethical bases of the document.) Then there are some "unacceptable practices", such as creating a human clone (3.1), "creating a human embryo for a purpose other than achieving a pregnancy in woman" (3.4), and creating a hybrid embryo

(3.9). Next there are some constraints on the clinical uses of reproductive technologies for "people who wish to make use of" them (5.1). For instance, there is the significant requirement that the procedures should "limit the number of eggs collected, consistent with the health and likely treatment needs of the participants, and limit, as far as possible, the number of embryos created to those likely to be needed by the participants in the course of their treatment" (5.5). Finally, there are ethical constraints on the use of gametes and embryos which, because they are no longer needed by their (original) donors/participants, are available either for reproductive use by others, or for research purposes.

The strategy in these *Guidelines* – faced with the diversity of ethical beliefs in our society – is thus to endorse what are thought to be prevailing "community views" that some things, such as cloning, are unacceptable (at present), that other things, such as IVF for those who are single or unmarried, and destructive experimentation on "spare" embryos, are more or less acceptable (at present), and then to introduce some ethical constraints, e.g. concerning information giving, counselling, consent, data keeping and so on, in order to rein in some of the more "unacceptable" ways of using reproductive technology in those contexts in which it is legally permitted.

Before looking at these constraints in more detail, I want first to ask how consistent the *Guidelines* are with respect to their own framework and strategy. The short answer is, "not very consistent". The fundamental problem is that if it really is "unacceptable" to create a human embryo for a purpose other than achieving a pregnancy in a woman (3.4) and if the creation of embryos is limited to the number "likely to be needed by the participants" (5.5), then the availability of "spare embryos" should be quite exceptional (e.g. due to the sudden death of a participant). If that is true, then the practice of donating gametes and embryos, and/or of using embryos in research, should also be quite exceptional – casting doubt on the business

case for many ART clinics and research projects. Yet the *Guidelines* assume that gamete and embryo donation, and embryo experimentation, are and will remain thriving enterprises – which is why they need ethical regulation! This assumption is only plausible on the further assumption that, in practice, participants generally wish for as many eggs as possible to be retrieved and fertilized, and clinicians take an expansive view of the number of embryos they “need” to create for treatment purposes, with the result that there will always be plenty of “excess” embryos.

Particular Regulations

The absence of a clear ethical principle about the proper use of reproductive technology has a number of consequences. First, the *Guidelines* are unable to explain *why* the practices deemed “unacceptable” are unacceptable, even if most of us agree they are. At first sight, of course, the list of unacceptable practices seems admirable. On closer inspection, there may be a significant loophole in relation to human cloning. What is deemed “unacceptable” is “creating a human embryo clone” (3.1), and “human embryo clone” is defined as “a genetic copy of another living or dead human”, unless created by the fertilisation of an ovum by a sperm (p. 48). The focus of this definition is the *outcome* of a procedure but, curiously, there is no definition of the cloning *procedure* itself. What if a scientist were to claim that all he or she is doing is “passing a somatic cell nucleus through a denucleated ovum in order to obtain embryonic stem cells” without ever creating a human embryo clone? Would a procedure thus (albeit tendentiously) described be acceptable under these guidelines?

Secondly, the guidelines for the most part can only focus on *process* and *procedure*: on the giving of information to potential participants, e.g. about the success rates achieved by a clinic (6.2.1), on the role of counselling, on how informed consent is obtained – noting the need for separate consents to storage of gametes and to subsequent donation of gametes (6.14), on

record keeping – noting that staff must be able “to trace what happens to an individual embryo, egg or sperm sample from the date of collection” (7.4), and so on. Among these items are some notable ethical advances for which AHEC is to be congratulated:

- Donors of sperm or ova must consent to the release of identifying information about themselves because persons conceived using reproductive procedures are entitled to know their genetic parents and genetic siblings (10.4).
- Although the guidelines assume that surrogacy arrangements will occur, they insist that clinics should not facilitate such arrangements in the absence of State or Territory law that provides certainty about a child’s legal status and parentage (5.4).

The effect of this guideline will be to stop that current practice in which IVF clinics, assisted by various other professionals, make their own judgments about whether to facilitate a proposed surrogacy arrangement. Whether surrogacy is to be permitted is surely a matter for government legislation, not clinicians.

- Pre-implantation genetic diagnosis (PGD) of an embryo should only be used to obtain information about a serious genetic condition or disease (8.1), and so not – as is currently the case in some well-known and expensive IVF clinics – for the purpose of sex selection (now euphemistically known as ‘family balancing’!).

A recently publicised case indicates that this latter requirement needs further clarification. As it stands, guideline 8.1 permits PGD only in order to exclude from implantation an embryo with a serious disease. In a recent Victorian case, PGD was used to identify embryos that could be suitable tissue or cell donors for an existing, but ill, sibling (with unsuitable – *though possibly quite healthy* – embryos presumably left on the “surplus” bench). Screening for a “positive” result is

even more ethically problematic than screening for a "negative" result, such as a genetic disease.

- The guidelines rightly separate clinical activities from research. The crucial requirement is that persons for whom an embryo is stored are not to be approached about donating that embryo for research until the embryo has been in storage for a year, and until "after they have decided, independently of any discussion about research... that their embryo is no longer needed for implantation" (16.2.3 & 4).

The effect of this constraint should be to ensure that the collection of gametes or the number of embryos created in a treatment programme is in no way influenced by future research "needs" (especially the "needs" of the treating clinician or other clinicians at the same clinic!). It is at this point that the recording and monitoring conditions in the guidelines become critical – are they tight enough to prevent research "needs" from shaping clinical practices?

- The guidelines permit research that is harmful to, or destructive of, human embryos only if the research offers a likelihood of a significant advance in knowledge, or improvement in technologies for treatment which could not reasonably be achieved by other means" (16.2.1).

An appendix offers criteria for assessing the validity of such research with respect to each of these conditions. For example, there must be evidence that "the knowledge sought is likely to improve understanding of a particular human illness", evidence that the research aims are achievable, evidence from animal studies that the aim cannot be achieved without harming human embryos, evidence of good research methodology and of the researchers competence (p. 45). Presumably, the guidelines intend that *all* of these and the other stated criteria need to be met, and not just some of them. This should be made more explicit than it is.

- The guidelines highlight the importance of accurate record keeping and data reporting (e.g. about numbers of eggs collected, embryos created, implanted, stored, etc.), with a view to accreditation and monitoring of a clinic's activities. Other goals of record keeping are to assist participants' decisions about their treatment options, and to facilitate long-term follow-up studies of the effects of reproductive procedures, especially for the benefit of people born as a result of reproductive technology (7.7).
- The guidelines on fetal research are very brief and inadequate. Non-therapeutic research on a fetus for the sake of knowledge is permitted if the risks to the mother or fetus are "minimal" (18.1.3). However, in the case of non-therapeutic research on a subject unable to give consent, the only defensible standard is that in the *CHA Code of Ethical Standards*, viz. that "there is a moral certainty of causing no harm to the life or integrity of the embryo or fetus" (II. 6.13). No right-minded parent would consider exposing his or her unborn fetus to even "minimal" (i.e. small, but *real*) risk, just for sake of science.

Harm minimisation

It will be apparent that these draft guidelines seek to introduce some entirely reasonable safeguards on the use of reproductive technology, primarily in the interests both of the children who will be born as a result of this technology, and of the human embryos that will be destroyed or abandoned. For many of us, these safeguards do not go nearly far enough: in the end, they give priority to the interests of those wanting children and those wanting to use human embryos and fetuses for research purposes. Those who believe that most uses of reproductive technology are unethical in the first place – because they remove human procreation from its marital-sexual context, may be tempted either to question the whole exercise of developing these guidelines or to regard the

result as grossly inadequate. If we accept, however, that clinical uses of technology to create human embryos, along with research uses of technology that destroy human embryos, *are* nonetheless legally permitted in Australia, then our legitimate – indeed urgent – goal should be to minimise the harms that these activities inevitably involve.

These guidelines accept the separation of procreation from marital sexuality, but they rule out some of the more objectionable uses of reproductive technology, uses that some scientist somewhere would no doubt like to explore; they attempt to limit the number of embryos created by technology, though the attempt is fairly half-hearted; they challenge some prevailing practices, such as anonymous sperm donation and PGD for sex selection; they establish somewhat restrictive criteria for when research that is destructive of embryos may be approved; they demand record keeping that might enable activities to be monitored (but only if there are also procedures to enable public scrutiny of data collection). Yet, loopholes remain, and it would be naïve to think that some scientist/entrepreneurs will not be looking to expand their activities wherever they can. Even if these guidelines are tightened in the ways I have indicated, it is still disappointing to realise that the constraints they introduce may well be the best we can achieve at present.

Footnote

1 The Director of the Murdoch Children's Research Institute, Professor Bob Williamson, is reported as endorsing therapeutic cloning, which he describes as "removing the nucleus of a human egg cell and replacing it with DNA material - such as skin, heart or nerve - from a donor" (reported, *Sydney Morning Herald*, July 30, 2002).

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Right or wrong, it's a matter of ethics

Chris Lindsay¹

"Ethically at 3am when you've got your wife in the back seat of the car about to give birth, and its safe on the roads to do so, then you can jump a red light," says John Quilter, lecturer at the Australian Catholic University's School of Philosophy at its Strathfield campus.

"But does this mean we should change the law to allow jumping red lights in such cases? How pregnant, how imminent is birth, before it is legal to jump the red light - once you get into the details it gets stupid."

It is an argument John uses when discussing the difficult question of euthanasia, and how to approach it from an ethical basis, that is one part of the Ethics of Health Care courses taught within the school and through the Plunkett Centre for Ethics in Health Care.

John says that once the two opposing views are raised - that there are situations of no hope, or terminal disease and serious pain at which point proponents of euthanasia claim it is appropriate to accede to someone's request to end their life, and the other view, that at no time, nor for any reason is it permissible to do so because life is sacred - there is the difficult grey area in between.

The Catholic Church, of course, leans heavily towards the position that life is sacred, at least as one of the philosophical bases from which to look at the issue.

But what does the School of Philosophy say to its students about this?

"The answer differs from lecturer to lecturer. I can only speak from the School of Philosophy (theology is a different matter, it can make certain assumptions that as philosophers we can't)," John says.

"I think that broadly among all of us there is a recognisable influence of sympathy for the basic outlines of the Catholic position. Some are more conservative and some more liberal.

"But none of us has much time for the extremist liberals, such as Australian philosopher Peter Singer or euthanasia activist Dr Philip Nitschke."

John agrees that Nitschke lost a lot of public sympathy on two points: his raising of suicide as an option for depressed teenagers and the death of Nancy Crick, who killed herself and then was found not to have a terminal illness.

"On euthanasia, in my view, there is an awful lot of confusion about ethical questions and the socio-legal positions," he says.

"Many people on both sides of the debate argue that if the ethics of euthanasia or some other ethical questions are x, y, z then the law should be a, b, c.

"That's a huge jump. That's an awfully big jump from what the ethics is to what the law should be.

"I like to argue like this: OK, let's give Nitschke and company their ethical position for the sake of the argument; let's assume it

does follow that we should change the law.

"But what happens if we change the law? Let's think that through.

"What would happen if we said that in certain circumstances you can take a life?

"Well it's very difficult to codify what those circumstances would be - to trust that ordinary people would necessarily get it right all the time, or act wisely all the time.

"There are a lot of pressures in life; grandma could start to cost a lot of money; she might have been an old bugger all her life anyway.

"You might pray for her to die and now you can knock her off. The potential for abuse of legalising such killing is frightening.

"Instead of killing people, we could sit and talk to them and make them feel as if someone cared for them; we could work harder at controlling their pain."

He agrees that the problem of leaving the decision to doctors raises the problem of "which doctors" and "what ethical background do they come from?"

John says: "In Nazi Germany there was a process of doing away with deformed children. But what deformities? A hare lip? Deafness?

"There is a kind of pious myth in a lot of people's minds about just how sure of ourselves we are as citizens in a free democracy.

"Most of us are quite impressionable, and we aren't always certain about what we think is good in the circumstances.

"Most of us can be swayed - even if we are sure we know what is right - under other influences and pressured away from our positions, away from doing what we think we ought to do.

"My guess is that the vast majority of any population is highly impressionable and suggestible. That is one of the reasons why stupid marketing strategies work so well.

"It is why people in a mob can be made to do things they wouldn't normally do - things they wouldn't even think of doing by themselves.

"So if we create an environment by changing the law regarding the taking of lives, after following a couple of what would be relatively easy steps for society, we are sowing the seeds for problems in our general attitude to life.

"It is a most dangerous path to tread. And as a social policy it would be barbarous.

"Freedom is a value, but it is not an absolute value. Freedom is important, letting people have space to do what they want is important, but not when it costs other people their lives.

"I reckon the argument for changing the law to uphold such 'freedoms' just doesn't hold up."

While the lecturing staff have their own well-worked out views in these kinds of topics, they don't try to force feed them to the students.

"In a course like ours, because it is ethics, it is essential people's consciences be formed quite maturely," John says.

"We want to get out of the kind of childish, slavish inability to think through issues for

themselves, or to engage in debates with people who they can't agree with, or understand others' points of view.

"To think things through, people need to be able to respect sensible points of view and to criticise intelligently less good aspects of opposing debates and positions.

"We want to help people avoid becoming slaves to fashion or pet philosophical theory."

John says the school tries to encourage students to become well informed about the debates; so, in health care, for example, they need to have a grip on the science of the things they are talking about.

"We try to equip people with a good exposure to the range of positions, at least the influential positions that are in play or are making their claim in the public space about these debates," he says.

"We try to inform them fully. A lot of people may think or expect, particularly those unrelated to a Church, that because it is a Catholic university all we teach is Catholic theology.

"What people forget is that this is a philosophy school. The theology faculty will teach the theology.

"As a school of philosophy we take seriously our responsibility to inform people of the state of philosophical contributions to health care and business ethics.

"We look at utilitarian writers, contractarian writers, the great figures from history of moral philosophy.

"As far as possible we look at all the voices, we engage with these writers in a philosophically rigorous and open way.

"At the same time, what is true is that in the School of Philosophy at this University I think all of us are of the view that one of the most significant and articulate intellectual voices in ethical debate over the centuries has been the Christian tradition.

"We take seriously theological writers, philosophers who write philosophically but with religious conviction as contributors to the debate.

"We present them to students to take or leave on their merits as they in their own conscience best accept.

"Many of our students have a Catholic background but not all; roughly half and half, I would think. We can't assume religious commitment in our students; there are certain basic positions we can't take for granted.

"For a number of us, the influence of our own substantive views, the way we weight arguments regarding any serious religious commitment that we have, will probably be visible to people - and we don't resile from that."

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Footnote

1. This article is reprinted by kind permission of the *Catholic Weekly*, March 2, 2003

Advancing the field of clinical ethics: particularity and practicality

Bernadette Tobin

Clinical ethics is concerned with the particular rather than the general. The objective of ethical reflection is to guide action, not merely to contemplate what should be the case in an ideal world.¹

At a conference on medical ethics, a palliative medicine physician presents a case for ethical reflection. To show that she has paid her bioethical dues, she begins by acknowledging the four principles of bioethics: *beneficence*, *non-maleficence*, *autonomy* and *justice*. Then, setting those principles aside, she proceeds to reflect on the tiny things that really make a difference in clinical medicine: a slight deterioration in the patient's condition; the temporary absence of a key family member; a new focus of the patient's anxiety; uncertainty about whether to disturb a patient who has finally settled into a comfortable sleep; etc. The simplicity and directness of her language reveal more about the ethical challenges of clinical medicine than could any discussion of bioethical principles.

This should not surprise us. When Aristotle wanted to explain the character of ethical reflection to his students, he used the analogy of clinical medicine.² Sick people ask doctors to help them get better and doctors profess to be technically competent and ethically committed to doing so: thus, clinical medicine is an inherently ethical enterprise. The subject matter of ethics is something particular, not something general - doctors need to work out what to do with a particular patient in a given situation.

Yet, particularity and practicality are not features of most ethical reflection on medicine and healthcare today. Rather the reverse. Abstract generality and a focus on rules of conduct are more the order of the day. Why is this so?

Contemporary bioethics is still dominated by a "principles" approach to ethics. This originated 25 years ago with the work of two philosophers, Tom Beauchamp and Jim Childress, of the Kennedy Institute for Ethics at Georgetown University, Washington, DC.³ They argued that rules for healthcare ethics should be based on four principles: *beneficence* (the obligation to provide benefits and balance benefits against risks); *non-maleficence* (the obligation to avoid causing harm); *respect for autonomy* (the obligation to respect the decision-making capacities of autonomous persons); and *justice* (the obligation to be fair in distributing benefits and risks).

The justification for adopting these principles came in part from the history of medical ethics and in part from contemporary American political philosophy. Non-maleficence ("above all, do not harm") and beneficence ("the benefit of the sick") go back at least to the Hippocratic origins of modern medical ethics (though the Hippocratic oath itself makes no direct reference to the former). Respect for the patient's autonomy echoes political liberalism in its emphasis on the importance of individual freedom, both in political life and personal development. The influence of liberalism is also reflected on a

concern with the rights of individuals: autonomy-based rights to truthfulness, confidentiality, privacy, disclosure and consent, and justice-based rights to a fair distribution of the benefits and risks of medicine.

However, neither these principles nor any rules based on them are genuinely action-guiding. Principles or rules are no more than background generalisations, basic "givens" about which there is often no interesting disagreement. At best, principles may serve as reminders of the general ethical contours of clinical medicine, reminders that may usefully reorient clinicians when mistakes have to be rectified. At worst, they are untrue to clinical medicine's challenges: how to respond to this particular patient in these particular circumstances.

And no amount of talk about how, when they are applied, principles become responsive to the complexities of each patient's circumstances will help. Principles do not and can not dictate their own application. Whether we are aware of it or not, once we start to derive specific decisions from principles (as we must if we are to respond to a particular patient) we are relying on other considerations, from philosophical ethics or from clinical medicine, to guide our decision-making. This is obvious when principles conflict with each other - when you can not, for example, both act beneficently and respect the patient's autonomy. For the principles themselves can not adjudicate that conflict, no matter how one tries to apply them in a clinical encounter.

The "four principles" approach often exacerbates the very problem it is meant to resolve - because of its influence, a whole generation of doctors, nurses and other health professionals has been taught to think that the subject matter of bioethics is the attempted resolution of often-irresolvable

"dilemmas" and that, if a decision does not cause any felt difficulty or tension between opposing viewpoints, it is an ethically unimportant decision.

Indeed, the "four principles" make sense only within a wider framework of ideas about medicine itself and its place in people's lives. The principle of beneficence expresses the idea that the goal of clinical medicine is the patient's medical good. True enough, but what about the place of a patient's medical good in relation to the person's overall wellbeing? The doctor may be a (fallible) expert on the former, but the latter is not the kind of thing about which anyone can be expert (we all just muddle along as best we can!) and anyway is a matter for the individual patient. The "four principles" approach can not help us here: all it can do is remind us of what we already know, that what might be justified in terms of the principle of beneficence may not be justified in terms of the principle of respect for patient autonomy. When exponents of "principlism" advise you to "balance" one principle against another you know for sure that they have run out of steam!

"Principlism" is not the only theoretical interest in contemporary bioethics. The classical theories of philosophical ethics are even more remote from reflection on the practical challenges of clinical medicine. These include "consequentialism", "deontology" and "virtues ethics".

Consequentialism is the idea that all that matters from an ethical point of view are the likely consequences of a proposed course of action.

Deontology is the idea that consequences are not all that matter, that actions have other right-making features (such as respecting a

patient's rights) and wrong-making features (such as lying to the patient).

Virtue theory is the idea that the people who are most likely to do what is right are those who possess certain reasoned, thoughtful capacities ("virtues") that enable them both to work out how to behave in concrete, practical situations and to be disposed so to act. An understanding of these theories can assist and exemplify clear thinking - for example, it is incoherent to espouse consequentialism in one arena (such as resource allocation) and deontology in another (such as patient care), as the two are contradictory - but focusing on these theories in a study of bioethics can draw us even further away from particularities and practicalities of clinical medicine.

Good clinical ethics avoids the abstract theorising of much contemporary bioethics in favour of a discussion of some recurring themes in clinical ethics that is as close as possible to the clinician's desk (if not the patient's bedside). Its goal is to improve the quality of patient care by identifying, analysing and attempting to resolve the ethical problems that arise in the day-to-day practice of clinical medicine, using the clinical encounters between doctor and patient as the starting point.

The ethical challenges in clinical medicine arise in the context of specific doctor-patient relationships. These challenges are often as dynamic and unpredictable as the relationship itself. They can deepen or resolve in the flux of time. They are coloured by differences (even conflicts) of value among doctors, patients, families, the law, social mores, cultural and religious convictions. And they are present even when that relationship is free of tension and obvious difficulty.

At its best, ethical reflection is sensitive to the details of actual situations, discerns what is ethically at stake in them, and works out what should be done, for what reasons, by whom and in what spirit!

Since doctors, like other people, generally act on what they think they ought to do, it matters that their ethical instincts are transformed into a reasoned, thoughtful ability to choose what to say and what to do.

Footnotes

1 Reprinted with kind permission of *Medical Journal of Australia*, Volume 174, 19 March, 2001.

2 Aristotle. *Nicomachean ethics*. 1104a9; 1140b5.

3 Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*: 4th ed. New York: Oxford University Press, 1994.

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