

Religion, ethics, law and human rights in obstetric research

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Religion plays an important role in the lives of many medical researchers. In many cases, it has provided the basic impetus for them to engage in medical training and practice.

An important part of that training, however, is to learn how to mesh their personal religious views with the principles of medical

ethics (as derived from the Hippocratic tradition, as well as modern institutional domestic and international guidelines); health law (derived from legislation and judicial decisions); and human rights (as derived from constitutions or United Nations treaties such as the *International Covenant on Civil and Political Rights*).

The tension between fetal and maternal rights

The ethics, law and human rights of involving pregnant women and fetuses in research has been dominated by norms that try to achieve an uneasy and often improbable balance between: the protection of the vulnerable fetus; and the autonomy and privacy of the pregnant woman and her right to exclude interference with her body. In this protracted and often heated debate, viability (that is the period when the fetus is deemed to have reached a capacity for independent existence outside the womb) has formed a point of division. Prior to viability, the rights of the woman have tended to dominate and after viability, the State has more interest in protecting the vulnerable fetus. This distinction is more than a matter of convenience. It reflects the fact that no superior court has accorded full legal personality to a fetus, chiefly because the fetus lacks the interests and capacities that are normally associated with human existence. Some religious groups hotly contest this conclusion and assert that the fetus should have an enforceable right to life from the moment of conception. This, however, has never occurred in any jurisdiction.

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In developed countries, fetal viability occurs at approximately 24 completed weeks of gestational age, as determined by competent and reliable ultrasound dating. The viable fetus, when the pregnant woman presents herself for medical care, is ethically a patient, although that may not be its status at law. The pre-viable fetus is a patient solely as a function of the pregnant woman's decision to confer this status on the fetus and present herself for care.

Chervenak and McCullough^{3,4} recommend that some research principles which may operate in this area include:

1. The proposed fetal intervention is reliably expected (usually on the basis of previous animal studies) either to be life-saving or to prevent serious and irreversible disease, injury or handicap for the fetus.
2. Among possible alternative designs, the intervention is designed in such a way as to involve the least risk of mortality and morbidity to the fetus (which will satisfy the United States requirement of minimal risk to the fetus).
3. The mortality risk to the pregnant woman is low and the risk of diseases, injury or handicap to the pregnant woman is low or manageable.

Many international instruments now protect the rights of women and children involved in clinical trials. Prominent amongst these is the *Nuremberg Code* (created after the Nazi doctors' trials and the first to champion the necessity for free consent); the World Medical Association's *Declaration of Helsinki*; the *International Covenant on Civil Political Rights* (ICCPR) (Article 7 requires free consent before medical and scientific experimentation); and the Council for International Organizations of Medical Sciences (CIOMS) international ethical guidelines for research. The European Union has a directive on good practice in clinical trials and a *Convention on Human Rights and Biomedicine*. UNESCO has recently developed a *Universal Declaration on Bioethics and Human Rights*.

Artificial reproductive technology issues

Research involving patients who have used artificial reproductive technology (ART) relies heavily on ethical guidelines published by the National Health and Medical Research Council (NHMRC) – ethical guidelines on the use of ART in clinical practice and research – for their chief guidance. Legislation such as the *Parentage Act 2004 (ACT)* establishes that, where semen donation is used to produce a pregnancy, the husband of the pregnant woman is presumed to be the father (s17). Where a pregnancy has arisen from ovum donation, the woman who underwent the ART procedure is presumed to be the mother (s17).

One controversial area in ART involves pre-implantation genetic testing for sex selection. Some argue that the embryo is not a legal entity or that parents should have the right to determine the gender mix in their family, especially in a situation where some selection is taking place anyway (the embryo growing most vigorously is implanted). Others believe that discarding embryos for such a reason (rather than the presence of a sex-linked genetic disease), instrumentalises them ethically (makes embryos valuable only for another's use, not according to their own intrinsic dignity). Another controversial area of research involves whether anonymous sperm

donation should be used when children conceived this way may subsequently have health and personal reasons for trying to locate their genetic father.

Debate also arises about research seeking to test a child for a genetic disease (for example, onset in middle-age of Huntington's disease), where the parents do not wish to be tested themselves. Such testing might deprive the child of their human right not to know their genetic predisposition to disease. All babies in Australia are subjected to a heel-prick test for certain inherited diseases that are easily treated. The status of the blood taken and stored is controversial, as in the future it may provide a vast amount of information about the individual to the State.

Another topical debate is the research involving excess ART embryos. National uniform legislation has been implemented to ban human cloning and other unacceptable practices involving excess ART embryos. The NHMRC assesses applications for licenses to use human excess ART embryos for research under the *Prohibition of Human Cloning Act 2002* and the *Human Embryo Research Act 2002*. Such legislation is under review, as it may have the unintended effect of inhibiting the creation of patents that would establish Australia as a world leader in this area and eventually provide relief for conditions involving organ failure and spinal cord damage.

The need for consent

Institutional review boards or ethics committees will scrutinise consent forms and procedures so that effort is required on the part of researchers to prevent coercion of a woman's decision by internal factors, such as unreasoning desperation; and external factors, such as partners and family members, especially when their involvement is mandated by regulations.

To avoid legal action for assault or battery (trespass to the person), doctors and other health professionals must obtain a patient's free consent as to the 'nature' of what is proposed before they undertake any medical procedure or treatment [*Chatterton v Gerson (1980) 3 WLR 1004*]. This applies even where the proposed treatment would clearly benefit the person and a failure to treat them may result in harm that could have been avoided.

Case law dealing with the level of information necessary for an informed decision has predominately concerned itself with the type and amount of information that needs to be given in relation to the potential risks of a procedure. The High Court in *Rogers v Whitaker (1992) 175 CLR 479*, said that a doctor must inform a patient or research subject of the 'material' risks and that the risk is material if:

'In the circumstances of the particular case, a reasonable [that is, an "ordinary"] person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.'

Printed materials are the best way to give the objective risk information to a research subject, further allowing adequate time for the patient to reflect upon it and discuss it with relatives and friends. Unusually inquisitive subjects however, may need to be given more information about the associated risks [*Chappel v Hart (1998) 195 CLR 232; Rosenberg v Percival (2001) 205 CLR 434*].

Research subjects should ask for the risk information to be given to them in writing and to then be able to go home and consider it. When asked to sign a 'consent form', the patient should ensure they have not been given a 'pre-med' (sedative or sleeping pill), or are in some other way not thinking clearly. If they have particular concerns,

they should be sure that the doctor or themselves note them on the form, as well as the doctor's answers. If language is a difficulty, the patient should ask for an interpreter.

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There are several situations in which less information may be justifiable. The first is in an emergency where treatment is necessary to protect or sustain the patient's life or health. The second case is where the patient waives the right to be given information. Ethically, a doctor should confirm that the reasons behind such a refusal do not involve a misunderstanding. The third situation is a doctor's limited discretion (therapeutic privilege) not to disclose information where he or she has reasonable grounds to believe and is prepared to document that disclosure of the information may itself harm the patient or subject (for example, if the patient is suicidal or mentally ill). Mere anxiety in the patient is not a sufficient reason on this ground for a doctor to withhold information.

Different considerations apply for children and adults who have an intellectual disability or suffer from severe mental illness. If the person is a child (under 18), either parent or a guardian may generally consent to a medical procedure. The parent or guardian is entitled to the same information as an adult patient. However, an older child may also be able to consent if they are sufficiently mature enough to understand the nature and risks of a procedure. This will depend on the child's age and level of maturity, as well as the particular procedure [*Gillick's Case (1986) AC 112*]. In the cases of abortion, reproductive sterilisation, or medical procedures concerned with contraception, and of a mentally handicapped minor, the parent or appointed guardian alone cannot consent. The relevant Guardianship and Management of Property Tribunal must be involved and possibly a court [*Marion's Case (1992) 175 CLR 218*].

Chervenak and McCullough^{3,4} state that patients are sometimes not aware when they are subjects of research. Phrases such as 'innovative therapy' or 'experimental therapy' should not be used in consent forms or in discussions with pregnant women about their participation in fetal research. Instead, the consent form and related discussions should consistently use 'fetal research' or similar terms and be explicit about the fact that the clinical intervention is research or experimentation.

References

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