Journal of Medical Ethics 2000;**26**:139–140

Ethics briefings

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End-of-life and advance directives

On 18 January, a parliamentary bill entitled Medical Treatment (Prevention of Euthanasia) was published by the United Kingdom government. Although ostensibly about the prevention of euthanasia, some lawyers saw the bill as reversing, if passed, the common law on advance decision making and refusals of treatment. Its principal clause focused on the prohibition of withdrawing treatment with the purpose of hastening a patient's death. No legal provision was made in the bill for valid treatment refusal, either contemporaneously or in advance.

Recent research has shown that only a quarter of all UK National Health Service (NHS) trusts have (or intend to develop) policies to improve understanding and compliance with the law on advance directives.[1] The study, undertaken by members of pro-euthanasia groups, surveyed trusts to find out about provision to recognise advance directives. They found a high level of support for the development of national guidelines to improve understanding and compliance with the law on advance decision making, and believe that this would help to support a consistent approach to end of life care across the NHS.

Advance directives have traditionally been promoted by pro-euthanasia groups who, in addition to pressing for legalisation of assisted dying, seek to encourage people to take control over the end of their lives in other ways. For similar reasons, pro-life groups which oppose patients' rights to refuse life-prolonging treatment often describe any refusal of treatment which might prolong life as "passive euthanasia" and therefore unacceptable.

Controversy and confusion over advance decision making have led to many years of debate about whether legislation would be helpful. However, the UK government has specifically rejected this. In detailed proposals for decision making for incapacitated adults, the government said that "it is a general principle of law and medical practice that all adults have the right to consent to or refuse medical treatment ... it follows that the Government respects the right of people with capacity to be able to define, in advance, which medical procedures they will and will not consent to at a time when that individual has become incapable of making or communicating that decision".[2] The government went on to say that the guidance contained in case law, together with the British Medical Association's (BMA) code of practice,[3] (which is now on its website: www.bma.org.uk) is sufficient to provide clarity and flexibility without the need to introduce legislation governing advance statements at the current time.

The new bill also seeks to introduce a distinction between medical treatment and artificial nutrition and hydration, fuelling the controversy about withdrawing or withholding life-prolonging medical treatment which has raged since the British Medical Association published guidelines last year.[4]

Xenotransplantation

During 1999 the UK Xenotransplantation Interim Regulatory Authority (UKXIRA) received its first applications to undertake clinical trials in xenotransplantation. Ultimately, neither of the applications progressed to the stage at which the authority would have been required to make a recommendation to UK health ministers, the process which all applications must follow. UKXIRA also produced draft reports on infection surveillance and on biosecurity considerations.[5]

At an international level the Council of Europe has established a working party on xenotransplantation—under the joint responsibility of the steering committee on bioethics and the European health committee—tasked with drawing up draft guidelines on xenotransplantation within three years.

Medical organisations, including the BMA have always emphasised that a cautious and thorough approach should be taken in relation to xenotransplantation, in view of the complex scientific and ethical issues it raises. They are particularly concerned by the surveillance requirements to be imposed on xenograft recipients and their "close contacts", as proposed by UKXIRA.

Preimplantation genetic diagnosis

In November 1999, after two years' work, the Human Fertilisation and Embryology Authority (HFEA) and the Advisory Committee on Genetic Testing (ACGT) issued their joint consultation document on preimplantation genetic diagnosis.[6] Although often hailed as the panacea for those at risk of serious genetic disorder—because it allows parents to begin a pregnancy knowing the child will not be affected by the disorder for which there is otherwise a risk—the document highlights the likely impediments to its widespread adoption. Still, however, it predicts a time when use of the technology may be requested by those who are not at risk of a genetic disorder; those, for example, who are undergoing in vitro fertilisation and wish their embryos to be screened before replacement to select those most likely to result in the birth of a healthy child. Is this a new form of eugenics or a legitimate expression of the parents' desire to act in the best interests of their future child? What of those not requiring IVF at all? Although it seems unlikely that many people would want to start a pregnancy in such a clinical way where other options are open to them, if they wish to do so, should they be prevented from using the existing technology? Much of the consultation document focuses on the regulatory framework to be developed and the way in which individual operators' skills should be assessed

and monitored, but these more speculative questions are by far the more interesting from an ethical perspective. Among the type of questions now being raised for policy debate are issues such as: would it ever be acceptable to replace an affected embryo at the request of the parents? Should the embryo selection process exclude carriers or only those affected by the disorder? Does our continual striving to improve methods for avoiding the birth of affected children have a negative effect on society's attitudes towards existing people with disability?

Reform of mental health legislation

In November 1999, a government consultation paper was issued in England and Wales which described a framework for new legislation to update the principles and processes established by the 1959 and 1983 Mental Health Acts.[7] The proposals sit alongside a number of other areas of policy development: the Lord Chancellor's statement of the government's proposals for making decisions on behalf of mentally incapacitated adults, *Making Decisions*[2] and a consultation document, *Managing Dangerous People with Severe Personality Disorder*,[8] which set out government policy objectives for one particular high-risk group.

A number of key proposals have been put forward. In particular, it was proposed that there should be greater flexibility in the assessment and treatment of patients and that there may be occasions where patients can receive compulsory care in the community rather than in the hospital setting. In addition, the government suggested that the key principles underlying compulsory care of mentally disordered individuals should be expressly stated in the act itself. The assessment procedures for all patients who come within the scope of compulsory powers are to be changed: different criteria will apply where the patient is considered to possess capacity and a higher threshold has been set. The government also proposed a process for independent decision making in all cases where patients are subject to compulsory care and treatment for longer than 28 days.

Revision of the Helsinki Declaration

The World Medical Association's (WMA) Declaration of Helsinki, commonly reckoned to be a benchmark for the ethics of medical research on humans, has been under review by the WMA since 1997. Although initially slow to generate international interest, the debate around Helsinki plunged into controversy in 1999 and focused attention on some complex ethical issues which went far beyond the scope of what was originally intended by the WMA's review. A radically revised version of the declaration, drafted by Professor Robert Levine of Yale University, aimed to take a new approach to several contentious areas. One concerned whether there was any point in retaining the distinction between "therapeutic" and "non-therapeutic" research. Traditionally, it had been assumed that less rigorous moral safeguards would be required in cases where the health of the research subjects was expected to benefit directly from participation. Such a distinction, however, was eliminated from the draft revised version.

A second issue concerned the use of placebos in HIV vaccine trials in developing countries. In developed countries, vaccine trials are obliged to include antiretroviral regimes as standard treatment for all trial participants, whereas in developing countries this option is commonly not offered on grounds of cost. In the late 1990s, debate about international research ethics highlighted the arguments for and against universal standards. Lower standards and use of placebos instead of proven therapies in developing countries, it was argued, would predictably lead to hundreds of preventable HIV infections. On the other hand, insistence on the same standards of care as were available to trial participants in affluent countries would effectively deter pharmaceutical companies from carrying out research in those parts of the world and delay the development of sustainable solutions for patients there. Profess Levine's draft revision of the Helsinki Declaration came down in support of diverse standards for trial participants in different countries by obliging researchers to ensure access *only* to those therapies that would otherwise be available to patients in that setting, rather than providing the same standards of care as were available in the sponsoring country.

In October 1999, the WMA began the revision process again, setting itself a new one-year deadline. It posted the current version of the Helsinki Declaration on its website (www.wma.net), inviting respondents to endorse or suggest amendments for each paragraph. In addition, two specific questions were posed, inviting comments on the two main issues of controversy: whether a distinction should be retained between "therapeutic" and "non-therapeutic" research and whether the best proven treatment must always be provided to trial participants, regardless of whether the research is conducted in developed or developing countries. The WMA also envisaged that its website debate forum would provide a means of soliciting comments from relevant groups in a structured way. It is expected that the new revision (which is likely to differ only in minor ways from the existing Helsinki Declaration, last endorsed in 1996) will be published at the 52nd WMA General Assembly in Edinburgh in October 2000.

References

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