People considered legally incompetent

Minors (under 18 years of age), mentally disabled adults, people who can no longer express consent because of their health (such as those in a coma or with Alzheimer’s disease), and embryos and fetuses are all considered legally incapable. All of these groups, except for unborn children, are considered to be vulnerable research subjects and therefore benefit from special protection. Nevertheless, it is important to make certain distinctions between these groups. For example, the 4 March 2002 law specifies that minors and adults under guardianship must be asked for their consent if they are able to express their preferences and participate in decision making. If the individual cannot express his or her preference, no intervention or investigation may be carried out.1

In France, informed consent in clinical care and clinical research has evolved in accordance with national, European, and international texts rather than in reference to standards, as is the case in the United States. However, whether in the context of clinical care or clinical research, the question of how to communicate risk is still central. This question might best be answered by consensus between the physician, the patient, and the patient’s family and close friends rather than the law, although the law may need to specify a minimum standard in case of dispute. Free and informed patient consent remains an issue in France, where the question of obligations to patients, following that of their rights, is at the heart of the debate.

Commentary: communicating risk in the United Kingdom

Michael Powers

Mazur describes how in the United States clinicians are changing their practices in accordance with what the law demands. In the United Kingdom the medical profession should take the credit for the changes in clinical practice that have driven the law on informed consent. Within certain limits, it is the clinician who decides how and what to impart and, unless there is an adverse outcome, patients are unlikely to complain and cannot sue about inadequate information.

A report by the chief medical officer for England on clinical negligence acknowledges that communication and information sharing has to be improved.1 Exchange and provision of information is at the core of an open and honest relationship between healthcare professionals and patients.2 Mazur questions whether relatives should be informed when the patient does not want to know. Although this may be prudent, a relative still cannot give consent on behalf of a living patient. However, recent inquiries in the United Kingdom (Royal Liverpool Children’s Hospital and the Isaacs reports) have emphasised the need to communicate fully with the next of kin to obtain consent for organ retention from deceased children and adults.

Bolam test

Adequacy of information in law is assessed by the Bolam test—that is, whether the act or omission complained of accorded with what a responsible body of professionals would have done at the material time. As Mazur reminds us, the United States adopted the concept of a “reasonable person” standard in 1972.

3 Cour de Cassation, Chambre des Requêtes, 28.01.1942, Dalloz, 1942.

This approach was rejected by the House of Lords in 1985 (Lord Scarman dissenting). Their lordships reiterated the applicability of the Bolam test to issues of consent, although they included the caveat that disclosure of risk in some circumstances was so obviously necessary to a patient’s informed choice that no reasonably prudent doctor would fail to make it.3

By 1997, the medical profession had effectively introduced its own “reasonable person” standard. The Royal College of Surgeons reminded surgeons that they must convey sufficient information “in detail required by a reasonable person in the circumstances of the patient to make a relevant and informed judgment.” In the case of Bolitho, the House of Lords said that even though a

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responsible body of medical opinion (the “Bolam test”) might hold something to be reasonable, this opinion was susceptible to destruction by logical analysis: an unreasonable failure to disclose may now render a clinician liable in damages whatever his colleagues declare to be responsible practice. The fine balance between benefit and risk, the more clinicians need to be attentive to informing the patient fully.

Clinical research

For consent in clinical research, Mazur espouses a “reasonable volunteer” standard. No such standard exists in the United Kingdom. Although we can agree on the need for more emphasis on “explicit detailing of information” in obtaining consent, the principles remain the same provided there is a potential therapeutic benefit to the individual volunteer. When genetic tissue can be stored for future research programmes Mazur sees the burdens on clinicians increasing still further in order to satisfy US data protection legislation; this is also true in the United Kingdom. Although therapeutic research may provide a benefit to balance against any risk to the volunteer, non-therapeutic research, by definition, cannot, and even when volunteers have the capacity to consent there are tight moral and absolute legal limitations. Incapacity makes consent to non-therapeutic research unobtainable, but in the few cases where it can be “convincingly shown” that a therapeutic research procedure is in the “best interests” of an incapable patient, the clinician in an emergency (and the court when time permits) can ensure that the balance between humanity and human autonomy is maintained.

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3 Sidaway v Board of Governors of the Bethlem Royal Hospital and The Maudsley Hospital [1985] AC 871.
5 Bolitho v City & Hackney Health Authority [1998] AC 292.

Risk communication in practice: the contribution of decision aids

Annette M O’Connor, France Légaré, Dawn Stacey

As patients want to participate more in decision making, and as the range of medical options expands, clinicians are challenged to improve their communication of risk and supportive skills. Are practitioners’ counselling skills up to the job?

Different decisions require different strategies to communicate risk and support decisions, and we consider that two broad classes of decisions exist for patients. The first class lies in the area of “effective” health services, in which the benefits are large compared with harms—the participation of patients improves control of chronic conditions and the widespread underuse of these beneficial options. The second is in “preference sensitive” health services, in which the ratios of benefit to harm are either uncertain or dependent on patient values—participation of patients improves quality of decisions and prevents overuse in the subset of informed patients who don’t value the options.

We investigated practical and effective approaches that doctors and practitioners can use when counseling patients about these two classes of decisions. Box 1 shows the sources we used. These approaches should help patients to understand options, benefits, harms, probabilities, and scientific uncertainties; clarify the personal value of the ratio of benefit to harm; and participate in decision making according to needs.

“Effective” versus “preference sensitive” decisions

The goal in decision making is to select health services that increase the chances of valued health outcomes and that minimise the chances of undesired consequences according to the best available scientific evidence.6,7

In some cases, the best strategy is clear to both practitioners and patients because the scientific evidence of benefits and harms is known and the harms are minimal relative to the benefits. Most

Box 1: Sources for study

- Wennberg’s definition of “effective” and “preference sensitive” health services8
- Classification schemes for evaluating health services according to the strength of scientific evidence and the magnitude of ratios of benefit to harm9
- Recent reviews of decision support interventions for “effective” care decisions10
- Cochrane systematic review (2005 update) of trials of patient decision aids for “preference sensitive” options, including an inventory of hundreds of decision aids and 62 ongoing and published randomised controlled trials describing their efficacy11
- Reviews of papers describing patient centred communication12,13 and evidence based patient choice14,15
- Personal experiences of training health professionals to develop their decision support skills in practices and call centres in Canada, the United Kingdom, the United States, and Latin America