SELECTED SUMMARY

Informed consent

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Mazur D.J. Influence of the law on risk and informed consent. *BMJ* 2003;327:731–5

Obtaining informed consent is now a routine part of both clinical practice and research, but the focus on giving information about risk has evolved differently in clinical and research settings. The law has played a large part in informed consent in clinical practice. Consent in clinical research has been codified in international regulations.

Informed consent related to clinical care has evolved through legal cases

In clinical care, disclosure of risk developed from the obligation on doctors to obtain their patients' consent before intervening medically. Gradually the notion of consent evolved into informed consent, with the emphasis being on information about risks. The professional standard of consent to treatment has been espoused as a judicial concept since a British case in 1767 in which the physician initially set the patient's femoral fracture in accordance with practice at that time but at a follow up visit re-broke the healing fracture and placed the re-broken bone in a newly invented mechanical device with teeth. The judge concluded that obtaining a patient's consent was a custom of physicians and ruled for the patient that consent should have been obtained by the physician as part of his professional duties. Thus consent was judged under 'professional standard of behaviour'.

Much later, the notion of information became linked to consent. The term 'informed consent' was first introduced into the judicial lexicon in 1957 in the written opinion of an appellate court judge in California and a new judicial standard—the reasonable person standard—was established by Judge Robinson in 1972 whereby the decision about whether a patient should have been informed of a risk is based on whether a reasonable person in that patient's position would want to be informed. Many countries have adopted this standard or are moving towards it.

The primary use of the concept of informed consent in the courts is in retrospective decision-making after an injury. Only derivatively is informed consent a prospective view on what a physician should say to a patient. Indeed, court views of informed consent also include a therapeutic privilege for physicians not to inform a patient who may be harmed by the disclosed information.

If a patient makes an explicit instruction not to be told of risks, this request should be honoured. However, the question remains whether family members or partners should be informed if the patient does not want to be told about risks. Cultural issues may also arise, for example, in Japan, the cultural practice has been not to inform a patient that he or she has a terminal illness.

The courts, however, require information to be disclosed to the patient in a discussion with the physician. Thus, simply handing patients a consent form may not be considered enough by the courts unless the issues are discussed with patients and they have an opportunity to ask further questions.

Another issue is the fact that much of the discussion of risks of invasive procedures still takes places when the patient is admitted for the intervention. Informed consent in clinical care in the US is usually obtained by the physician performing the procedure. But the hospital also has a role in overseeing informed consent.

Informed consent in clinical research is more regulated and requires more a structured approach to disclosing risk information

The Declaration of Helsinki forms an important basis for the conduct of research in humans. The Belmont report (1) rejects the 'professional standard' and 'reasonable person standard' and instead recommends the use of the 'reasonable volunteer standard'. The need for patients to fully understand is greater in clinical research because participation is voluntary, alternatives may exist, and the participant may not benefit and could be harmed by participation. As a result, more emphasis has been put on detailing information that must be disclosed to people considering participating in a clinical study. Informed consent forms contain an increasing array of information.

The US Code of Federal Regulations also specifies vulnerable groups who need extra protection because the potential for their unethical use in research. These groups include children, prisoners, pregnant women, and people who are mentally disabled, economically or educationally disadvantaged. Clearly, the concern is that these groups may not fully understand the nature of research and the fact that research is not clinical care.

Judicial view does not provide an inclusive enough for communicating risks and alternatives

The judicial system has played an important role in developing informed consent. However, it cannot provide an all-inclusive framework for the multiple problems that exist in communicating information about risk for all the circumstances that physicians are confronted with in the real world. We need to bring in perspectives from cognitive psychology, the decision-making sciences, and consumers to help clinicians overcome a broader range of conversational dilemmas.

Commentary

Informed consent became an integral part of clinical practice in the 1970s. Initially, informed consent was taken more for a perceived legal protection than with the intent to provide information to the patient. This created some farcical situations. In 1973, while I was a fellow at Cook County Hospital in Chicago, the hospital administration decreed that the then current three or four patient consent forms for invasive procedures would be replaced by more than 70 forms, each designed for a specific clinical setting. Thus there were forms for performing a history and physical examination, for starting an intravenous infusion, for transfusions, a special one for biopsy of each organ etc. This flurry of legal activity was clearly precipitated by the 1972 California decision referred to in the above article. The hospital administration, inexperienced in the nuances of tort law, overreacted. A lot of attention was placed on the form and not the substance of the law.

In academic medicine, as teaching of medical ethics became formalized, starting in the 1970s, moral principles of respect for autonomy (the obligation to respect the decision-making capacities of autonomous persons); non-malfeasance (the obligation to avoid causing harm); beneficence (obligations to provide benefits and to balance benefits against risks): and justice (obligations of fairness in the distribution of benefits and risks), enunciated by Thomas Beauchamp and Daniel Callahan, assumed a central role.

Thirty years later, informed consent is still written with the intent to protect the medical profession from lawsuits. Partly, this results from the fact that informed consent becomes an issue only in retrospect, as the above article points out. However, the law cannot script the consent as it has scripted the Miranda warning given by the arresting officer to a suspect—every word is loaded with meaning and shortening the recitation can invalidate the arrest. Therefore, what should be included in an informed consent is still a matter for debate and research. It is important to convey the probability of success in simple language and, to point out the element of uncertainty, without scaring the patient. The language should avoid medical jargon. In the USA, the form must be readable and understandable to a person who has studied up to the sixth grade. In India, where the majority possess only rudiments of literacy, the language would have to be even simpler. Perhaps, pictures would be more effective than words in conveying what procedure is being planned.

We often assume that resources are infinite and every patient has a right to decide and get any procedure done that is deemed necessary. But, as we know, and as pointed out by Professor Bloche (2), in many clinical situations, each choice is accompanied by substantial monetary and social costs that are ignored by clinicians when discussing therapeutic options. Should these not be spelled out and be a part of the consent process? Should discussions involving allocation of scarce family financial resources or assumption of responsibilities by other family members remain a matter for family dynamics and not be 'medicalised' by being included in the consent process? Should the family become involved only when there is cognitive impairment? In India, a patient often lets someone else make decisions for care, then, should this surrogate sign the form in addition to the patient?

A great deal needs to be learned about the content of the 'informed consent' form, the ways to explain the intricacies of risk in modern medicine, the psychosocial processes involved in decision-making, before we can be rest assured that a truly informed patient has made a wise decision.

References

1. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont report: ethical guidelines for the protection of human subjects of research*. Washington, DC: DHEW Publications, 1978, http://ohsr.od.nih.gov/mpa/belmont.php3 (accessed August 21, 2003).
2. Gregg BM. Rights and efficiency in American health law. *Human Rights: Journal of the Section of Individual Rights and Responsibilities* 1998;25:19.