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Influence of the law on risk and informed consent

Dennis J Mazur

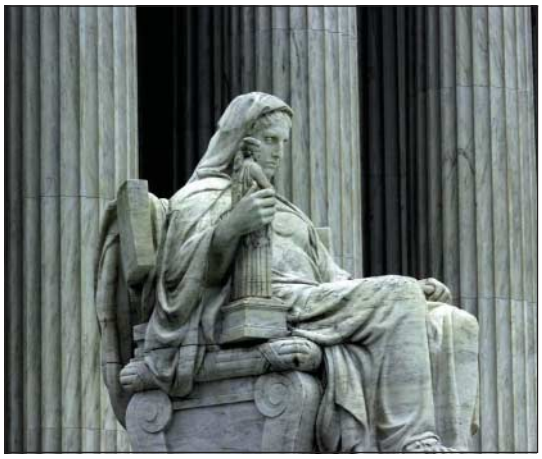
Patients are now routinely given information on risks of treatment as part of informed consent. This has occurred partly in response to legal judgments, but further issues continue to be raised by modern medicine and research that need to be approached proactively

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 each setting. Whereas the law has played a large part in determining how informed consent is handled in clinical practice, consent in clinical research has been codified in international regulations and is much more formalised. I describe the evolution of informed consent in clinical care and clinical research and discuss the aspects that are still controversial.

Evolution of consent in clinical practice

In clinical care, disclosure of risk developed from the obligation on doctors to obtain their patients' consent before intervening medically. In absence of emergency, doctors who acted without their patients' consent were initially accused of battery or intentional harm and later of negligence. 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.[1] In that case the physician initially set the patient's femoral fracture in accordance with practice at the time but at a follow up visit rebroke the healing fracture and placed the rebroken bone in a mechanical device with teeth. Physicians called into court to testify reported that physicians usually secured their patients' consent before embarking on a medical intervention, but there was little said in the judge's written opinion



KENNETH LAMBERT/AP

US Supreme Court

about what should be said to patients before an experimental intervention, as opposed to a clinical intervention. 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 particular physician as part of the duties of his profession. It was much later that 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 judge in California.[2] It too was considered under a professional standard of disclosure. The judicial, medical, and ethical interpretations of informed consent

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Two boxes on informed consent forms and data protection are available on bmj.com

created much controversy, prompting the creation of a new judicial standard—the reasonable person standard. Under a reasonable person standard, 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.

The reasonable person standard was established by Judge Robinson in 1972 in a landmark US Federal case *Canterbury v Spence* and has been adopted by the Supreme Court of Canada.[3] Courts in England and Australia are also moving towards it[4]: an Appeal Court judgment in England in 1998 applied this standard.[5] States in the United States are about evenly divided, half following the professional standard and half following the reasonable person standard.

Limits to judicial concept

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. Judge Robinson recognised the potential harm that information on risk could cause, yet he also recognised that extensive use of the privilege of non-disclosure would overwhelm the obligation to secure a patient's informed consent.

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 judicial doctrine of informed consent in clinical care has been based primarily on one type of medical decision—when one medical intervention surfaces as medically justifiable and is recommended by the physician. Thus a surgeon recommending surgical removal of the gall bladder of a patient with gall stones may discuss the intervention in the context of the risks of continued episodes of abdominal discomfort; the risks of surgical removal; alternative treatments, including non-intervention; and the risks of delay if more opinions are obtained. Each of these risks has to be weighed against the possible benefits both in general and for the particular patient.

Doctors may adopt specific practices to accommodate the requirements of informed consent in their particular practice settings. For example, in university medical centres, groups of cardiologists often develop elaborate informed consent forms that explicitly explain the sequence of events that can be expected for patients referred for, say, angiography. The informed consent forms would start with a discussion of the anatomy and physiology of the heart and then shift to the intervention being recommended: what happens, how long the procedure will take, who will perform the procedure, and the risks of each aspect of the procedure. The courts, however, require information to be disclosed to the patient in a discussion with the physician. Thus simply handing patients an explicit 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.

Box 1: Influences of risk on research in humans

- Side effects, complications, severe adverse outcomes
- Nature of study (new drug *v* drug, new drug *v* placebo)
- Liability issues (who is going to pay for hospital treatment and compensation for severe adverse outcomes related to the research)

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.

One recent study examined 1057 consultations with 59 primary care physicians and 65 general and orthopaedic surgeons in community based private offices.[6] Information related to the nature of the decision was discussed in 71% of consultations, patient preferences in 21%, alternative treatments in 11.3%, the risks and benefits of the recommended procedure and its alternatives in 5.8%, the patient's role in decision making in 5.9%, uncertainties associated with the decision in 4.1%, and patient understanding in 1.5%. Surgeons were more likely to cover each aspect of decision making than primary care physicians (21.8% *v* 18.9%; Fisher's exact test, $P = 0.03$).[6]

Informed consent in clinical care in the United States is usually obtained by the physician or group performing the procedure. But the hospital also has a role in overseeing informed consent. In the United States, the Joint Commission on Accreditation of Healthcare Organizations oversees how informed consent is carried out in hospitals.

Informed consent in clinical research

Disclosure of information on risk in informed consent in clinical care is relatively simple compared with the disclosure required in research with human subjects (box 1). Investigators must develop scientific protocols and informed consent forms to be used in research studies, but these are then approved by an institutional review board.[7] Institutional review boards also conduct reviews of each research study, and the riskier the study, the more frequent the reviews need to be.

The Declaration of Helsinki forms an important basis for the conduct of research in humans. In 1974, the United States created a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to identify the basic ethical principles that should underlie the conduct of research in humans. The Belmont report, published in 1978, summarises the commission's conclusions[8] and continues to serve as a framework for information disclosure in research and as guidance for institutional review boards.

The Belmont report rejects the professional standard and reasonable person standard of informed consent and instead recommends using 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 (see box A on bmj.com).

The risks of participation in a study go beyond those of the treatment—for example, to issues of privacy and confidentiality of the data obtained about the individual during participation in the study. Also, what may the information be used for and how should it be handled once the study is completed? This places information for patient decision making in yet another light as a new question is being asked: what information must be disclosed to participants for them to make a decision to authorise use of their personal health information for research purposes? US law protects personal data rather strictly (see box B on bmj.com).

Vulnerable participants

The US Code of Federal Regulations also specifies vulnerable groups who need extra protection because of the potential for their unethical use in research.[9] These groups include children, prisoners, pregnant women, and people who are mentally disabled, economically disadvantaged, or educationally disadvantaged. Clearly, the concern is that these groups may not fully understand the nature of research and the fact that it is not clinical care.[10–12] The concept of "therapeutic misconception" highlights problems that research participants may have over time in distinguishing the clinical care they receive from their participation in research.[13]

Awareness is growing of the need to help patients distinguish the risks of clinical care from the added risks of participation in clinical research. But there are also debates on how to assess decisional capacity. The Belmont report specifies that individuals considering participating in research must be able to both volunteer their participation and recognise that they can withdraw at any time and be safely placed on standard treatment. Problems can arise when the research requires participants with fluctuating mental capacity (for example, people with delirium and mania) or progressive diseases that affect cognition over time (for example, Alzheimer's disease). Advance research directives are needed to allow an individual to participate in research at a future time.[14] The problem, as with any advance directive, is determining whether people have changed their mind between signing the directive and the start of the research.

Box 2: Debates on risk in clinical research

- When are placebo studies acceptable?
- Can permanent damage occur during drug washout phases or while receiving placebo treatment?
- What is the role of advance research directives to clarify issues related to research participation in fluctuating states of cognition and states of progressively impaired cognition?

Summary points

The primary focus of informed consent is disclosure of risk

Informed consent relating to clinical care has evolved through legal cases

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

Debate continues over what risks study participants should be allowed to bear in clinical research

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

Emerging areas of research

Newly emerging protections in clinical research are focusing on genetic research, research on the human genome, and the storage of uniquely identified genetic tissues and unique proteins for "future" research purposes. In these cases informed consent to study participation needs to be expanded to include the risk to past, present, and future family members. Discussions of genetic research within families often generate controversies because the resulting risks to insurability and employability have not yet been systematically addressed by all governments.

Traditionally, research on informed consent forms used in research has been on readability. Even though research has now begun to examine what is being said in informed consent forms,[15] much deeper content analyses are needed to determine risk communication and research participants' substantial understanding of risk. We need to determine how best to communicate risk and chance (numerically and verbally, and whether verbal probability terms are satisfactory in terms of communicating risk), how risk is understood by individuals, whether investigators systematically review what is understood about risk in relation to their study, and how accurately the risks are disclosed. The ultimate question still remains: what do study participants substantially understand about the risks of study participation after reading well formulated informed consent forms? Debates also continue about the risks of research and what risks are acceptable (box 2).

The judicial system has had a valuable role in developing 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 sciences, and consumers to help clinicians across a broader range of conversational dilemmas.

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presented his work in informed consent and risk communication at national and international meetings over the past two decades and has written three books on the subject.

Competing interests: None declared.

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Commentary: informed consent and risk communication in France

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As Mazur emphasises, the primary focus of informed consent when interpreted in a judicial context is disclosure of risk. To the uninitiated, it might seem that the notion of informed consent in clinical care in France was discovered only after the law on patient rights and healthcare quality was passed on 4 March 2002.[1] However, this law, which covers individual rights in relation to the healthcare system and rights of users of healthcare, also refers to a far older and complex right: the right to free and informed consent.

Although the Nuremberg Code is often cited in France and elsewhere as the origination of informed consent, French jurisprudence established the need to obtain informed consent as early as 1910.[2] This notion was reinforced by a decree of the French Supreme Court on 28 January 1942 stating that all doctors have a fundamental obligation towards the state to obtain their patients' consent.[3] In 1950, Louis Portes, then president of the French Medical Association, presented a paternalistic reflection on patient consent that later became a reference in the annals of medical law.[4] The 1994 bioethics law[5] and the 4 March 2002 law confirm the notion of informed consent previously established by jurisprudence.

Informed consent in clinical care is a complex issue as it is one aspect of a judicial whole that is much larger than an individual's subjective rights (freedom of thought, conscience, and speech). It encompasses an individual's right to accept or refuse that which is proposed. Obtaining a patient's consent is one form of respecting a person's wishes. This fundamental issue leads to the problem of establishing the difference between people who are legally competent to consent and those who are not.

Informed consent of legally competent people

Everybody must be able to decide on their health care with full knowledge of the facts, just as they may decide not to be treated or not to be informed. Although we distinguish between informed consent in clinical care and clinical research, in both cases the person concerned must consent before the medical intervention is performed. This obligation stems from the Latin adage *Noli me tangere* (do not touch me). Schematically speaking, a person is comprised of two parts: body and mind. As such, a person's body benefits from all protection connected to the person. This line of thought is found in many French,[1 6] European,[7] and international texts,[8] all of which state the need to obtain free and informed consent.

For a patient's consent to be informed, he or she must receive all the necessary preliminary information. Judicial precedents and various other texts specify that it is the responsibility of healthcare professionals to provide this information after evaluating the patient's mental capacities. The 4 March 2002 law specifies that such information must "pertain to … the frequent or severe risks that are normally foreseeable."[1] Nevertheless, as pointed out by Mazur, communication of risk raises other questions: should information be transmitted orally or in writing? how much information is required? will such information increase the patient's anxiety?

For clinical research in France, the National Commission for the Protection of Human Subjects of Biomedical Research oversees the consent of participants, except when a person wants to remain uninformed. This committee was instigated by the Huriet-Serusclat law of 20 December 1988.[9] This law, which is currently being revised, emphasises the need to obtain written consent.

The need for proof of providing information, including risk communication, rapidly became evident to healthcare professionals. In France almost every discipline has since designed informed consent forms to give the patient or to be signed, or both, on the principle that a signed document is the ultimate proof. However, jurisprudence (reinforced by the 4 March 2002 law) favours proof by any means.

French texts sometimes refer to the notion of free and informed consent. Such freedom is directly related to the independence of competent adults. Only the

person concerned can consent to the use of his or her body. But what about people who are not legally able to consent?

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.

Competing interests: None declared.

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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.

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Royal Courts of Justice, London

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."[4] 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[5]: an unreasonable failure to disclose may now render a clinician liable in damages whatever his colleagues declare to be responsible practice. The finer the 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,[6] the clinician in an emergency (and the court when time permits) can ensure that the balance between humanity and human autonomy is maintained.

Competing interests: None declared.

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Risk communication in practice: the contribution of decision aids

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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?

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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[1] and the widespread underuse of these beneficial options.[2] The second is in "preference sensitive" health services, in which the ratios of benefit to harm are either uncertain or dependent on patient values[2]—participation of patients improves quality of decisions and prevents overuse in the subset of informed patients who don't value the options.[3]

We investigated practical and effective approaches that doctors and practitioners can use when counselling 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.[w3 w7]

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 services[2 w1]
- Classification schemes for evaluating health services according to the strength of scientific evidence and the magnitude of ratios of benefit to harm[4 5]
- Recent reviews of decision support interventions for "effective" care decisions[1 6–14]
- Cochrane systematic review (2003 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 efficacy[3]
- Reviews of papers describing patient centred communication[15–18 w2] and evidence based patient choice[w3-w6]
- 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