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.

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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.

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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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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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