Informed consent in medical practice

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How much information does a patient need in order to give full informed consent? The authors explain the ethical reasoning behind the introduction of public reporting of clinician performance data.

‘Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages. This is true except in cases of emergency, where the patient is unconscious and where it is necessary to operate before consent can be obtained.’

This was the judgement of Benjamin Cardozo in the case of Mary Schloendorff v the Society of New York Hospital in 1914.

The plaintiff, Mary Schloendorff, was admitted to New York Hospital and consented to being examined under ether to determine if a diagnosed fibroid tumour was malignant, but withheld consent for removal of the tumour. The physician examined the tumour, found it malignant, and then disregarded Schloendorff’s wishes and removed the tumour.

The court found that the operation to which the plaintiff did not consent constituted medical battery. Unfortunately for the plaintiff, the judge also ruled that the Society of New York Hospital (in effect the management board) was not responsible for the actions of the doctor and the case failed.

CONSEQUENCES OF ‘UNINFORMED CONSENT’

However, in the 1930s and 1940s, experimental studies were carried out on volunteers who had not given consent, and had certainly not given informed consent. In fact, the most infamous of these experiments, the Tuskegee experiment, continued until 1972, with regular published medical reports.

The problem for the medical establishment was converting the legal judgement of Cardozo into ethical principles that could be used to guide medical behaviour. The principle enunciated, initially for medical research but later for medical practice, was ‘autonomy’. It was the first of the ‘four principles’ of medical ethics and related to the right of the patient to give consent for medical treatment and the obligation of...
the medical practitioner to obtain consent for treatment.

The ‘principle’ has become embedded in medical and managerial practice, such that consent forms for treatment and consent forms for withdrawal of treatment are now commonplace in patients’ notes in many countries. Without these documents, treatment and care grinds to a halt under the threat of legal action from patients or their relatives.

**INFORMED CONSENT**

Consent is a pivotal issue in patient management and care, but a significant extension to the principle of consent then arises, which is ‘full informed consent’. The question being raised is ‘How much information does a patient need to give full informed consent?’

Some jurisdictions had assumed that complications occurring at the level of 1 in 1000 treatments needed to be included in the consent process. However, the novel approach of the Australian High Court was to include any potential complication that might occur if the patient attached significance to the complication. This re-emphasised the importance of the patient–doctor relationship in the consent process and highlighted the shortcomings of lists of complications associated with frequency ranges that had been used to inform the consent process.

However, the expectation of the healthcare consumer (previously patient) continued to advance, and separate events on different sides of the Atlantic combined to influence public and professional debate in this area.

In New York State, Mark Chassin initiated the seminal Cardiac Surgery Reporting System, which confirmed that merely by compulsory collection of outcome data and feedback of the risk-adjusted results to the practitioners, the reporting system could achieve a 40 per cent reduction in risk-adjusted mortality for coronary artery surgery in three years. This was thought to be an isolated finding until another Eastern US project confirmed that the voluntary feedback of risk-adjusted mortality data in cardiac surgery achieved the identical result.

The consequence in New York State was that Newsday (a current affairs programme) applied to the State Department of Health to publicise the information in the data collection. The argument on one side was that the public had a right to the information and on the other that the data collection would be compromised by the release of the hitherto confidential information. The judge empathised with both arguments, but found in favour of Newsday and released the database to the television programme. The next day, crude (not risk-adjusted) mortality rates for adult cardiac surgery appeared in the daily newspapers, but the data collection continued. It seemed that the public had a right to know the outcomes of medical procedures irrespective of the consequences for ongoing data collection to provide the figures.

In the UK, the enormity of the Bristol cardiac scandal was breaking over both the medical profession and the public, influencing the future of medical regulation and medical management. The case heralded the end of ‘benevolent paternalism’ as an option in the doctor–patient relationship, medical management and consent, but also stimulated healthcare consumers to demand more information on treatment outcomes at the time of giving consent.

**FULL INFORMED CONSENT**

The alignment of these influential healthcare events with the Australian High Court judgement led two ethicists from that country to embark on a study of ethical requirements for the surgical consent process. Using the information available from the North American Cardiac Surgery Databases and a series of structured interviews of clinicians in different countries, Justin Oakley and Stephen Clarke published their results in the *Journal of Medicine and Philosophy*.

However, the clinical relevance of their conclusions must not be overlooked, in spite of their publication in a philosophical journal. Clarke and Oakley concluded that a surgeon could not obtain ‘full informed consent’ and a patient could not give ‘full informed consent’ for a procedure if the surgeon could not provide the patient with the success and complication rate of the procedure* in his hands and also in the hands of his local and distant colleagues.* This conclusion appeared at odds with the current consent processes in modern healthcare, but flowed naturally from the New York State Court judgement, the ramifications of Bristol and the evolution of consent processes.

It was a small hand grenade delivered into the surgical world and required urgent consideration. This was provided in an analysis edited by the two ethicists, entitled ‘Informed consent and clinician accountability’. The authors assert that ‘A proper assessment of the issues raised in this volume requires drawing on expertise in philosophy and bioethics, along with expert knowledge of factors influencing surgical performance, clinical practice, the measurement and reporting of healthcare outcomes, relevant studies in healthcare quality and safety, professional regulation, and practitioner and consumer views on report cards.’

The arguments expounded are around the benefits and adverse consequences of public reporting of clinician performance extending into the murky areas of medical as well as surgical outcomes and their assessment. Extending the consideration of information or knowledge...
from the acute hospital sector to primary care and community settings emphasises the challenges in this radical approach to healthcare information management. However, difficulty in managing change is not a robust argument for refusing to change, and this axiom is repeatedly raised in the collection of papers. The reasoning employs three arguments for public reporting of outcome data. The first is autonomy-based arguments to conclude that surgeon performance information should be published to inform patient decision-making. The analysis also accepts that the public reporting of surgical performance is an international phenomenon and not contrary to intuitive professional or ethical frameworks.

The second strand of the argument is that the public reporting of clinician performance data is based on the ethical obligation that medical professionals have to the public. This would conform to the beneficence principle of the 'four pillars' of medical ethics.

The third strand of reasoning for publishing clinician performance is that the process improves the overall quality and safety of care. This would also represent beneficence and the three strands would be included in the expression of wisdom and conscience if a virtue ethics moral philosophical approach was applied.

Although initially resisted by the profession when they were first proposed, Florence Nightingale’s and Ernest Codman’s attempts at audit are now accepted without demure. The conceptual leaps that we are left to make are around risk adjustment of the figures and public disclosure, but the need for data collection and feedback is already decided. I believe that surgeons have always understood this better than physicians and are professionally prepared for comparisons on performance. However, the bigger challenges will occur in the practice of hospital-based physicians and primary care physicians, where meaningful comparisons in the public domain are difficult to find.

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REFERENCES