It's a matter of consent

Neil Saunders outlines research he undertook around the area of patient consent.

What do you do if a patient withdraws consent mid-way through an examination?

Introduction

The NHS and the allied healthcare professionals have transferred control from themselves to the patient, thereby empowering the ultimate consumer to have complete autonomy on how their diagnosis, care and treatment are managed.

It is a fundamental human right to have control over one's destiny. Giving sufficient information to a patient can allow them to make an informed choice as to whether to refuse or accept a proposed examination or treatment, as seen in Sidway v Bethlem Royal Hospital Governors[1] (see Case Study 1).

Empowerment can take many shapes and forms. An area central to the patient population, and now central to clinical practice, is that of consent. This has been espoused as a judicial concept since a British case in 1767 (Slater v Baker & Stapleton[2] – see Case Study 2). The ratio decidendi of the case was that obtaining a patient's consent was customary, and should be obtained as part of the duties of a professional practitioner.

There is much confusion and misconception surrounding consent, as is shown in legal dictionary definitions as well as the multiple descriptions and definitions given in legal cases.

Human Rights Act 1998

On 2 October 2000, the Human Rights Act 1998 came into force, incorporating the articles of the European Convention on Human Rights into our law in England and Wales. The Act:

- Requires all public authorities to implement the articles of the European Convention on Human Rights;
- Gives a right to anyone who alleges that a public authority has failed to respect those rights to bring an action in the courts of this country[3].

Although the articles do not cover consent specifically, some of the articles relate to issues that arise from the laws on consent. These are:

- Article 2: Right to life
- Article 3: Prohibition of torture
- Article 5: Right to liberty and security
- Article 8: Right to respect for private and family life.

A healthcare professional who falls below the standards set, and who does not respect the principles of autonomy, may be liable to both

legal action by the patient and disciplinary action by their respective regulatory or professional body. This may also leave open a claim to the employing bodies that are liable for the action of their employees[4], which may in turn leave a radiographer to be sued by their employer (vicarious liability).

The Health Professions Council (HPC), which sets standards and competencies for registered radiographers and other allied healthcare professionals in the UK, states that registrants must '*be able to maintain confidentiality and obtain informed consent*'[5]. As radiographers are professionally qualified practitioners, they are in a position to quantify the risks involved. However, the value placed upon that risk cannot be informed, since the likelihood of it occurring is only one of a number of factors that go into a patient's analysis of their own position.

Every healthcare professional has to work within the laws of the country in which they are practicing, so they have to know the basic legal principles that constrain or empower them. They also need to have a clear understanding of when it becomes essential to bring in legal advice and support. Ignorance of the governing law is no defence to either civil or criminal actions, and professional practice requires that practitioners have a good understanding of the way in which the law both enables and restricts them to perform their duties safely and professionally.

If a mentally competent person has freely given valid informed consent, then they have the right to withdraw that consent at any time, providing that they are still mentally competent[3]. If an examination or treatment is in progress and consent is then withdrawn, the Department of Health suggests that it is good practice for the practitioner to establish the patient's concerns and explain any of the circumstances for not completing the examination or treatment[6]. A case involving the withdrawal of consent is that of Ciarlariello v Keller[7] (see Case Study 3 overleaf) and a more recent one is that of Evans v Amicus Healthcare Ltd and others[8] (see Case Study 4 overleaf).

CASE STUDY 1
Sidway v Bethlem Royal Hospital Governors (1985)[1]

Mrs Sidway underwent an operation for a recurring pain in her neck, right shoulder and arm, performed by a senior neurosurgeon at the Royal Bethlem Hospital. There was a 1-2% risk of damage to the spinal nerve root and the spinal column. Although the risk of damage to the spinal column was less than to the nerve root, the consequences were more severe.

The plaintiff was left severely disabled after the operation. She brought a negligence claim against the surgeon, saying that she had not been given adequate warning of the risks. During the hearing, it was revealed that while the surgeon had told her of the risks of damage to the nerve root he had not told her about the risk to the spinal column. In acting in this way, he was conforming to what, in 1974, would have been accepted as standard medical practice by a responsible and skilled body of neurosurgeons.

The House of Lords rejected the claim. An 'informed consent' approach was rejected by all the Law Lords, except Lord Scarman. Some support was given to the suggestion that the test which a court should use in deciding whether the advice given was negligent was the same as that used in deciding whether medical treatment was negligent – the Bolam test, which says that a healthcare practitioner 'is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men'.

CASE STUDY 2
Slater v Baker & Stapleton (1767)[2]

The physician in this case 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 about what should be said to patients before an experimental intervention, as opposed to a clinical one.

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. It was much later that the notion of information became linked to consent.

Obtaining consent

It should first be noted that there is an assumption of competency/capacity for every adult, unless it has been rebutted by a qualified psychiatrist, or through a state of unconsciousness. Obtaining consent should not be viewed as an isolated event, and should be seen as a continual process, shared between the practitioner and the patient. During the consent process, practitioners should remain emotionally detached/impartial so as to allow the patient's decision/choice to be made voluntarily.

The information, when presenting the risk, benefits and alternatives to the patient, will have a greater resonance if it is put into the context of their expressed objectives. Risks were quantified by lawyers[11] at a level of 1:100,000, which HPA guidelines state to be minimal to very low risk. This level of risk should be held as a gold standard when giving reference to risk because it can be easily quantified either in terms of natural radiation days or in terms of risk of a malignant change.

Just providing information is not sufficient – a patient needs to have an understanding of the information in order to make an informed choice/decision. The practitioner has to take into account the ability of the patient to comprehend what s/he has to say – if a patient has not understood, they cannot be said to have given informed and valid consent.

If a patient refuses the examination after explanation, check their understanding, and try to address any concerns. If the patient still refuses the examination, you cannot proceed. Do not be forceful in your approach as consent obtained under duress is invalid.

If the patient withdraws consent during the examination, it must stop, and concerns addressed. If the patient does not consent again, the examination will have to be discontinued. It is noted that the patient is autonomous and has self-determination; therefore, s/he is free to make any choice, even if it is seen to be irrational.

Communication skills

It is recognised in Scott et al[12] that expressed and implied consent are both valid forms of consent. However, the consensus is that the ideal level of consent is that of informed consent. Professional or responsible bodies, ie, the General Medical Council (GMC), Nursing and Midwifery Council (NMC), and the Health Professions Council (HPC), all produce their own guidelines on obtaining consent and

CASE STUDY 3
Ciarlariello v Keller (1993)[7]

In the course of a medical test, an angiogram, administered after full explanation, the patient became agitated and asked for the test to be stopped. After 10-15 minutes, the test was resumed and the plaintiff suffered a severe injury of a very rare sort from the resumed test.

The trial judge found that, once she had calmed down, the plaintiff 'did agree to the final injection and the completion of the angiogram'. He had held that there was no need for a new explanation of the risks and benefits of the test, and that 'whether or not to continue the test is really a matter of medical judgement'. He accordingly dismissed the plaintiff's action for damages.

An appeal to the Ontario Court of Appeal having been dismissed, the plaintiff appealed to the Supreme Court of Canada.

CASE STUDY 4
Evans v Amicus Healthcare Ltd and others (2004)[8]

Ms Evans and Mr Johnson, anticipating the imminent infertility of the former, entered into an agreement to provide eggs and sperm and to fertilise them to form embryos, with a written form justifying the mutual consent. However, the relationship ended and Mr Johnson withdrew his consent to the subsequent operations and stated that embryos could be destroyed.

The decision of the court was highly controversial, determining that withdrawal of consent by one of the genetic material providers may only result in consent being rendered 'inoperative'. Bilateral consent is needed for implantation, not simply to the taking and storage of genetic material, and that need cannot be met if one half of the consent is no longer effective.

yet all professionals are bound by the same duty of care and legal expectation. Whether the practitioner is an assistant practitioner, radiographer or doctor, the time, consideration, sensitivity, understanding, and level of consent should be universal.

The consent process can also be seen as a fundamental communication skill, which should be taught, enhanced and instilled into practitioners at an early juncture in the respective training programmes (author's beliefs). As in the Bolam test, all practitioners are judged (in consent terms) by that of a responsible body of professionals (ie, other practitioners). As patients' expectations increase, so will the level consent (through education and evidence based practice), thereby increasing the level of proof/burden.

Radiographers should not wait for pressure to be exerted upon them by professional/responsible bodies, nor from the threat of legal action. They should work in partnership with patient groups, learn from past experiences, and individual patient feedback. This is essential, because there has been minimal research inclusive of patients, and the necessity to establish patient needs[11,13].

Areas of uncertainty

Consent itself can be said to be uncertain, due to it being founded on precedent and therefore susceptible to change via the courts, rather than by any Act or Statute. However, there are areas that have a greater uncertainty, primarily due to the lack of research and explanation. One such area is that of refusal or withdrawal of consent. This is covered in legal textbooks and journals, but literature aimed at healthcare professionals fails to cover this topic in any great detail. In most cases, no reference has been made as to the patients' rights in this area. Another area of uncertainty is that of the volume/nature of information given to patients. Throughout the literature, there are discrepancies. Some authors define risks in terms of quantifiable information[11], whereas others have left the level of information in an interpretive state with descriptive words such as 'sufficient' or 'reasonable.' Ultimately, if there is a dispute, the decision as to whether the information provided to a patient is 'sufficient' or 'reasonable', will be taken by the courts.

To date, no cases involving radiographers through either background research or via the literature review have been found. Thereby, the tenuous position of the radiographer has not been challenged through legal proceedings. However, as current practice stands, and noted in Mathers et al[11], informed consent for examinations is seldom obtained. Therefore, as patients become more aware of their rights, practices have to be questioned and altered. It may only be a matter of time before a health professional finds themselves charged with battery.

Recommendations

There is a dearth of literature relating to consent and the consent process. This has been recognised by both Mathers et al[11] and Leino-Kilpi et al[cited in 12]. This has led to a lack of empirical data and it is difficult to assess the current level of knowledge held by healthcare practitioners, but also the degree to which patients are informed participants in the consent process. Therefore, studies in the following fields would be a firm recommendation (also recognised by Duman and Charnock[cited in11]):

- Patients' uptake of information
- Their perception of its value, and the extent it adds to their knowledge base; and
- How it influences their preconceived constructs.

Also, in conducting primary research in the field of consent, the author believes that a national survey of radiology departments and radiographers should be conducted to establish the current level of awareness and practice by both parties. This information could then be analysed in conjunction with the legal framework (current at the time). This would allow a snapshot of radiology consent practices to be formulated, which would be invaluable. A national survey would also show any regional variation of practices. If current practices are falling below legal standards, measures/recommendations should be introduced to address the situation.

About the Author

Neil Saunders is a radiographer in functional MRI at the Medical Research Council – Cognition and Brain Sciences Unit, which looks into a number of conditions. Recent research has involved patients in a vegetative state, which made national news in the latter part of last year for its pioneering research.

This research was undertaken for a BSc from Suffolk College, validated by the University of East Anglia.

References for this article are at: www.sor.org/members/pubarchive/pub_search.htm