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Original Article

The consent process in radiotherapy

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Abstract

Over the past two decades The Department of Health has made the *consent process* one of its main focus and has issued numerous guidelines on how the process must be conducted in order to make it valid. This mandate has been in accordance with the new patient-centred health service, which has patient autonomy as its fundamental standard. This paper will critically appraise the consent process in a radiotherapy department against the Department of Health's recommendations. The ethical and legal principles governing the process will also be discussed using guidance from medical professional bodies and reference to English case law. Additionally, the function of written consent and consent forms will be assessed in order to establish whether implied or oral consent has any role in radiotherapy. The paper found that to a large extent the Department of Health's recommendations are followed in the radiotherapy department evaluated. One key outcome arising from this paper is that written consent is the most appropriate form of consent in radiotherapy; however the record of consent should not be solely confined to a consent form. Rather it is critical that adequate notes of all areas of the dialogue that took place during the consent process with the patient should be written in the patient's medical notes.

Keywords

consent forms; consent process; radiotherapy

INTRODUCTION

Consent to medical treatment is a developing doctrine and not a static set of rules.[1] Over the past two decades, The National Health Service has witnessed a shift in paradigm from traditional medical paternalism to patient autonomy. This shift may be deemed a direct resultant of the Department of Health's mandate to create a health service that has all aspects of patient care as its primary foci; and in doing so provide *patient-centred care*.[2] A facet of the *New NHS* and its patient-centred care comprised a review of the whole *consent procedure*. In keeping with its precept, the Department of Health issued a reference guide to health professionals who take consent.[3] The reference guide outlines what the consent process should entail and highlights the importance of patients receiving sufficient information in order to facilitate consent, as one of the key aspects in the procedure.[3]

This paper will seek to take a close look at the consent procedure in the authors' radiotherapy department and analyze the procedure against the reference guide given by the Department of Health.[2,3] In addition the consent process will be critiqued in view of the ethical and legal principles governing the process. References will also be made to related studies conducted by other reserchers.[1,4,5,6] Consent modalities in terms of implied, oral and written will be examined in

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order to establish the role of written consent forms in radiotherapy. It is important to verify here that reference to the consent process in this paper will be done in terms of an adult patient with sufficient mental capacity who is fully competent; therefore consideration will not be given to adults lacking capacity and children. The decision to limit this discussion to only adults with full mental capacity was made in order to give scope to this paper, and also because only adult patients who are fully competent are treated in the authors radiotherapy department.

THE CONSENT PROCESS

In formal terms the consent process embodies the *ethical* and *legal* principles that is the fundamental right of a patient to determine what happens to his or her own body.[3,4] The law recognizes that the patient has a right to self-determination and that health care professionals have a duty of care, and should therefore provide sufficient information to allow patients to make choices about their care.[7] Having these choices is critical to validating consent. When consent is given it may be viewed as an agreement, which indicates that a patient is willing to undertake invasive procedures and accept care from health professionals. The consent process has been put forward as a core clinical activity, fundamental to patient care, best practice and clinical governance.[4] And should therefore form a part of the framework through which organizations continuously improve the quality of their services. The consent procedure should be undertaken in all aspects of patient care. The two primary principles of the consent process indicated above will now be discussed in view of an adult patient with sufficient mental capacity.

Ethical principles

The Department of Health dictates that ethically, patients have a right to obtain information about their condition and the treatment options available to them.[2,3]

In recognition of patient's right and respect of the patient, it is critical that health professionals seeking consent promote the empowerment of patients by providing information about the patient's proposed care path. Effective communication is key to enabling patients to make informed decisions.[7] The information offered to patients must therefore be clear and understandable in order to enable patients to make a decision about his or her care. It is imperative that health professionals obtaining consent use the Departments of Health's guide and find out what patients need to know, and find out from patients what they desire to know about their diagnosis and treatment options.

In Radiotherapy there has been some debate as to the detail of the pre-consent information offered to patients. A survey examining the information given to patients about adverse effects of radiotherapy before commencing treatment, concluded that the information requirements among patients can vary widely; and that it is difficult to predict how much information patients feel they need before giving consent.[5] The information that is provided will need to take into account the patient's age, language and preferences. In Appendix B of the *Statements for Professional Conduct* written by the College of Radiographers concerning consent, it clearly states that patients must be presented with sufficient information in a manner that is user friendly and in a form they can understand and *that is appropriate for the examination or treatment that is to be undertaken.*[8] The General Medical Council advocates that the amount of information you give to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patients own wishes.[7] In radiotherapy, a wide range of malignancies with varying treatment intent are treated. The site and treatment intent will invariably result in a broad spectrum of different types of side effects that will have varying degrees of toxicity and morbidity. When the above statements by the College of Radiographers and the General Medical Council are considered, it can be argued that consent in radiotherapy should be site-specific and the information offered to patients should be tailored to the area on the patient's body that will be treated.

In our department it is our practice that the consultants obtain site-specific consent, completing and signing, and having patients sign the

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relevant site-specific consent form. Information regarding serious and frequently occurring risks for the site to be treated is discussed with the patient during the consent procedure, and written indication of this is recorded on the consent forms. The intended benefits of the treatment are also outlined. Palmer has proposed that this alone is not sufficient and that notes of the questions asked by patients and of the nature of the explanation given to patients are recorded in patient's medical notes.[1] Perhaps this is a recommendation that should be instituted because the Department of Health specifies that a part of a patient's right is to ask questions and have them sufficiently addressed.[3] Record of this may become particularly crucial if a patient complains or decides to pursue litigation.

Legal principles

As health professionals we must be fully aware that we currently practice in a litigious culture. One health professional group highlights that 'one of the reasons for seeking consent is to provide those concerned in the treatment of patients a defense to a criminal charge of assault or battery or a civil claim of damages of trespass to the person'.[9] This statement may seem profoundly harsh and may be said to indicate a departure from the traditional 'doctor knows best' and the 'anything the doctor says' culture. It is however a reality that patient will undertake litigation if they believe they that their rights have been breached in any form, whether through negligence, trespass or battery. We shall see in the case law presented below that due to the nature of the consent process, legal proceedings primarily result from disagreement over the amount and quality of information provided. As a result charges of negligence are the major category of litigation brought against health care professionals seeking consent.

In English law the courts believe that doctors have a duty to warn positively about material risks and to answer truthfully any question put to them by patients.[1] The cases that will now be examined demonstrate that the consent process presents a platform for doctor/health professional to exercise their duty of care, and any negation of this duty has the potential to result in litigation against the health care professional administering care.

In the case of Bolam v Friern, the plaintiff brought a charge of negligence against a consultant because he was not warned of the very unlikely risk of fracture that may occur when undergoing electro-convulsive therapy.[10] The risk of fracture occurring was in the order of 1 in 10,000.[10] The courts ruled in favor of the consultant and decided that the consultant did not breach the legal standard of care and was therefore not negligent because a responsible body of similar professionals supported the practice of not telling the patient about the one in ten thousand risks. This case helped to set the precedence for similar cases in England and heralded the introduction of the Bolam principle/test. The Bolam test in its simplest form states that a medical practitioner does not fail to reach the standard of care if a responsible body of similar peers supports the action in question.[11] The Bolam principle relies heavily on the judgment of other medical professionals.

More recently there have been significant changes in the legal standard of care to an approach where the court will take a more enquiring stance to test the medical evidence offered by both parties in litigation, in order to reach its own conclusions.[11] This approach has been coined the *Bolitho approach* because it was manifested in Bolitho v City and Hackney Health Authority case.[12] It has been suggested that the *Bolitho approach* marks a judicial move at the highest level to shift the balance from excessive reliance on medical testimony to a court based verdict.[11] This revised approach is significant and may viewed as a methodology by the government to mold the legal principles of the consent process into the *New NHS*. One document writes that the Bolitho approach is within the framework of patient-centred care as it represents a shift from the traditional 'accepted practice' to one where the standard of care is set by the court on the basis of 'expected practice'.[11]

The case of Chester v Afshar follows that Miss Chester underwent surgery to remove three intervertebral discs.[13] The surgery was done by Mr Afshar, who failed to inform Miss Chester

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of the small risk (1–2%) of cauda equina syndrome associated with such surgical interventions. Miss Chester subsequently developed cauda equina and was rendered paralyzed. The House of Lords, by a majority of 3:2 reached a decision that lack of knowledge of this particular risk denied the patient the chance to make a fully informed decision. In essence it was argued that had the patient received adequate information concerning the adverse effects of surgery she would have been equipped to make a decision whether to undergo or forego surgery. The ruling by the courts in this case emphasizes the magnitude of the extent of information, especially about adverse side effects, that should be given to patients before consent is sought. As a result of this case The NHS Litigation Authority recommended that *'careful and comprehensible warning about all significant possible adverse outcomes must be given'*.[13]

The Chatterhorn v Gerson case is another vital illustration of the consequence of incomplete pre-consent information. Mrs Chatterhorn underwent surgery for a painful scar in the right leg subsequent to consent, during which the patient was informed in general terms of the nature of the surgery.[14] The operation was performed twice unsuccessfully and the patient was left with complete loss of sensation in the right leg and was unable to walk without a stick.[14] The patient sued Mr Gerson (the surgeon) for negligence and trespass.[14] The presiding judge ruled that 'In my judgment once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of the action on which to base a claim for failure to go into risks and implications is *negligence*, not trespass. Of course, if information is withheld in bad faith, the consent will be vitiated by fraud'.[14]Like the aforementioned cases the issue of inadequate information in this case formed the premise for the law suit. It must be noted that due to the nature of consent under English law *express consent* applies as opposed to *informed consent* therefore only charges of negligence will hold any credence in court once the patient is informed of the general aspects of a medical intervention.

The cases mentioned above illustrate the value of the information given to patients during the consent procedure and demonstrate how litigation against health professional can arise, especially when information concerning low probability side effects is not given. In radiotherapy researchers have identified that there is a wide variation in the quantity and quality of information given to patients before consent is sought.[5] These researchers found that of a population of 82 patients surveyed, 44% wanted to be informed of a 0.1% risk for severe side effects, whereas 16% only wanted to be informed if the risk was either 50 or 100%. If this is taken as a representation of the extent of information generally required by radiotherapy patients, it may be said that a significant majority of patients expect information about uncommon, low probability side effects. The study concluded that a patient-centred approach must involve tailoring information to individual patient requirements.[5] It may however be challenging for health professionals to decide on what information patient's desire and this may account for some of the disparities seen in the information given.

In our department site-specific consent forms are used. These forms outline the various side effects relevant to the site to be treated. It may be argued that this is one way of ensuring that all patients receive the same information from all the consultants about the side effects (low risk and high risk), that may result from their radiotherapy treatment. This practice permits commonality in the information offered during the consent process in our department. It may be further argued that is view of Bolam's principle this commonality may prove vital if the legal duty to inform patients is considered in a court of law. At the same time it must be remembered that with a seemingly judicial shift towards Bolitho, commonality in the consent process holds less credence.

Forms of consent

The Department of Health reference guide outlines that 'the validity of consent does not depend on the form in which it is given; written consent only serves as evidence of consent'.[3]

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The Department of Health further elaborates in its 12 key points on consent, that consent can be written, oral or non-verbal.[15] The document also states that a signature on a consent form does not itself prove the consent to be valid—the point of the form is to record the patient's decision and also increasingly the discussions that have taken place. Other authors lends credence to this in stating that written consent is neither sufficient nor necessary for valid consent and need not be set out in any specific form.[16]

An evaluation of these arguments may suggest that there is no definitive role for consent forms, as the consent modality is irrelevant. What is of great consequence is that patients have been equipped with sufficient information to make an informed decision about their own care.

In our department one of the checks done by radiographers before a patient begins their course of radiotherapy is to ensure that the 'consent form is signed'. I think I can safely say that is rhetoric throughout many radiotherapy departments. I have worked in departments where radiographers have refused to treat patients because the consent form could not be found. And the patient was only treated after a new consent form was signed. Could it be argued that the fact that the patients has freely attended for treatment and is willing to climb onto the treatment couch and receive treatment is enough evidence of consent? Fleming wrote that that if a patient is aware of the procedure and the likely consequences and does not register any protest at imminent intervention, then the patient's consent has been given by implication.[17] Is there then a role for implied consent in radiotherapy? And can oral consent from a patient be sufficient to deliver radiotherapy treatment to that patient?

The Medical Defense Union states that written consent is required if patients are to undergo general anaesthetic, minor operations, invasive procedures or where potentially hazardous investigative techniques or treatment is used.[17] The College of Radiographers have also stated that it is essential that written consent is obtained for all cancer care procedures.[8] Radiotherapy is classified as a potentially hazardous cancer treatment, the opinion can therefore be drawn that implied or oral consent cannot be applied in radiotherapy. Rather the traditional written consent is the most appropriate modality.

CONCLUSION

This paper has demonstrated that the consent process for an adult with full capacity in the authors' radiotherapy department does to some degree follow the Department of Health's guidelines. Additionally, the general ethical and legal principles governing consent are adhered to. However there are deficiencies in terms of the record of consent, as patients' questions and the explanations given are not documented. This paper has also shown that the information offered to patients' in the consent process is of fundamental importance, as it is the right and desire of patients to receive detailed, understandable information about their proposed care, the advantages and disadvantages before they make a decision about their own care. Moreover if a health care professional does not provide comprehensive information about an intervention and the associated risks, charges of negligence may be brought against that health care professional if the patient suffers from a side effect of the intervention that was not discussed. With the departure from the Bolam principle towards Bolitho, the courts are now relying more on a judicial assessment of reasonableness as opposed to a medical one. This demonstrates that the courts are advocating the patient-centred focus of the new health service. Health professionals seeking consent must be mindful of this and know that the testimonies of their counterparts may no longer be relied upon in legal matters.

It has been shown that the role of consent forms in radiotherapy is established, written consent is indispensably the most appropriate form of consent due to the potentially hazardous nature of radiotherapy treatment. It must however be remembered that intrinsic rudiments such as adequate information, patient free will and capacity must apply in order to make consent valid.

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