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Original Article

Consent and information giving in radiotherapy

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Abstract

This paper explores some of the issues around implementing a consent policy within the radiotherapy department. Consent can be defined as a patient's agreement for a health care professional to provide care. The NHS Plan[1] highlighted the need for quality care centred around the patient and for changes in the way patients are asked to give their consent to treatment. This led to the Department of Health (DoH) publishing a Good Practice in Consent Implementation Guide (2001)[2] for use within all NHS Trusts from 1 April 2002, which aimed to provide consistency across the NHS and provides a policy model and generic consent forms.

The policy recommends that the health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done, as it is they who would be held responsible in law should a case be made by a patient against a health professional. In radiotherapy, it is the Clinical Oncologist who obtains consent as they are responsible for prescribing courses of treatment; however, it is the Radiographer's role to deliver this treatment. This paper discusses some of the issues around implementing a consent policy in terms of who can give and confirm consent, and what are the requirements for training if the patient is to receive the appropriate information before making the decision to consent to treatment.

Keywords

consent; consent policy; patient information; radiotherapy

INTRODUCTION

Consent as defined by Gillon[3] is 'a voluntary, uncoerced decision made by a sufficiently competent or autonomous person on the basis of adequate information and deliberation, to accept or to reject some proposed course of action which will affect him/her'. The Bristol Royal Infirmary Report[4] into paediatric heart surgery supports this by concluding that what consent is not, it is a signature on a form: it is the outcome from a process of communication between clinician and patient over the nature of the treatment and investigations proposed and the risks and benefits that could occur. It is a continuing process that can be withdrawn by the patient at any time, even after the patient has signed the consent form. It is widely accepted that communication should be a two-way process, and the patient's questions should be answered fully and honestly. The DoH Reference Guide on obtaining consent[2] states that the clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins, although the consultant responsible for the patient's care will remain

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ultimately responsible for the quality of medical care provided. The General Medical Council guidance states that 'the task of seeking consent may be delegated to another health professional, as long as that professional is suitably trained and qualified'. This obviously has implications for training and competency standards within each department, and in this paper the author will attempt to investigate these issues, taking into account the varying levels of staff grades engaging in information giving to patients and their carers.

WHY DO WE NEED CONSENT IN RADIOTHERAPY?

Gillon's definition of consent makes particular reference to being given adequate information, and Dimond[5] adds weight to this by saying that information must be given to the patient about any reasonable foreseeable risks of harm, which could occur even if all care were taken. This is particularly relevant in radiotherapy where the use of ionising radiation is known to have a biological effect on nuclear DNA with consequent permanent damage to genetic material.[6] Treatments are planned with extremely high levels of accuracy, and treatment volumes kept as small as practically possible to minimise the dose to the surrounding normal tissue, but chronic effects do occur and the patient needs to be aware of the risks involved in receiving radiotherapy. It is important that staff groups giving information to patients are competent in doing so, and that they understand the rationale behind the possible side effects. However, it is not only in radiotherapy that such rationale needs to be understood, and furthermore, as Aveyard[7] with reference to nursing procedures states: 'it is often assumed that consent is required only prior to major medical clinical interventions or where an intervention presents significant risk to the individual'.

This means that nurses have to be aware of a patients' autonomy in all nursing care procedures, not just the major ones, as patient autonomy may be infringed by some, but not necessarily all, nursing care procedures. Such examples could be bed bathing or asking patients to remove items of clothing, which are necessary procedures and hence justifiable. This is often mirrored in radiotherapy where there are some procedures where patients might be seen to lose their autonomy without giving informed consent, for example, the removal of clothing to access the treatment area. Again, this could be seen as an infringement of a patients' autonomy, but is justified in ensuring accurate treatment delivery.

CONSENT AND THE HEALTH CARE PROFESSIONAL

The Society and College of Radiographers (SCoR) in March 2002 published Statements for Professional Conduct that provides guidance to all levels of Radiographers (including assistants and students) on the high standards of behaviour required to maintain the professions' integrity and reputation. Statement 2 reads: 'Radiographers have a duty to work in a co-operative and collaborative manner with other professional staff and carers in the interests, and with the consent, of their patient(s) except where there is a legal requirement to do otherwise'.[8] While the SCoR supports the multidisciplinary aspect of cancer care, there is also reference being made to the need for consent from patients, and Appendix B of the document provides Radiographers with supporting information relating to consent and the implications for future practice. But is this enough? If the requirement for consent is so fundamental to the process of radiotherapy, then should not the professional body be doing more to actively support its members in this complex issue. A study by Houghton et al.[9] found that 37% of the junior doctors questioned admitted to obtaining consent for procedures of which they had little understanding. Understanding here means understanding of the procedure, but I would argue that also in question here could be the understanding of consent itself, as the patients could not have been given the most adequate information in order to make an informed decision.

WHO SHOULD OBTAIN AND CONFIRM CONSENT?

Newcastle Upon Tyne Hospitals NHS Trust's policy for Consent to Examination or

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Treatment[10] is a comprehensive guide, and states that the health professional carrying out the procedure is ultimately responsible for ensuring that the patients is genuinely consenting to the procedure being carried out. The Trust policy stipulates that if a treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side effects' or complications) then written consent is needed prior to the procedure taking place, and the standard consent forms provide a space for a health care professional to provide information to the patient, and also to sign to say that this has been carried out. In order to promote good practice within the NHS and improve the consent procedure for both patients and health care professionals, the Department of Health consent policy[11] provides four model consent forms for differing situations:

- Consent form 1—patient agreeing to investigation or treatment, for patients able to consent for themselves
- Consent form 2—parental agreement to investigation or treatment, for those with parental responsibility, consenting on behalf of a child or young person
- Consent form 3—patient/parental agreement to investigation or treatment, both for patients able to consent themselves and those with parental responsibility where the procedure does not involve any impairment or consciousness
- Consent form 4—patients who are unable to consent to investigation or treatment, for use when the patient is an adult unable to consent to investigation or treatment

In addition, the local departmental policy for consent to radiotherapy is as follows:

- The Consultant Clinical Oncologist (CCO) or Specialist Registrar (SpR) has initial discussion with patient regarding the procedure itself, the intended benefits and the serious or frequently occurring risks associated with treatment. This usually takes place in the peripheral clinic, and is signed and dated by the patient and the doctor.
- When the patient attends for either imaging or treatment, the consent is confirmed before the procedure takes place, that is if the patient still wishes to go ahead with radiotherapy.

Note that the information-giving process does not take place for a second time, only that the wishes of the patient remain as they were when the original consultation took place, and that consent is still being given by the patient. The time delay between procedures 1 and 2 depends on the current waiting list for radiotherapy, but undoubtedly the relevance of information will have changed during that time. This may mean the patient needs further information in order to be able to make an informed decision about consent.

Procedure 2 can be completed by a Radiographer of any grade, including students and assistant practitioners.

The Trust policy includes a paragraph that allows for students and assistants to confirm consent. It reads: It will be appropriate for any member of the health care team to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves. This effectively allows students and assistants to complete the confirmation of consent. Some might argue that this is unacceptable as they are not qualified or registered; but if we consider the training and education these groups have, then the author suggests that they may be in a better position than some to be giving this information to patients, as undergraduates are actively acquiring the most up-to-date underpinning knowledge of radiotherapy and oncology and are supervised while training. Both students and assistants must demonstrate competency in information giving to patients before being allowed to undertake the activity without supervision. As a result, there has been a direct impact on staffing levels on the treatment units. In a department currently experiencing staff shortages, the strategy of using students and assistants has relieved many registered radiographers of this role, therefore allowing them to concentrate on the tasks and roles for which registration is essential, that is, treating the

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patients. Conversely, it has also determined local policy in terms of who cannot give new patient information, that is, radiographer helpers who do not undertake an accredited education programme are not able to give new patient information as they do not have the underpinning knowledge and understanding of radiation side effects and how to manage them; therefore, they are not perceived as being competent in carrying out these tasks. This has an impact on their job role and job description, as it excludes this aspect of assisting radiographers working clinically with patients. Potentially, this could be frustrating for the radiographer helpers in the department who wish to extend their role within the department and perform these tasks, without realising the complexity of the background knowledge required. Furthermore, the author feels that if the helper role did include giving new patient information and confirming consent without this underpinning knowledge, then why are assistant practitioners encouraged to study at a higher education level in order to develop their knowledge and understanding? They could be completing this aspect of their clinical work without the stress and pressure of further study, and how would their qualification as assistant practitioners set them apart from helpers? This question appears to be very much locally determined as to the service need and staffing arrangements within a department so it will vary across the country—but is it acceptable, given the legal implications of not obtaining fully informed consent, to allow this practice to take place?

INFORMED CONSENT

For consent to be valid it needs to be sufficiently informed,[12] the outcome of which is that the person seeking consent must understand the risks and benefits of the procedure to an appropriate standard. Lupton[12] goes on to argue that it is preferable, if not always possible, for the person performing the procedure to seek consent from the patient, not just the closest available clinician. This notion is disputed by Chadha et al.[13] who published a paper in 2003 on consent processes in common nose and throat procedures. They surveyed 40 otolaryngology Senior House Officers (SHOs) across England and Wales, and found that SHOs were responsible for consenting ENT patients in 95% of departments, and 6 months after the April 2002 deadline for the implementation of the DoH consent policy, the model consent forms were only being used in 72.5% of departments. These results highlighted a variation in consent and information-giving procedures to patients nationwide (albeit relating to ENT departments), and suggested a need for agreed written consent protocols to be available within departments for the SHO to refer to, as well as written sheets to supplement patient information. This is a practice that has been adopted into radiotherapy for many years, as it is thought to be of benefit to the patient and their families and carers.

HOW MUCH IS ADEQUATE INFORMATION?

What is a more difficult issue is what is exactly meant by adequate information. How do we measure what is adequate—it will undoubtedly vary between patients who carry different views on what they would like to know about their disease. Fallowfield[14] commented on the fact that the amount of information needed for informed consent is a contentious issue, as the patient who does not want to know about their illness should have as much right not to know as a patient who does. It seems apparent that this aspect of the information-giving process warrants further research if we are to deliver the aims of the NHS Plan and provide quality care centred around the needs and wishes of the patient, as for some patients, less is definitely better.

DIFFICULTIES IN COMMUNICATION

Jimison et al.[15] found that communicating highly technical and specialised knowledge to someone who is not educated in that subject is a challenging problem. The general anxiety of patients about their medical condition and the pressures of time also hamper effective communication. A French study by Moumjid et al. in 2003 also supports the point about time by stating that

'time is potentially a limiting factor in doctor–patient communication'.[16] This could be relevant to patients claiming they had not been given enough information. Clinical experience shows that many patients, when asked what they had been told already, replied 'not much' even though they had signed a consent form outlining the aims of treatment and the risks and benefits associated with it. This could also have been attributed to the patients' high state of anxiety related to a diagnosis of cancer. Davis[17] claims that the diagnosis and treatment of breast cancer can result in a range of psychological and emotional challenges. Furthermore, Fallowfield et al.[14] reported that 29% of women suffered depression after a mastectomy and 22% after conservative therapy. Considering that patients usually consent to radiotherapy after they have had surgery, then the fact that they are in an emotionally fragile state needs to be considered when they receive the information necessary for informed consent. In Fallowfields'[14] paper, it is suggested that many cancer patients are dissatisfied with much of the communication that takes place within hospitals, and the omission of adequate information about the diagnosis, prognosis and potential therapeutic options can increase anxiety and uncertainty. This will undoubtedly have a detrimental effect on the patients' emotional and psychological state, and is something that should be addressed within the radiotherapy department.

IMPROVING THE PATIENT EXPERIENCE

One such provision so far has been the opening of the Cancer Information Centre, based in the waiting room at NCCT. The centre provides paper- and web-based resources to encourage patients, and their carers and families to become more informed about cancer and actively research their own disease. The facility was opened with a skeleton service in December 2002, and has been fully staffed with volunteers since June 2003. Data up to the end of September 2004[18] shows us that the number of enquiries since opening is 1764 and 1589 were people who 'dropped in'. These 'drop-ins' could have been patients or their families and carers, and they account for 90% of the total number of enquiries. This suggests that the facility is well appointed and is providing a much needed service to cancer patients. It serves as an important resource for those who wish to know more than the doctor has told them. Conversely, for the groups of patients mentioned earlier who wish to know little about their disease, they will simply not engage with the Information Centre.

CAPACITY AND COMPETENCE

Under English Law, valid consent must be given by a person who has the mental capacity to understand the information, as a competent adult is someone over the age of 18 who is able to:

- Understand and retain information
- Believe the information given to them
- Weigh the information given to them in the balance with other considerations, when making their choice

Lupton, 2004[12]

The NUTH Consent policy[10]specifies that when an adult patient lacks the mental capacity to give or withhold consent for themselves, no one else can give consent on their behalf. The caveat here is that treatment may be given if it is in the patients' best interests as long as it has not been refused in advance in a valid and applicable advance directive. In terms of radiotherapy, these circumstances may arise due to the patients' illness, for example, in palliative care where the disease is incurable, and any treatment available is designed to improve quality of life for the patient and improve their symptoms. Patients who have cerebral metastases often have cognitive impairment and therefore may be unable to make the decision about whether to have treatment for themselves. Moreover, the drugs they may be prescribed for their condition may also impair their mental state, as sometimes happens with taking some strong opiods for pain relief. Verhaak et al.'s paper[19] on informed consent in palliative radiotherapy in Holland describes a study into the participation of patients and proxies in treatment decisions, and interestingly the authors of this paper

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comment on the fact that the patients entered into the study were all referred for palliative radiotherapy but were all generally in a good condition and far from terminal care. Clinical experience shows that this is not always the case; and although it would be ideal if all such palliative patients were fit and well, the reality is often the opposite.

CHILDREN

When babies and young children up to the age of 16 are referred for radiotherapy, it is the parents who give consent for the treatment to go ahead, after they have been given adequate information and understand the risks and benefits related to the proposed treatment. They then have the power to decide whether their child does or does not undergo the radiotherapy. This aspect of children and consent appears clear cut. However, Griffiths[20] comments on the fact that a child who has reached 16 years of age has a right to consent to treatment as if they were at the age of adulthood (deemed to be 18 years), that is, they have been given adequate information and can make an informed decision about their treatment. The author feels that in the field of radiotherapy, the complex issues regarding chronic effects may be beyond the patients' cognitive ability and they may require some additional support in making these choices, whether that comes from parents, carers or other health care professionals—possibly counsellors.

Another complexity of children and consent is the issue of parental responsibility. As the Childrens Act (1989) states: parental responsibility is conferred automatically on the mother of the child and the father if he was married to the mother at the time of the birth.[21] This assumes married parents stay together, which does not always happen. A father who is not married to the child's mother and is not registered as the child's father may still have parental responsibility under an agreement with the mother or by order of the court, but in emergency situations this would obviously have an impact on the timeliness of consent and could potentially delay life-saving treatment. In today's society, there are many combinations of parents, step-parents and remarried families, which may impact on and complicate the legal issue of consent and children. Moreover, the age of the child is important here too; as the older the child gets the more autonomous they become in decision-making processes, and parents can advise, but not decide for, the child.

DISCUSSION

The NHS Cancer Plan has prompted the need for improved patient-centred care, and one facet has been the issue of consent. By defining consent as making an informed decision based on the patient being competent to make the decision, having received sufficient information, and not to be under any duress, it can be seen where some of the issues and potential problems may lie.

The need for valid consent is paramount in radiotherapy where ionising radiations, capable of inducing secondary malignancies later in life, are used. Furthermore, the treatment of palliative and terminally ill patients has an impact on consent in as much as the patients are not always capable of giving consent themselves, whether due to the extent of their disease and/or the side effects of medications needed to counteract their symptoms. With regard to who should obtain consent, if it is necessary that the person seeking consent has the necessary level of knowledge and understanding, then who should that be in the radiotherapy department? This in turn has an impact in terms of training and education to be able to utilise the skills of workers other than registered radiographers, for example, assistant practitioners and students. Since the advent of assistant practitioners is a relatively new phenomenon in radiotherapy, there is scope for further work into how their skills could or should be used within the radiotherapy department.

Overall, the push towards a more formalised process of consent, tied in with the aspects of being able to offer information and answer patients' questions, would appear to be more productive for both patients and health care professionals.

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