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Original Article

Consent for Investigating and Treating Adults with Cancer

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ABSTRACT:
The importance of the consenting process, as a key activity in patient care, has been recognised by the Department of Health with the production of a policy aimed at ensuring patient focused national standards. Cancer treatments are complex and multi-disciplinary encompassing difficult issues around outcomes and toxicity. This article looks at the process within the UK Cancer network and addresses some of the situations which occur in clinical practice. Examples of difficult scenarios are given to illustrate the application of the basic principles. Tait, D. M., Hardy J. (2006). *Clinical Oncology* **18,** 23–29

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Consent for Cancer Patients in the National Health Service: the Wider Picture

Introduction

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Consent is a patient's agreement for a health professional to provide care. It is a core clinical activity, fundamental to patient care, best practice and clinical governance. The need to change the way in which patients are asked to give consent for treatment, care and research was identified in the National Health Sevice (NHS) Cancer Plan [1], but is part of a wider, European and international awareness of this need [2,3]. The Bristol Royal Infirmary Inquiry Report [4] also pointed to the importance of a patient-focused consent procedure. As a result of this, all NHS Trusts and primary organisations were asked to adopt the standard NHS model to consent policy by October 2002 [5]. Within the broad model of patient-centred consent practice set out by the Department of Health, individual Trusts are asked to develop guidelines determining what form of consent is appropriate for individual procedures at a local level.

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The primary aim was to ensure that the process of obtaining consent was properly focused on the rights of individual patients. Full guidance regarding the consent procedure can be found on the Department of Health web site [5]. This paper highlights some of the key points to be considered and the potential problems that may be encountered when obtaining consent from patients with cancer. Regulations concerning consent for research are currently under review and are not covered here.

Consent Within the Cancer Network

Most patients with a cancer diagnosis in the UK will be treated within one of the Cancer Networks. The Network brings rationalisation of resources and concentration of skills, but, for the patient, it may, at least initially, add further uncertainty and insecurity because of the inherent 'fragmentation' of treatment with different physical surroundings, personnel and procedures. This will inevitably lead to multiple consenting sessions and variation in the quality and content of information given.

The management of most patients will involve at least one of the three major cancer specialities, surgery, radiotherapy and chemotherapy. For many, it will involve two or three of these. In addition, patients are exposed to other medical or surgical specialists, and diagnosticians along the management pathway. Many other healthcare professionals (e.g. nursing, rehabilitation and palliative care) will have considerable input in giving information, carrying out procedures and involvement in various

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aspects of the consent process. The Network must ensure that all partners are aware of the fuller picture of the patient pathway, and that co-ordination does not just involve the mechanics of waiting times and economic service provision.

Although a consent policy may currently be viewed as a Trust issue, the evolution of the Network service will demand that consent be considered in this wider context and probably be best done via the Tumour Working Groups. Many of these are currently enthralled with the development, implementation and audit of guidelines, but an adjunct to this should be the development of Network information services and collaborative or standardised consenting procedures.

Consent from the Perspective of the Cancer Patient

In NHS planning, much emphasis is placed on fabric, facilities and easily measurable targets. Patient priorities may be more focused on the quality of his or her relationship with the health professionals. The NHS Cancer Plan [1] summarises patient priorities extracted from patient survey data. Patients seem to be quite clear how important the elements of this relationship are: (1) being treated with humanity — with dignity and respect; (2) good communication with health professionals; (3) being given clear information about their condition;(4) receiving the best possible symptom control; and (5) receiving psychological support when they need it.

Patients are also clear on the essential attributes of a health professional (i.e. a willingness to listen and explain, sensitivity, approachability, respect and honesty). Nowhere more than around the consent process are these attributes palpable and the qualities of the health professional visible, but where does this microcosm of clinical activity fit into the NHS Cancer Plan? Right at its heart, for the consent process should underpin the entire patient experience. It should ensure that, at a time of crisis, fear, symptoms and disruption, the patient is well informed of his or her clinical situation, the choices of care available and be comfortable with the elected path. However, there are additional challenges in cancer care and in the Network collaboration. The consent process for patients with cancer is highly significant and involves more crucial information and choices than that for most other medical circumstances. Cancer is perceived by patients to be different to other diagnoses, because it could potentially be life threatening, involves complicated treatments that are outside the patient's previous experiences and often requires input from multiple specialities and disciplines.

It encompasses a wide spectrum of toxicities, which can, in a small group of patients, result in treatment-related mortality. Some of the toxicities (i.e. infertility) can become a major issue. As patients are often invited to participate in research activities, they may also have to grapple with the relatively complicated scientific rationale behind clinical trials. All this in the setting of varied psychosocial responses to the new diagnosis.

The Scope of Consent

As described, the scope of consent will be wide for most patients with cancer. They will be faced with a request for consent on many occasions and for many varied functions. The major treatment modalities (surgery, radiotherapy and chemotherapy) are the obvious categories, but even here huge variations can be found in practice, and the uncertainties around outcomes complicate the process. During diagnostic phases of management, which aspects of clinical examination and which investigations require specific consent have to be considered, in addition to the mode of consent: written, verbal or implied. Implied consent is relied on widely in clinical care, and its affect on nursing-care procedures has recently been discussed [6]. Less routine, but increasingly common, are issues around genetic screening, tissue retention and sperm banking. These, and many other issues, may raise far-reaching concerns for patients, and demand careful consent procedures to accompany them. Moreover, a number of other activities, such as the use of patient data for service planning and audit need consideration, as do the tools for involving patients in running the service, such as patient surveys, questionnaires and focus groups.

The Role of Consent

In formal terms, the consent process embodies the legal and ethical principle that it is the fundamental right of a patient to determine what happens to his or her own body. Consent, in these terms, is valid only if the following conditions are met: the patient is competent to consent; provided with sufficient information; and is making a voluntary decision.

This all sounds rigid and legalistic, but what the process should achieve is a patient–professional partnership, in which information about the risks and benefits is presented to the patient in a way that it can be comprehended, and during which there is adequate opportunity to ask questions. They must be given time to come to a decision and be aware that they have the right to change this decision at any time. These requirements are all simple aspects of best practice, changing the culture from one of 'paternalism' to 'partnership'.

For the patient, the consent process provides information and knowledge, involvement in the decision-making process and empowerment. For the practitioner, the process provides assurance of patient agreement and avoidance of the consequences of failure of this process, such as dissatisfaction or anxiety on the part of the patient, NHS complaints, and, more rarely, action by professional bodies, negligence claims and even civil or criminal action [7]. Together, these consequences pose a major burden for patients, professionals and healthcare services.

Information Basis for Consent

One of the fundamental requirements for valid consent is that the patient is given sufficient information. What is sufficient for one patient will not be sufficient for another, and there