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Ethical Issues in Psychosocial Research among Patients with Cancer

Anne Eardley, Alan Cribb and Laura Pendleton

The ethical implications of psychosocial research among patients with cancer are discussed. Two key issues were identified: obtaining informed consent and the impact of participating in research. Barriers to obtaining genuinely informed consent are described, as well as the costs and benefits of participation in research. Recommendations are made for the conduct of future research, relating to the removal of barriers to informed consent and monitoring the impact of the research process on its subjects.
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INTRODUCTION

ETHICAL ISSUES arising from the involvement of patients in clinical research have received considerable attention [1–4] and a report by the Royal College of Physicians [5] emphasises the vulnerability of patients who are asked to participate in research while they are receiving treatment. Ethical committees are concerned with the conduct of both clinical and psychosocial research, but decisions about the latter are often based on intuition or common sense since there is little relevant evidence.

With the growing interest in assessing the quality of care, it is likely that cancer patients will be increasingly involved in psychosocial research. The extent of involvement will vary from the superficial contact required in patients' satisfaction surveys to the longer contact in longitudinal studies of the impact of treatment, illness or disability. It is important that the ethical implications of such research are understood, and surprising that research which is undertaken specifically to improve the lot of patients has largely overlooked the impact of participation on the patients themselves.

We discuss here the findings of those studies that have attempted to identify ethical issues and problems associated with the conduct of psychosocial research among seriously ill patients, and supplement these with insights from a study of our own.

STUDIES EXPLORING ETHICAL ISSUES

Four studies have specifically monitored the impact of participation in research. In two [6, 7], the subjects were women with breast cancer in studies of the psychosocial outcome of cancer-related surgery and who were interviewed once 3–12 months after operation. The third study [8] included two projects, each of which used the sickness impact profile (SIP) to measure health status. The aim of the first project was to identify factors influencing preventive health behaviours among elderly patients and those with a chronic illness. Data were collected by personal interview, telephone interview and self-administered questionnaire; the SIP was administered by an interviewer. In the second project, the aim was to examine the clinical usefulness of SIP data in managing patients attending a rheumatoid arthritis clinic. These patients were asked to complete the SIP at home themselves several times over 6 months. The fourth study [9] was an epidemiological investigation of risk factors for cervical cancer. Three groups were interviewed on one occasion: women with invasive cervical cancer, women with *in situ* carcinoma of the cervix and a non-cancer control group. They were asked about their sexual and reproductive history, contraception, smoking, cervical screening and diet.

Our research was a longitudinal study of patients undergoing radical radiotherapy to the bladder and prostate. One of our main aims was to monitor side-effects both in the short-term and during the year after the completion of treatment. Patients were interviewed on arrival at the cancer centre and in their homes some 2 months and 12 months after the completion of treatment.

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Methods of assessing the impact of research on patients who had participated were similar in three of the four previous studies. In the two studies of breast cancer patients and in the epidemiological survey, patients were sent a postal questionnaire between 6 and 12 months after the interview. However, in the SIP study [8], patients' views were sought during the study via the self-completed questionnaire and at a telephone interview between 2 days and 1 month after the end of the study. Topics covered varied between the four studies, but included reasons for participating in the research, whether the interview or questionnaire was understandable, whether there were any upsetting aspects, whether they gained any benefit from the research and whether they would participate again or recommend participation to a friend. In all cases, the "impact" data were collected by the original study's investigators.

In our research, patients were asked a series of questions about the study during the final interview to identify whether they had felt disturbed by the content of any of the interviews and how they felt about their involvement with the study over approximately 1 year.

FINDINGS

Two main issues emerged: informed consent—obtaining it initially, and in longitudinal studies, keeping it—and the impact of the research on those participating in it.

Informed consent

There is evidence of several barriers to obtaining genuinely informed consent. One problem is that patients may misperceive the nature of the research. In Funch and Marshall's study to assess the outcome of surgery for breast cancer [6], almost 1 in 3 participants said that they had taken part either because they thought their doctor wanted them to or because they thought it had something to do with their care.

Even when patients do differentiate between taking part in a research project and receiving a service, they may perceive (with some justification) that the research will meet some unmet needs if there is a gap in service provision. For example, patients in our study were pleased to hear that they would be visited at home by an interviewer, regarding it as part of a follow-up service, despite having been given verbal and written explanations of the nature of the research.

A further problem is when patients do not have the opportunity to decide whether or not to participate. In a study of advanced lung cancer patients reported by McCorkle and her colleagues [10], in about a third of cases of refusal, it was the patients' doctor who refused on their behalf. Even with the less seriously ill, such "gate-keeping" can occur. Webb [11] has described the many difficulties she encountered in recruiting women for a study of hysterectomy for non-cancerous conditions.

Impact of the research: cost and benefits

One of the reasons why there may be reluctance among health professionals to allow patients to be approached for possible inclusion in a research project is that it is felt that the research may be distressing for patients. What evidence is there that participation may have such adverse consequences? In the two studies of the outcome of breast surgery, adverse reactions were few. In Funch and Marshall's study [6], just 4% of participants said that they had been bothered in some way by the interview, and 5% wished they had not participated. Fallowfield *et al.* [7] found that out of 101 women, 1 found the questionnaire

embarrassing and 2 found it difficult to understand. 3 found the interview emotionally distressing. In both studies, positive effects of participation were recorded. Funch and Marshall found that 58% of women said that they had obtained some benefit and that those with more advanced disease and those having difficulty resuming their normal activities were more likely to record benefit. 85% of the women in the study by Fallowfield and her colleagues said that they found the interview helpful, and the investigators concluded that the research had a therapeutic effect on cancer patients, who often have few opportunities to express emotional traumas.

Benefits were also recorded by Carter and Deyo [8], whose findings are of particular interest since the impetus for their investigation of the impact of the research on participants was that an ethical committee was concerned about possible adverse consequences of asking elderly or chronically ill patients to complete a health status questionnaire. In fact, several of the participants suggested that even more detailed information should be collected, including areas ethical committees often consider sensitive or offensive. 78% of the patients felt that participation had been positive, and 90% said that they would recommend the study to a friend.

However, Carter and Deyo found that half the patients answered "yes" to at least one of the questions screening for possible adverse impact. These covered whether the study had caused them to think more about their health, whether they had experienced surprise, annoyance, discomfort, distress or difficulty, and whether any of the study activities were rated negatively. Most of this group said only that the study had caused them to think more about their health and there was no evidence that this experience had any adverse consequences. The fact that more negative responses were uncovered in this study than in the two breast cancer studies may be a function of the way in which information about impact was collected—both by self-completed questionnaire and by telephone interview. Carter and Deyo found that "no adverse responses were identified by written solicitation included with the self-administered questionnaires, and general questions posed by an interviewer provided very little yield. Only by asking questions directed at specific study instruments and specific negative reactions were most of the adverse effects identified".

As for judging the likelihood of patients being upset by completing a health status instrument, it is hard to adopt the viewpoint of participants whose experience is different from our own. If the content of an instrument lies within a patient's experience, it is unlikely to be disturbing. Such lack of congruence may account for the large amount of negative feedback obtained by Savitz *et al.* [9], together with the fact that specific questions about the research were employed to gauge its impact. 1 in 4 of the participants in this epidemiological study of risk factors for cervical cancer were bothered in some way by the interview, and the proportion rose to 39% for women with invasive disease. A quarter of this group also stated that they had wished the interview could be stopped, although the option of terminating the interview was explicitly provided. 30% of all the participants were bothered by questions about sexual partners, and this rose to 75% among controls. Despite this, 44% stated that they felt there had been some benefit to their participation, and 90% would encourage a friend to take part.

In our research, when patients were asked to describe their experience of the side-effects of radiotherapy, answers to the "ethical" questions at the final interview suggested that two types of benefit could accrue. First, the interviews provided an opportunity to discuss concerns that might not otherwise have arisen: "You don't just ask me general questions, you ask specific things which you never get to discuss with anyone else". Secondly, the interviews provided an opportunity for patients to set their experiences of side-effects in a wider context. In part this was derived from informal information given by the researchers to patients who asked how other people in the study were progressing, and in part it was a function of one of the data collection instruments employed: a series of cards was shown to patients, each listing a possible side-effect. For those patients with side-effects for which they had been unprepared, this provided some reassurance. The wife of one of the patients remarked: "I got a lot of help from those cards . . . afterwards, I could put it to him that these (side-effects) were normal. . . . To me, that told me that this was the reaction to the treatment. I've said it quite a few times to him, 'It was on those cards' ".

Only 1 patient expressed reservation about reviewing his experiences at a year: "(Having treatment for cancer) is an incident I should like to forget about, but I never will. I wouldn't want to go through that again. It's rather a funny feeling". This statement stood out as the nearest indication of any adverse impact. It came early in the series of final interviews, and as a consequence we decided that subsequent patients be specifically asked whether they felt that the third interview was "raking up the past" in any way. No further support for this viewpoint was found.

Thus research can have a positive impact on patients if the subject under investigation is perceived by patients as relevant to them, or if the research meets patients' needs in some way, for example, by allowing them to express their concerns. This can occur among patients with widely differing health status. Two studies of patients with advanced disease provide further insights into the impact of research when health is declining. Patterson and Freeman [12] described the problems they encountered in collecting quantitative data from patients with advanced cancer. The study involved tracking patients' medical status over time, and patients were asked to record their perceptions of their health, and their expectations and concerns about their health in the future. It was clear that for some patients, the experience of committing their assessment of their health to paper by completing a linear analogue scale was traumatic. Two such scales were reproduced, completed by a woman on two occasions a year apart. The first is "correctly" completed with lines marked. In the second, completed when she was terminally ill, no points on the scale were selected, and sentences were written instead, avoiding making any commitment. Thus, in answer to the question "how would you describe your present state of health?", which required a mark to be made on a scale ranging from "excellent" to "very poor", she wrote "trying to gain weight". The investigators described other problems, such as the validity and reliability of data collected from severely ill patients, and also the traumatic effect on the researcher attempting to elicit information in these circumstances. They concluded that "research with a terminally ill population may require a more qualitative approach".

In contrast, Cannon [13] gave a moving account of her experiences of obtaining "experiential accounts" from women with breast cancer of how it felt to have the disease. She studied women over 5 years with semi-focused interviews which allowed women to discuss a given topic in whatever way they chose. In this way, women could control the extent of their exposure to stressful topics.

DISCUSSION

Obtaining informed consent

There are several difficulties in obtaining genuinely informed consent—perceived external constraints on the part of the patient, misunderstandings of the nature of the research, and "protection" of the patient by health professionals which can mean that the patient does not have the opportunity to decide whether or not to participate. For perceived external constraints, patients should always be told that participation is voluntary, that any information will be confidential and that they can withdraw at any point. In longitudinal studies, patients should be given the option of refusing to take further part in successive phases. To lessen the likelihood that patients will misperceive the purpose of the research, it must be made clear when consent is sought whether or not the research is part of the care being offered, what the aims of the research are and whether the research is designed to benefit participants. Misconception of the nature of the research may be a particular problem in psychosocial studies in which patients are encouraged to discuss their feelings. Although patients may well find the experience therapeutic, any benefits that they obtain are incidental; in the main, research does not set out to benefit its subjects.

In the vetting of research, either formally by ethical committees or informally by clinicians or other health professionals, it is important that there is some independent system whereby patients' interests are safeguarded and that grossly invasive research is prevented. Having obtained ethical approval, researchers may still find that their access to patients is blocked by those with responsibility for their care. While this may be done with the best of intentions (i.e. to shield the patient from any additional stress), the result is a diminution of the patient's autonomy which is particularly significant in the health service context where there are many other threats to patients' ability to make decisions and to their sense of personal control [14]. Problems are less likely to arise if the relevant clinicians are involved in the planning of the research, and if the schedule is first tested on volunteers.

In practice, there is little evidence that patients are resistant to research, and studies that have explored reactions to participation have found that feelings of altruism are a common impetus. When asked to explain why they took part in the research, 91% of the women in Funch and Marshall's study [6] endorsed the statement "I thought it might help other women having breast surgery", and an identical proportion of the participants in the epidemiological study by Savitz *et al.* [9] said they took part because they perceived the study to be important in the prevention of disease. If one of the aims of the research is to improve patient care in the future, this can be stated. While the vulnerability of patients must not be exploited, voluntary participation in research perceived to be useful can provide respondents with a sense of achievement. What is essential is that the researcher distinguishes between moral obligations that patients may feel to participate in the research and external constraints to comply. The former do not raise doubts about informed consent, provided that the respondents are clear about the purpose of the research. Indeed, allowing patients to exercise moral judgement by choosing to participate or withdraw is essential to respect.

Measuring the impact of research

Having obtained truly informed consent, researchers should not assume that their ethical responsibility to the respondent has been discharged. It is important that the effects of participation in research be monitored for two reasons. First, patients coping with a serious illness are likely to be emotionally vulnerable, and the research may further expose this vulnerability. Secondly, in a longitudinal study, initial willingness to answer questions may alter as patients experience additional stresses as a result of their illness or treatment. One method of assessing the costs and benefits associated with the research is to build in questions to elicit respondents' feelings about being interviewed. In addition to direct questions about what they liked or disliked about the research, and their overall assessment of the experience, indirect indicators can be used, such as recording respondents' reactions to the research (what questions did they ask the interviewer, did they hesitate over certain questions or fail to complete them, did they become distressed by certain topics or did they express appreciation over any aspect of the research?). All these reactions are triggered by the research, and should be recorded as part of the overall assessment of its impact.

There is undoubtedly some tension between protecting patients from research and respecting their right to choose to participate in it. However, the more reliably we can assess patients' perspectives, the less need there is for paternalism. The emphasis hitherto has meant that some of the time, patients will be "protected" from experiences which they themselves might feel a need for or view as a benefit.

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