Patient and clinician collaboration in the design of a national randomized breast cancer trial

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Abstract

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Objective To show breast cancer patient involvement in the design of a national randomized trial of hormone replacement therapy (HRT) in symptomatic patients will increase accrual.

Setting and participants Three stakeholder groups [(1) researchers from the Lynda Jackson Macmillan Centre, (2) the Consumers' Advisory Group for Clinical Trials (CAG-CT), (3) clinicians responsible for a pilot randomized HRT study in breast cancer patients] developed this collaborative study.

Methods (1) Nine focus group discussions were conducted to identify issues relevant to breast cancer patients about HRT and a national trial: six involved women from breast cancer support groups nationwide and three patients who had previously participated in the pilot randomized HRT study. (2) Recommendations from the focus groups (analysed by Grounded Theory) were debated by the research stakeholders and focus group representatives at a 1-day meeting and consensus reached (using a voting system) on mutual priorities for incorporation into the design of a national HRT trial. (3) Representatives from the CAG-CT and focus groups participated in subsequent national HRT steering committee meetings to ensure that these priorities were accounted for and the resulting trial design summary was circulated to the CAG-CT and all focus group representatives for comment.

Results Focus groups demonstrated that the complexity of factors relating to trial participation was not just restricted to the research topic in question. Patient–clinician interaction provided a platform for negotiating potential conflicts over trial design and outcomes. Patient feedback suggested that mutually agreed priorities were accounted for in the trial design.

Interpretation Clinical research planning should involve all research stakeholders at the outset. Quantifying the impact of patient involvement in terms of trial accrual may be too simple given the complexity of their motivations for participating in trials.

Background

Randomized-controlled trials are considered to be the most reliable basis for evaluating new breast cancer therapies.¹ However, as few eligible women participate in trials, research to enhance the implementation of randomized trials has become a priority within the National Health Service (NHS) with successful outcome being quantified in terms of improving trial acceptance rates. Lay and professional difficulty in understanding the concepts of clinical uncertainty and randomization have long been identified as important factors inhibiting trial implementation. The fact that women may be deterred from participating because their objectives differ from those of clinicians responsible for the design of clinical trials has not received significant attention.² A need to involve women with personal experience of breast cancer in the selection and judgement of research questions was highlighted by a report of women's views of breast cancer treatment and research.³ It has recommended that researchers requiring funding should produce evidence that patients have been consulted when drafting research protocols.⁴ Whilst the principal of patient involvement has now gained acceptance, practical methods for doing so require development.⁵ This paper describes a collaboration between patients and clinicians in the design of a protocol for a national randomized trial of hormone replacement therapy (HRT) in symptomatic women with breast cancer.

The use of HRT in women with a diagnosis of breast cancer is controversial, as most breast cancers are known to be oestrogen-dependent. However, many women request intervention for troublesome oestrogen-deficiency symptoms (e.g. hot flushes, night sweats, vaginal dryness) experienced as a direct effect of their breast cancer therapy, which may include anti-oestrogens (e.g. tamoxifen), aromatase inhibitors (e.g. arimidex) and ovarian suppression or ablation (e.g. chemotherapy, gonadotrophin-releasing hormone agonists).^{6,7} The experience of such symptoms following breast cancer diagnosis and treatment can have a significant, negative impact on quality of life.⁸ In the absence of effective

alternatives to HRT for symptom relief, women with breast cancer are being prescribed HRT on an *ad hoc* basis. Observational studies have not shown HRT to exert an adverse effect on breast cancer survival but uncertainty will continue in the absence of randomized-controlled trials.⁹ To determine the feasibility of undertaking a national randomized trial of HRT in symptomatic women with early stage breast cancer in the UK, a small pilot study was conducted in which 100 post-menopausal women with early stage breast cancer who were experiencing oestrogen-deficiency symptoms were randomized to receive HRT or nothing for 6 months. The primary end points were acceptance and continuance rates. Whilst the present study demonstrated encouraging acceptance and continuance with allocated treatment (40% and >80%, respectively) despite the provision of detailed information about a potential recurrence risk with HRT, it was designed without patient input.⁸ Factors important to women, which might adversely affect recruitment to a subsequent national randomized trial were not identified. The present study, which was funded by the NHS Research and Development Programme, was designed to look at methods of enhancing accrual into clinical trials.

The collaborative study described here was developed jointly by three stakeholder groups: (1) The Lynda Jackson Macmillan Centre at Mount Vernon Hospital, which has experience of patient–health professional collaboration in cancer research;¹⁰ (2) The Consumers' Advisory Group for Clinical Trials (CAG-CT) a joint breast cancer patient–health professional group consisting of eight members (four patients, three of whom had received treatment for breast cancer and four health professionals involved in breast cancer research, i.e. a health education officer, a data manager and two surgeons) that was established to improve the quality of breast cancer research^{11,12} and (3) clinicians involved in the undertaking of the previously described pilot HRT study.

The aim was to involve breast cancer patients in the planning of a national randomized trial of HRT so that issues and outcomes relevant and

acceptable to patients could be defined for incorporation into the design of the protocol and thus enhance accrual. Funding support was limited to 1 year.

Methods

Two consultations were carried out to identify issues of relevance to breast cancer patients about the use of HRT. The first explored the experience of those women who had participated in the HRT pilot study; the second was a national consultation with breast cancer support groups to discover their response to a proposal for a multi-centre randomized trial of HRT. Summaries of the findings from these consultations were used to inform discussions between the CAG-CT, representatives from patient groups and clinicians proposing the national HRT trial. The evidence in the two summaries was examined and priorities (i.e. action points) agreed for incorporation in the proposed national HRT trial design. A summary of the trial protocol was circulated to members of the CAG-CT and patient representatives for their comment. Finally representatives from the CAG-CT and patients groups attended meetings of the national HRT trial steering committee to ensure that the agreed action points were incorporated into the protocol. A summary of the methodology, which was approved by an ethics committee, is given in Fig. 1.

Stage 1: consultation with breast cancer patients

Focus group discussions were organized with breast cancer patients to explore attitudes to the menopause, HRT and a proposed trial of HRT in breast cancer patients. The focus group discussion topic guides are shown in Table 1. Women participating in the focus groups gave their written, informed consent. Nine focus group discussions were undertaken. Three explored the experiences of women who had participated in the pilot HRT study and six were conducted with women from breast cancer support groups who had not participated in this

study. Forty-six of the 99 UK breast cancer support groups registered in Cancer Link (1994) responded to invitations to participate that were placed in Cancer Link and Breast Cancer Care newsletters. Breast cancer support groups were chosen in preference to random samples of patients as they are usually comfortable talking about cancer and have their own internal support systems. These groups were telephoned and asked a set of questions to check that they were active groups of a sufficient size, comfortable talking explicitly about cancer and able to accommodate the researchers within the timetable of this study. Six groups were selected from different parts of the UK: St Albans, Swansea, Torbay, Sheffield, Carlisle and Inverness.

All discussions were tape-recorded and transcribed. Transcripts were analysed using the NUD*IST software package (Non-numerical, Unstructured Data: Indexing, Searching and Theorising, Sage Publications Inc.) and key themes were identified for a detailed analysis based on Grounded Theory.^{10,13} Two reports were produced: (1) 'The views of women in breast cancer support groups on a proposed clinical trial of HRT after breast cancer' and (2) 'Patients' views of participating in a pilot study of HRT after breast cancer',^{14,15} which outlined the findings of the focus group discussions and key recommendations for debate.

Stage 2: the patient-clinician decision-making forum

A preliminary, half-day joint meeting was convened to provide an opportunity for the three stakeholders (researchers from the Lynda Jackson Macmillan Centre, the CAG-CT and clinicians involved in the HRT pilot study) to meet informally to discuss queries relating to this study and the scientific rationale for a randomized trial of HRT. This meeting was held after the focus group discussions had been conducted but before the final reports had been written.

At a second joint stakeholder meeting, researchers from the Lynda Jackson Macmillan Centre presented five key recommendations for discussion, which they had identified from the

Figure 1 Patient and clinician collaboration in the planning of the national UK randomized trial of hormone replacement therapy in symptomatic women with early stage breast cancer. The plan of the study was funded by the NHS Research and Development Cancer Programme.

Table 1 Guide for Breast Cancer Support Groups

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1. What are your views and experiences of HRT for people who have had breast cancer?
 2. What experience have you had of menopausal symptoms?
 3. What help did you seek? Where would you go for help or advice?
 4. Under what circumstances would you take HRT?
- Doctors are thinking of investigating the relationship between breast cancer and HRT. The research would be carried out in the form of a clinical trial.*
5. Do you know about clinical trials or have had any experience of them?
 6. Would you take part in a clinical trial on HRT and breast cancer?
 7. Some women will have HRT as part of the trial and some offered something else, what else should be offered and for how long would you take HRT as part of the trial?
 8. We are visiting six breast cancer support groups in order to discuss this topic. What thoughts do you have about this form of consultation for planned research, could it be improved?
- Guide for women who had participated in the pilot HRT study
1. What did you find useful about it and what not so useful?
 - Information provided
 - Understanding of what was involved
 - Expectations and satisfaction with outcome
 2. How could the study be improved?
 - What alternative to HRT should be offered if any?
 - For how long would you take HRT as part of the trial?
 3. Can you tell me about your reasons for taking part in the study
 - What experience have you had of menopausal symptoms?
 - What help did you seek?
 - Where would you go for information or advice?
 - What are your views about HRT for people who have had breast cancer?
 - Under what circumstances would you take HRT?
 4. Did you know about clinical trials or have any experience of them previously? What are your views now?
 - Having taken part in the trial would you make the same decision again?
 5. We are discussing this topic with two other groups who took part in the pilot study and breast cancer support groups in order to improve planned research by asking patients their views. What thoughts do you have about this form of consultation, could it be improved?
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focus group reports. Copies of the two focus group reports were circulated to delegates in advance. To ensure adequate and fair discussion, two independent representatives from the King's Fund facilitated this meeting. One woman from each of the six breast cancer support focus groups was invited to join the meeting to ensure their continued participation in this collaboration.

Delegates were divided into two discussion groups, each consisting of an equal mix of patients and clinicians/researchers. Both groups nominated a chair and scribe who were responsible for ensuring that the five recommendations were debated equally for 30 min and the responses recorded and tabled for general viewing. The responses were categorized as areas of common ground, difference of opinion, or priorities for action by the group participants. Each

delegate was then allocated five votes and asked to use these by placing a tick by the comment or issue they personally deemed to be the most important. The aim was to identify issues of greatest relevance to both patients and clinicians and to produce a summary of priorities for action, points of principle and areas of difference to be considered in the design of the trial.

The following ground rules were implemented and observed:

- Everyone present was to have an equal opportunity to express an opinion, irrespective of background, training and experience.
- Everyone should be open and honest with their comments and opinions.
- Everyone must listen and consider other delegates' points of view.

- Differences of opinion were bound to occur and should be respected.
- Every delegate must agree to maintain the confidentiality of the discussions.

Stage 3: development of the national HRT trial design

To ensure that the agreed action points were accounted for and incorporated in the design of the national HRT trial, representatives from the CAG-CT stakeholder group (i.e. the chair and two of the invited focus group members) and an independent patient advocate (to protect patients' interests) from the Lynda Jackson Macmillan Centre were invited to join the trial steering committee. Two meetings of the trial steering committee were convened to finalize a plan for the national trial. A summary outlining the proposed trial design was then circulated to all members of the CAG-CT and the focus group representatives for comment.

Results

Issues identified from the focus group discussions

Characteristics of the women who participated in the focus group discussions are summarized in Table 2. Overall, patients considered that being consulted about their experience of breast can-

cer, participation in the pilot HRT study and the planned national HRT trial was of value as it acknowledged the information and experience they had to offer. The overall themes emerging from all the focus group discussions are illustrated below. The key discussion points emerging from the two individual reports are summarized in Table 3.

Importantly, factors unrelated to the specifics of the trial in question (i.e. HRT) and rather to good clinical practice, such as the reputation of hospitals, responsiveness of the recruiting researcher and personal experience of previous trial participation, contributed significantly to the decision of women to take part in the study.

'This of course is the hospital which we are all prepared to travel hundreds of miles barefoot to be seen in, we all consider ourselves lucky that we are here.'

'I've had a lot out of the system and you've got to put something back in...taking part in a trial is one way you can do that.'

Oestrogen-deficiency symptoms and their impact

The provision of information about the oestrogen-deficiency side-effects of breast cancer therapies and in particular the vasomotor-like symptoms induced by tamoxifen, was considered inadequate, leaving women ill prepared to cope and unconfident. Doctors were perceived

Table 2 Characteristics of women who participated in the focus group discussions

	Women from breast cancer support groups	Women who had participated in the pilot HRT study
Total number of women who participated in focus groups	69	14
Number of focus groups	6	3
Mean age of participants (range) (years)	53.8 (32–70)	55.4 (48–69)
Mean time from diagnosis (range) (years)	4.5 (0–25)	7.3 (1–22)
Mean age at leaving full-time education in years	17.3	19.9
% currently taking tamoxifen	81.1	50
Number of women who had		
Taken part in a previous clinical trial	4	5
Were currently taking HRT	3	5
Had experienced menopausal symptoms	42	12
Number of women in the pilot HRT study randomised to		
Control arm		8
HRT arm		6

Table 3 Focus group findings and their application in the design of the national hormone replacement therapy (HRT) trial

Views of women in breast cancer support groups on a proposed trial of HRT after breast cancer	Features of the national HRT trial resulting from patient negotiation
<p>Discussion points</p> <ul style="list-style-type: none"> • Does HRT use a research priority? • Is the climate right for the trial? • Is the trial going to give any meaningful answers? • Should women with a good prognosis be invited into a trial of HRT? <p>Recommendations</p> <ul style="list-style-type: none"> • Review of ethical and scientific need for a trial of HRT • Greater openness among patients and clinicians about side-effects of breast cancer treatment and investigation of their management • Better interdisciplinary communication about the management of menopause-type symptoms so patient care is centred <p>Patients' views of participating in the pilot HRT study</p> <p>Discussion points</p> <ul style="list-style-type: none"> • How can informed consent be ensured? • Should women with no severe symptoms be recruited to a trial (1) where the end point is survival and (2) where there is a chance they may be in a control group and therefore denied effective treatment? <p>Recommendations</p> <ul style="list-style-type: none"> • Adequate information about the trial (i.e. treatment side-effects, types of HRT, access to research papers) • Information about trial investigations including feedback of results • Patient support during the trial (GP and hospital-based) 	<p>Eligibility criteria</p> <ul style="list-style-type: none"> • Issuing of patient information booklet 16 and specific trial information both designed with patient input • Only centres where staff agrees the rationale for the trial can recruit patients <p>Trial Design (Fig. 2)</p> <ul style="list-style-type: none"> • No placebo arm as patients wanted to know if they were taking HRT (i.e. masking effect) • Patients informed about different types of HRT and alternatives prior to randomisation so they can make an informed choice about which preparation they would like to receive once randomized. • Prompt access to breast cancer specialist/gynaecologist as required <p>Information and support for patients and health professionals during the trial</p> <ul style="list-style-type: none"> • All cancer organizations to be informed when the trial is launched • Clinicians, patients and GP principles will be updated about new studies on HRT and breast cancer and receive feedback whenever trial analyses are performed • Accessible, trained, dedicated trial nurses at each recruiting centre to counsel women about the trial (at outset and during participation)

as unwilling to consider the importance of treatment outcomes other than survival, ignoring the impact of symptoms on well-being.

'I think of the times I've produced symptoms and said please listen to me and been told "No, no, shut up, it's not the tamoxifen", so they've not been written down.'

'You feel guilty about saying anything but "I'm fine."'

'Will they take any notice of you when you say well I think this might be a side effect of that drug.'

Information about HRT

Anxiety about HRT was provoked by inconsistent advice from hospital specialists, GPs and media reports. The lack of independent, lay literature about HRT after breast cancer was commented on. Women participating in the pilot HRT study found the provision of up-to-date information about HRT, including the uncertainties, gave them a feeling of being in control and were an important factor in allaying their fears. The willingness of the researcher to indi-

vidually explore issues at the outset of the pilot study and during its course with participating women was appreciated. Little was known about alternatives to HRT but these were assumed to be less efficacious.

'At that time my surgeon turned round to me and as I was having awful side effects from the menopause, really chronic, and he said, "Well you're going to have to put up with it...anybody who has had breast cancer can't even think about HRT."'

'I never knew that medical opinion had changed about the link between hormones and breast cancer so it was a real plus.'

'You see when (the researcher) spoke to each of us she treated each of us like an intelligent human being.'

Factors influencing participation in a trial of HRT

Women from breast cancer support groups were asked about whether they would consider the use of HRT in the context of a randomized trial. The women who had participated in the pilot HRT study explored their decision and motivation to do so. The decision to use HRT was complex but predominantly involved individual assessment of benefits of HRT and perceived side-effects weighed against their understanding of why they had developed breast cancer. For some of those who had participated in the pilot HRT study, quality of life considerations overcame anxieties about the potential risk of disease progression. Others participated purely to obtain the perceived benefits of additional monitoring. Most women expressed a preference for a particular treatment arm. Women who participated in the pilot HRT study considered that lack of a placebo arm was a positive aspect of the study design, as they wanted to know if they were taking HRT. Women from breast cancer support groups expressed that they would prefer for a trial of HRT not to have a placebo arm for the same reason. Potential risk of disease recurrence was felt to be an important consideration in the planning of the proposed national HRT trial. Women were unable to state

for how long they would be prepared to take HRT. The main reason given for discontinuing HRT after the end of the pilot HRT study was that the degree of symptom relief did not match their expectations.

'I was anti, anti-HRT...but because of the change (suggestion that women with breast cancer might take HRT) I'm sort of level pegging but there's still for and against.'

'To take that minimal risk (of recurrence) you've got to be really bad to do it.'

'It was a case of my coming to terms with the possible risk and instead of having a life with many embarrassing interludes (menopausal symptoms) I prefer the possibility that it (the breast cancer) might grow again...but if it grows again it will be treated again.'

'The researcher did say that if you go on to HRT we can't guarantee that it does not cause breast cancer. I said, well I'll just take the risk. If it comes back I've got a very good hospital, I've got a very good GP, so I'll take my chance.'

Action points for negotiation in the design of the national HRT trial

The five key recommendations identified from the focus group reports for debate at the joint stakeholder meeting were: (1) Is HRT a research priority? (2) Is the climate right for the study? (3) How can informed consent be ensured? (4) Should women who are not suffering severe symptoms be recruited to this trial when the end point for the study is survival? and (5) Will the study give meaningful answers? The negotiated action points for incorporation in the design of the proposed national HRT trial are given in Table 3. It was agreed that research should be undertaken to improve the management of the menopause but that both HRT and alternatives should be evaluated for the relief of oestrogen-deficiency symptoms. Whilst it was acknowledged that randomization removes patient choice, women felt that it would be a positive action, if HRT is allocated in the proposed national trial, to be able to express a preference for the type used (clinical necessity dictates that

Figure 2 Plan of the national UK randomized trial of hormone replacement therapy in symptomatic women with a history of early stage breast cancer.

a range of HRT products are available that can be administered orally or transdermally). The overall message emanating from the patient–clinician consultation process was one of ‘doing the trial with’ rather than ‘having the trial done to’.

Assessment of the design of the national trial

The plan of the national HRT trial is shown in Fig. 2. It was finalized following the two meetings of the trial steering committee that included the CAG-CT chair, focus group representatives and patient advocate from the Lynda Jackson Macmillan Centre. An outline of the trial protocol together with the features in the trial design resulting from the agreed action points (summarized in column 2, Table 3) were circulated to people who attended the joint stakeholder meeting for their comment. Six of the 12 CAG-CT members and focus group representatives provided written responses. There were two reasons for a lack of response. First, the time taken to review the circulated summary was underestimated and secondly, the phrasing of

the accompanying letter caused confusion in that some women did not appreciate that a written response was required. All respondents considered that the negotiated action points had been accounted for, but they expressed concern that the costs necessary to meet the detailed information and counselling needs of women participating in a national HRT trial could be underestimated by funding bodies because of a lack of perception of their importance.

Discussion

This collaborative study has shown that focus group methodology can be used to identify issues of relevance to breast cancer patients about a specific research question and through negotiation with clinicians, formulate priorities, which can be practically applied in the design of a breast cancer trial. The use of qualitative methods for exploring patient opinion about research has been recommended.⁴ Here focus group methodology was selected as it is less time-consuming than individual interviews but yields similar information.¹⁷ Irrespective of the

Figure 3 Patient booklet 'Breast Cancer, Hormones and HRT'.

methods employed, patients must be in an environment that is conducive to them expressing their preferences if the ideal of a shared model of collaboration is to be achieved. It is important, therefore, that the planning, execution and analysis of the information obtained is carried out by independent researchers. Likewise, any negotiation between research stakeholders requires facilitation by trained, independent personnel.

One of the most important considerations in the development of any interaction between patients and clinicians is how the complexities of conflicting clinical and health system goals can be negotiated and what trade-offs are acceptable given the potential differences in their respective values. In the design of the national HRT trial patients stressed the importance of quality of life as an end point of the trial but expressed a preference for no placebo arm, which could

Contents

- What is the link between hormones and breast cancer?
 - What are hormones and what do they do?
 - How do the different breast cancer treatments work?
- Will I have menopausal symptoms during or after treatment?
- The effects of the menopause
- What can I do about the effects of treatment?
- Questions you might want to ask about your own treatment
- Where to go for help

render quality of life analysis difficult. This, however, was considered to be acceptable by clinicians as it was deemed inappropriate to design a placebo that potentially could induce withdrawal bleeding, a common side-effect of combined HRT. A further difference emerged related to the question of at what stage after diagnosis it would be appropriate to invite patients to participate in a trial of HRT. Following discussion it was agreed that some women might welcome the potential of symptom relief soon after diagnosis and therefore it would be appropriate to discuss the trial with women shortly after initiation of treatment. This project highlighted the importance of adequate information for patients upon which to base decisions about trial participation and demonstrated a clear perceived gap in the provision of information about the oestrogen-deficiency side-effects of breast cancer therapy.⁵ As a result the

Table 4 Involving patients in the design of clinical research protocols

General principles

- Trial design should be based on the principle of joint ownership therefore all stakeholders in research should be involved at the very outset
- Involvement of all stakeholders will ensure clarification about issues of representation, objectivity, accountability and role

Identification of issues of relevance to patients

- Use of appropriate qualitative methodology (i.e. focus groups, questionnaires)
- Data should be collated by independent researchers to avoid any conflict of interest with the research topic in question

The patient–health professional collaborative process

- Negotiation between stakeholders requires facilitation by trained, independent personnel
- Patients may require background training/information if research is complex
- Budgeting must allow for patient travelling costs
- Patient feedback must be provided to ensure accountability and representation
- Allow sufficient time for negotiation and feedback
- A minimum of two patients and a patient advocate should be involved in a clinical trial steering committee

Lynda Jackson Macmillan Centre, with active input from patients and Cancer BACUP, produced a booklet for patients – ‘Breast Cancer, Hormones and HRT’ (Fig. 2).¹⁶ Obtaining informed consent from women invited to participate in the national HRT trial is likely to be time-consuming and a further trade-off between patients and clinicians is an understanding that this may not lend itself to rapid trial recruitment. Whilst the consultation process outlined here did not identify significant conflicts between the individual stakeholders, we consider that the interactive process described could be used as a basis for developing consensus in planning other clinical research where different treatment options, their benefits and risks and outcomes are uncertain.

An essential part of planning any collaboration is providing sufficient support to patients at all stages including the provision of sufficient time for the collaborative process and subsequent patient feedback. A criticism of this study is that time constraints prevented a complete response from all the CAG-CT and focus group representatives about the planned national HRT trial design, although those obtained were all favourable. Points of practice recommended when planning any health professional and patient collaboration are summarized in Table 4.

Reliance solely on quantitative outcomes, in this case trial accrual, does not necessarily reflect

the complexity of patient decision making or the perceived quality of the trial. For example, the focus group discussions revealed that the use of HRT could not be considered simply as a research question in isolation and that good clinical practice (e.g. adequate counselling about breast cancer treatment side-effects) rather than specifics of the trial in question could influence women’s decision making. Previous experience of trial participation also influenced this decision. Cancer patients want to be kept well-informed about their illness at all stages; this should encompass management within the context of taking part in clinical trials.¹⁸ Strategies to ensure that patients and health professionals are regularly updated during the national HRT trial have been incorporated into its design (Table 3).

The needs of all stakeholders involved in research (i.e. patients, clinicians, management and funding bodies) should be taken into consideration at all stages of the research process. The establishment of organizations such as the National Cancer Research Institute Consumer Liaison Group are a timely move towards this aim.¹⁹

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