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What research means to patients, and the importance of partnership with practitioners in research

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Abstract

A brief general and personal history of research conducted in partnership with patients is outlined in order to substantiate the beneficial effect of this method in improving the quality of research and to illustrate the importance to patients of testing treatments in a manner that takes account of the outcomes they seek. Examples of two early initiatives, Radiotherapy Action Group Exposure (RAGE) and the Consumers' Advisory Group for Clinical Trials (CAG-CT), are used to demonstrate what can be accomplished by committed groups of patients working with policy makers and practitioners to improve the quality and provision of treatments for breast cancer.

Keywords

CAGCT, RAGE; history of active patient involvement in research; patient responsibility in research; trust and altruism in research; education of public about research; adequacy of patient information; shared decision-making; long-term effects of radiotherapy; UK DCIS Trial

INTRODUCTION

My intention in this article is to offer some thoughts about what research might mean to patients. I shall also try to convey why I believe it to be important that research is undertaken in meaningful partnership with practitioners in research. It is based on my first hand lay experience in 1991, informed by my own and others' observations and experiences since that time, and now substantiated by research findings about this new approach to conducting randomised controlled trials and other types of research in partnership. Like all new, useful innovative approaches, it began tentatively, gained support, gathered momentum and is currently rapidly expanding and developing. It is still in a state of development, but is at the stage when there is sufficient history to enable the benefits and drawbacks of patient and public involvement (PPI) to be the subject of scrutiny and research to assess its value. Like all interventions, new or old, it requires to be evaluated to see whether, on balance, it provides more benefit than harm to patients. Currently, on balance, it has been shown to be beneficial, attracting and justifying increased investment in furthering this approach.

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BEGINNINGS

My own sudden and dramatic introduction to research was as a patient when invited in 1991 to participate in the UK Randomised Trial for the Management of Screen-detected ductal

carcinoma *in situ* (DCIS) of the Breast.[1] This trial included radiotherapy in two out of its four options in a 2 × 2 factorially designed trial, with the stated objective of making possible separate evaluation of each of the two additional therapies (the other being tamoxifen) following complete local excision of the DCIS.

This invitation led me to an abrupt realisation of the need for research if uncertainties about treatment effects were to be reduced. As a layperson, it also caused me to consider many aspects of testing treatments from a patient's viewpoint. These included consideration of the ethics and practicalities of seeking informed consent from patients such as myself who had just been given a cancer diagnosis. Some of the problems that I identified and wanted to explore further were the inadequacy of the information provided; the timing of the invitation to participate; the impact on a prospective participant of randomisation in a trial with four very different, unbalanced options; the unsatisfactory trial aim (as I saw it) of only seeking ways to reduce the incidence of subsequent invasive carcinoma of the breast, rather than determine treatment effects on survival. I set out my views in an article that was published in *The Lancet* in January 1992.[2] This, and other activities, effectively set the 'patient involvement' ball rolling, while illustrating very well the potential benefit of publishing 'a patient's viewpoint' to begin to further the debates about conducting clinical trials that included a lay perspective. Recognition by *The Lancet*[3] that this new approach[4,5] was worthy of consideration provided the springboard for debate.

This initial invitation, interest and initiatives led to development of my own and other people's conviction about the benefit and importance of patient and public partnerships and their active involvement with practitioners in research. 'Research with' rather than 'research on' patients[6] can reasonably be argued to be a moral and ethical imperative, seeing that the purpose of undertaking any medical research should be for patient benefit, remembering that we are all likely to become patients before we die. I was fortunate that this initial experience and published exposure led to my having various opportunities for dialogues with open-minded health professionals in many fields of endeavour. These included leading radiologists Professor John Yarnold and Professor Ian Kunkler, who were only too ready to take these ideas further and offer help and opportunities to me and to other patients, at least as early as 1993 in my own case. Education of the public about research concepts was also identified as an essential component if research was to become an accepted and integral part of offering medical interventions, also enabling patients who wanted to be actively involved in the research process to be more effective.

THE UK DCIS TRIAL

The UK DCIS trial was contentious: not all clinicians were randomising patients to all four trial options. This probability had been foreseen by the working party who had drawn up the protocol in 1989. They stated that they hoped that the majority of clinicians would wish to participate in all four options, but made provision for those clinicians who might find 'either radiotherapy or tamoxifen essential or unacceptable to participate in single randomisation for the other therapy option, thereby only entering patients into one half of the trial'. I was unaware of this option at the time of my invitation to the trial and later commented that it seemed to me to be unfair that I should be labelled as having a prejudice against radiotherapy as a treatment option for DCIS when it was deemed acceptable for clinicians to opt out. It occurred to me that, had there been patient input into working up the trial protocol, this 'imbalance' would have been one of many shortcomings that might well have been addressed.

The diagnosis and treatment of screen-detected breast cancer, including DCIS, is a team effort. When I discovered that the DCIS trial was contentious, I wondered how conflicts of opinion about radiotherapy and tamoxifen trial options were resolved in breast unit teams where the trial was on offer, should, for example, the surgeon and the radiologist and the breast care nurse have fundamental differences of opinion, or disagreements. With this dilemma in mind, I wrote articles for Nursing journals,[7,8] and an article for the journal '*Radiotherapy Today*'[9] questioning the justification for

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this trial, pointing out that the potential harms of treatment would outweigh the benefits for a proportion of the participants, based on evidence about the known likely proportion of types of cases of DCIS that would and would not progress to invasive cancer. The eligibility criteria made no provision for this variability of DCIS diagnosis that would lead inevitably to over-treatment in some cases and under-treatment in others.

Prior to the introduction of mammographic screening, patients seldom presented with DCIS. But the NHS Breast Screening Programme (NHS BSP) was finding that about one in five breast 'cancers' were DCIS, that is, carcinomas that were confined to the ducts without invasion into the surrounding stroma. This rate has remained fairly constant: The NHS BSP Annual Review for 2007[10] reports that 1,891,408 women were screened; 14,841 cancers were detected; of which 3,019 were *in situ* cancers, that is, 20.34%, or one in five women. The management of this condition of asymptomatic screen-detected DCIS was identified then as a problem, and remains so today.

GENERAL BACKGROUND

In order that we might consider what research means to patients today, and the importance of partnership with practitioners in research, to help put it in perspective, it might be useful to reflect on the changes there have been over the last couple of decades—socially, culturally, politically, scientifically and technically.[11] These changes have been considerable. Inappropriate paternalism is being replaced by 'patient choice' (another contentious concept introduced by government without prior good evidence of benefit)[12] and shared decision-making. Availability of good quality information is regarded as vital—a medical intervention in its own right.

A new iterative relationship between patient and health professional, both individually and in groups, where patients are encouraged and allowed to play a greater part while taking more of the responsibility, is now being developed, encouraged and practised, and is politically endorsed. PPI in research has developed from being a novel idea in the early 1990s, to a structured and supported activity, with its own accumulating evidence of benefit/harm. The internet revolution has enabled rapid communication and access to information formerly unavailable to the general public. It has also impinged on the isolation of scattered patients so that they may benefit from being able to engage in worldwide, organised involvement that is better informed, in many types of constructive advocacy and research activities.

RAGE

Let us consider one pioneering group—Radiotherapy Action Group Exposure (RAGE)[13]—founded in 1991. Its emergence at that time, when breast cancer patients were expected to be grateful to be alive and not complain about toxicity or side effects, or query the cause of harms, illustrates very well what can be done by a small group of committed and determined patients for the benefit of fellow patients. Huge changes in attitudes have taken place since then: constructive outcomes of benefit to patients, researchers and the health provider have been achieved following this shocking exposure of post-radiotherapy suffering and undesirable paternalism. The considerable publicity given to Lady Audrey Ironside's injury following radiotherapy treatment for breast cancer, and her quest for acknowledgement and compensation, emboldened others who had suffered similarly to meet with her and found RAGE. At that time, little information was available to women, particularly about the possible long-term disabling effects of radiotherapy; discussion about treatment within the consultations was generally not encouraged—or even discouraged; no national standards governing delivery of radiotherapy had been drawn up; little research about these specific radiological problems had been initiated or undertaken. All this has since changed.

HEALTH COMMITTEE THIRD REPORT ON BREAST CANCER SERVICES, 1995

RAGE was called to give evidence, both written and verbal, to the Health Committee of

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the House of Commons, Session 1994–1995, published in their Third Report on Breast Cancer Services in 1995.[14] This enquiry provided opportunity for numerous organisations, institutions and people to submit written evidence on many aspects of the management of breast cancer treatment and care, as well as screening and research. Witnesses representing a wide range of involved agencies were called to give evidence to the Health Select Committee over 4 days, with RAGE uniquely representing a patient view on screening, treatment, breast cancer services and breast cancer research. Although not a member of RAGE, I was co-opted to present oral and written evidence, particularly with respect to research, where I advocated for patient involvement in the whole research process.[15]

The Health Select Committee Report on the Proceedings of the Committee devoted a section to 'Involving Patients in Research' (p. lvi, vol. 1).[14] The Ministers, on the basis of the evidence they had heard, had concluded that they believed '..that patient involvement such as the *Consumers Advisory Group on [sic] Clinical Trials* (CAG-CT) are to be welcomed.' They added: 'We recognise that patients who have long-term involvement in such groups will acquire a knowledge base in excess of the average patient, but we believe this kind of patient advocacy by a small group of well informed patients is far preferable to little or no patient involvement at all.' This was taken forward into their 'Summary of Conclusions and Recommendations' (recommendation no. 41, p. lxii). They stated 'We believe that our recommendations will help to improve the standard of care for women with breast cancer in this country' adding that they hoped that 'as other specialties follow the lead, they may help to raise the standard of care for all cancer patients.'

At the time of the Enquiry in March 1995, RAGE had over 1,000 members in England and Wales, as well as Northern Ireland. There were also many more victims who had not taken up membership, and a further 400 affected women in Scotland.

Members of the Health Select Committee were informed by RAGE that, although patients may have been generally made aware before treatment of temporary side-effects such as sickness and nausea, they were not made aware of the risks of serious and permanent injury, including arm paralysis and disabling consequential effects which they had identified as including

- Lymphoedema
- Lung burn, leading to severe breathing difficulties
- Deadened bones in the brachial plexus area, leading to spontaneous fracture and failure to mend
- Heart damage
- Jawbone pain and tooth loss
- Amputation of arm, as a means (mostly ineffectual) of last resort to relieve pain
- Severe fibrosis, leading to further nerve compression and paralysis
- Skin burn
- Psoriasis.

The exposure meant that government and health professionals could no longer ignore the shortcomings in the provision of treatment; the provision of information to women; the knowledge base that needed to be researched; or the Ministers' recommendation that research should be undertaken in partnership with patients.

Given my own experience, concurrent with the formation of RAGE, I could sympathise with their complaints about lack of information about radiotherapy treatments, but from the different standpoint of information provision to prospective research participants so that they might make a better-informed decision about participation in order to be able to give consent.[16] For an adequate and satisfactory decision-making process, prospective participants need information not only about the specific trial into which they are being invited, but also about research concepts, particularly about why randomised controlled trials are necessary.[17] 'Randomisation' is one of the biggest stumbling blocks for those patients who wish to understand these concepts before making their decision. It must be recognised, however,

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that many patients agree to participation based more on trust in the doctor and/or the institution, and for altruistic reasons,[18] than because they feel they have understood the information sufficiently well to be able to give 'fully informed consent'.

CAG-CT

The CAG-CT had been jointly founded in September 1994 by myself and Professor Michael Baum as a patient/profession working group, with the main aims of working directly with the profession to encourage consumer involvement in protocol development and patient information provision, and to advance public education about clinical trials. We saw ourselves as a 'facilitator for progress', bridging the gap between patients, clinicians and researchers.[19] Our objectives were

1. To assist the profession in ensuring that questions being addressed by clinical trial protocols are worthwhile and relevant to patients' needs.
2. To assist in the improvement of clinical trial design, providing trials that were more acceptable and understandable to potential research participants.
3. To advocate for co-operation and shared responsibility, demonstrating a new attitude to research which is not imposed on patients but more clearly expresses the patients' desired outcomes.

The CAG-CT began work at its first meeting by commenting on the draft of a feasibility study examining the use of hormone replacement therapy (HRT) in women with breast cancer. This work ultimately led to the development of a protocol for the multi-centre National Trial of HRT in Women with Early Stage Breast Cancer (ISRCTN 29941643)[20] (see INVOLVE website database, Project No. 44. www.invo.org.uk).

We successfully applied for funding from the National Health Service Research and Development (NHS R&D) Cancer Programme in 1995 against a call for proposals seeking applications against their priority area of improving accrual into trials. Our project 'Using a Consumers' Advisory Group to increase accrual into trials'[21] used independently facilitated focus group methods to identify and prioritise the desired outcomes of patients, researchers and clinicians around the topic of breast cancer and its treatments in relation to HRT use. Also identified by this work were the specific training needs for those who would be involved in conducting the trial, and the information needs of participants, patients and health professionals. Facilitators from the King's Fund, who set out clear ground rules and methodology for arriving at prioritisation, enabled satisfactory and equitable input from a very mixed group of researchers, clinicians, patients and advocates in this project.

PROGRESS AND EVIDENCE FOR PPI

In the UK, research activity involving patients has gathered momentum in the last 10 or 15 years to a point where major funders now require that research teams involve patient and the public in their projects, not just as passive participants, but as active participatory researchers.[22,23] Evidence suggests that benefit from participation outweighs the drawbacks.[24–30] Clinical research has become more sensitive, more relevant (to the patient), and of greater benefit to society and the NHS as a result.

CURRENT STRUCTURES FOR ENABLING PPI

Various organisations have been set up to provide a resource to facilitate involvement. For example, the United Kingdom Clinical Research Collaboration (UKCRN)[31] aims to improve patient care and allow people across the country access to the best treatment. A common theme that runs throughout its work is PPI. UKCRN believes that active PPI is needed if it is to achieve a programme of research which directly reflects the needs and views of patients and the public.

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Another is the NHS National Library for Health[32] which has a PPI Specialist Library. This aims to support the implementation of patient, user, carer and public involvement in health care by providing access, in one location, to the best information which is available on the web.

CURRENT NCRI/NCRN RADIOTHERAPY CLINICAL STUDIES GROUP PORTFOLIO OF TRIALS

The National Cancer Research Network (NCRN) Radiotherapy Clinical Studies Group[33] has a large portfolio of current and closed trials.[34] It is the practice within the NCRN to involve consumers in the Clinical Studies Groups and to have consumer members wherever possible on individual trial steering groups.

Consumer involvement in radiotherapy trials sprang from RAGE's exposure and action, aided by clinical researchers such as Professors John Yarnold and Ian Kunkler, who appreciated the extra dimension and value that patients and the public could bring to the setting up and running of randomised controlled trials.

CONCLUSION

It can be seen from this brief look at patient partnership with practitioners in research that huge progress has been made in the last decade and a half. Patients have not only come to recognise that research is essential if treatments are to be improved but also that they have a part to play in enabling and facilitating this progress in partnership with practitioners, by sharing the responsibility. There is evidence too, that health professionals and researchers are increasingly accommodating meaningful ways of involving patients and the public, appreciating the value that this mode of working can add. Structures are in place to facilitate this way of conducting research, with models, training, resources and assistance to help achieve it. It is important, now that there is a history of involvement, that care is taken to record and report any involvement in existing databases and registers, and to ensure that published reports of trials make clear exactly how lay people have contributed. It has been seen that roles for patients in research are many and varied and can even evolve in the course of a study:[35] it is important for researchers to reflect on the impact such partnership-working can have and to publish findings, preferably in a jointly authored paper, so that others may see the benefits and be enthused to emulate this way of working. As evidence of joint-working accumulates, further systematic reviews will build on our understanding of the benefits, drawbacks, limitations, barriers and challenges of this method of conducting research. Education of the public, and health professionals, about research concepts is vital.[17] Building on all these achievements to date will surely enhance and facilitate conducting better quality research that is more relevant and useful to patients?

References

1. Protocol of the UK Randomised Trial for the Management of Screen-detected Ductal Carcinoma (DCIS) of the Breast. December 1989. UKCCCR. Prepared by the Working Party of the BCTCS (Breast Cancer Trials Coordinating Sub-committee) of the UKCCCR (UK Co-ordinating Committee on Cancer Research).
2. Thornton HM. Breast cancer trials: a patient's viewpoint. Lancet 1992; 339: 44–45.
3. Acceptance letter from Dr Imogen Evans, The Lancet, dated 27th November 1991.
4. Baum M. New approach for recruitment into randomized controlled trials. Lancet 1993; 341: 812–813
5. Thornton H. A ladyplan for trial recruitment?—Everyone's business!. Lancet 1993; 341: 795–796
6. Meeting organized by the Faculty of Law, University of Trento, Italy, ''Sperimentare conference'' 29–30 November 2007.
7. Thornton H. ''The luck of the draw''. Nurs Times 1992; 88(37): 58.
8. Thornton H. A sacrifice for others? Ethical dilemmas surrounding the UK randomised trial for the management of screen-detected ductal carcinoma *in situ* of the breast. Prof Nurse 1993; 8: 402–404.
9. ''Preventive radiotherapy for early breast cancer?'' Radiother Today 1992; 58(661): 25–26.
10. NHS Breast Screening Programme Annual Review 2007. ISBN 1-84463-048-6. Available on URL: http://

https://doi.org/10.1017/S1460396908006584 Published online by Cambridge University Press

www.cancerscreening.nhs.uk / breastscreen /publications / 2007review.html

11. Lerner BH. The Breast cancer wars. fear, hope, and the pursuit of a cure in twentieth century America. Oxford University Press: New York, 2003.
12. Fotaki M, Boyd A, Smith L, McDonald R, Roland M, Sheaff R et al. Patient Choice and the Organisation and Delivery of Health Services: Scoping Review on Patient Choice and the Organisation and Delivery of Health Services for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO), 2005.
13. RAGE (Radiotherapy Action Group Exposure). http://www.rage.webeden.co.uk/
14. HMSO. Health Committee Third Report. Breast Cancer Services Volumes I and II. 6 July 1995.
15. Thornton H. The patient's role in research. (Paper given at The Lancet ''Challenge of Breast Cancer'' Conference, Brugge, April 1994.) Health Committee Third Report. Breast Cancer Services. Volume II. Minutes of Evidence and Appendices. London HMSO July 1995. pp. 112–114.
16. Thornton H. Informed consent. In: Early Breast Cancer, from screening to multidisciplinary management, 2nd edn. Querci della Rovere G, Warren R, Benson JR (eds). Taylor & Francis Medical Books, 2006.
17. Evans I, Thornton H, Chalmers I. Testing treatments: better research for better healthcare. British Library 2006. See: www.jameslindlibrary.org
18. Fallowfield L, Jenkins V, Brennan C, Moynihan C, Souhami R. Attitudes of patients to randomized clinical trials of cancer therapy. Eur J Cancer 1998; 34(10): 1554–1559.
19. Thornton H. Patients and health professionals working together to improve clinical research: where are we going? Eur J Cancer 2006; 42: 2454–2458.
20. Minerva BMJ. (2000) 320.p. 724 (Fertility and Sterility 2000; 73: 292–299).
21. National Cancer Research Network—Breast Cancer Trials Report. November 2002 NHS Research and Development (Cancer). Project No. NCP/D18. 1995 Jo Marsden, Jane Bradburn. Patient and clinician collaboration in the design of a national randomised breast cancer trial. Health Expect 2004; 7(1): 6–17.
22. Wright D, Corner J, Hopkinson J, Foster C. Listening to the views of people affected by cancer about cancer research: an example of participatory research in setting the cancer research agenda. Health Expect 2006; 9(1): 3–12.
23. Thornton H. ''Today's patient: passive or involved?'' Lancet 2000; 354: siv48
24. Hanley B, Truesdale A, King A, Elbourne D, Chalmers I. Involving consumers in designing, conducting, and interpreting randomised controlled trials: questionnaire survey. BMJ 2001; 322: 519–523.
25. Oliver S, Clarke-Jones L, Rees R et al. Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach. Health Technol Assess 2004; 8: 1–148.
26. Telford R, Boote JD, Cooper CL. What does it mean to involve consumers successfully in NHS research? A consensus study. Health Expect 2004; 7: 209–220.
27. Bastian H. Consumer and researcher collaboration in trials: filling the gaps. Clin Trials 2005; 2: 3–4.
28. Crawford M, Rutter D, Thelwell S. User Involvement in change management: A review of the literature, 2003. NCC SDO (National Co-ordinating Centre Service Delivery and Organisation) (And other SDO 'user involvement' reports on SDO website, www.sdo.lshtm.ac.uk
29. Davies C, Wetherell M, Barnett E, Seymour-Smith S. Opening the Box. Evaluating the Citizens Council of NICE. Report prepared for the National Co-ordinating Centre for Research Methodology, NHS Research and Development Programme. The Open University, 2005
30. Oliver S, Armes D, Gyte G. Evaluation of public influence on the NHS Health Technology Assessment Programme. Executive Summary. Prepared by the SSRU (Social Science Research Unit), Institute of Education, University of London. June 2006
31. UKCRC Patient and Public website: http://www.ukcrn.org.uk/index/patients.html
32. NHS National Library for Health Patient and Public Involvement Specialist Library. http://www.library.nhs.uk/ppi/
33. NCRI/NCRN Radiotherapy Clinical Studies Group. http://www.ncrn.org.uk/csg/groups.asp?groupID=13
34. NCRI/NCRN portfolio of trials http://www.ncrn.org.uk/Portfolio/index.htm
35. Thornton H, Edwards A, Elwyn G. Evolving the multiple roles of 'patients' in health-care research: reflections after involvement in a trial of shared-decision-making. Health Expect 2003; 6: 189–197.