EUROPEAN JOURNAL OF CANCER 42 (2006) 2454–2458

available at www.sciencedirect.com

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journal homepage: www.ejconline.com

Position Paper

Patients and health professionals working together to improve clinical research: Where are we going? ☆

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ARTICLE INFO

Article history:
Received 27 April 2006
Received in revised form
11 May 2006
Accepted 16 May 2006
Available online 10 August 2006

Keywords:
Patient involvement in clinical research
Independent facilitation in collaborative research
Relevant hypotheses and endpoints
Research governance
Semantic interoperability

ABSTRACT

The pace of active involvement of patients in clinical research has increased over the last 10–15 years. Advocacy for this engagement between patients and health professionals is briefly traced, based on the author's experiences both as an independent advocate and as co-founder and chairman (1995–1999) of the Consumers' Advisory Group for Clinical Trials (CAG-CT). A brief history is outlined. As the benefits and minor drawbacks of collaborative working have become increasingly evident, attitudes have changed and methodologies have developed. A new professionalism in relationships with doctors is being sought: common vocabularies need to be defined. Some research governance problems are identified: forward thinking to solve them is advocated.

1. Introduction

The question: '*Should advocates be involved in the design of clinical trials?*' was explored in a *Europa Donna* Workshop at the 5th European Breast Cancer Conference in March 2006. An advocate is an 'intercessor or defender', or 'someone who pleads the cause of another'. I, as an *Independent Advocate for Quality in Research and Healthcare*, was asked to talk about patient involvement in research. I also defined myself as a patient; a patient–researcher; an observer, and a commentator on this rapidly developing phenomenon of 'patient and public involvement in research'. A letter on bmj.com (March 2006) coined the terms 'emancipated patient' and 'experienced patient' in preference to 'expert patient'.[1]

Words such as 'advocate' and 'patient involvement' should be used with precision.

Words in common usage are often used carelessly: semantic interoperability should be striven for.[2,3] Wright and colleagues in their paper in the current issue of *Health Expectations* are similarly at pains to achieve precision when they define 'participatory research'[4] when they describe development of this activity. They also confirm that method-

☆ From a presentation given at the 5th European Breast Cancer Conference (EBCC) Nice, France, 21st–25th March 2006 in a Europa Donna Workshop 24th March 2006, entitled: '*Should advocates be involved in the design of clinical trials?*' against the given title: '*Patient involvement in research (including the work of the Consumers' Advisory Group for Clinical Trials (CAG-CT)*'.

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0959-8049/$ - see front matter
doi:10.1016/j.ejca.2006.05.022

ologies and recruitment strategies can continue to evolve[5] even in the course of work.

The rôle of involved patients was neatly defined by Roger Wilson, Chairman of the UK National Cancer Research Network Consumer Liaison Group. (NCRN CLG). He wrote:

> 'Members are nominated because of their individual experience, not because of their connections, even if their connections were the route by which they were contacted. Members of the CLG are appointed as individuals.
>
> There are very good reasons for this approach. First, the experience of cancer, whether as patient or carer, is very personal and it is that first hand experience that NCRN/NCRI needs to capture. Secondly, the role of many charities is advocacy, maybe not exclusively, but certainly part of their activity. The aim has always been that representation in the peer review process should be as an equal, not as an advocate (which, by definition, is external to the process).'[6]

Advocates can advocate externally FOR research (or other matters), but not from WITHIN research teams. A 'new professionalism' in relationships with doctors is being sought[7]: it has to be defined, learnt and cultivated.[8]

2. The establishment of the CAG-CT

Europa Donna Workshops provide a vehicle not only for health professionals and patients to learn from each other, but also to provide stimulus and ideas to newer member countries who may be glad to learn of the experiences of those who have been active for some years. With this in mind, it is hoped that this brief sketch of an early UK initiative might prove valuable and instructive.

The unique requirement for equality and individuality of input was emphasised at the first meeting of the *Consumers' Advisory Group for Clinical Trials (CAG-CT)* in September 1994.

We founding members were a group of eight people: four breast cancer patients and four health professionals. We comprised: a businesswoman; a male surgeon; an artist and poet; a clinical trials data manager; an academic lawyer; a research fellow; a language tutor; a health information officer. Between us we brought not only our professional skills, but also a wealth of subsidiary interests and skills, experiences, enthusiasms, foibles, faults and personal characteristics. Such are the dynamics of any group of people. But we had a common purpose that over-rode all other attributes: a belief in our activity as a joint working group of patients and health professionals. The only absolute requirement for membership was total commitment to the ethos. It was more important than achieving a large membership. This was a difficult concept to grasp for some people who viewed what we were doing: misunderstood by some. We were a *working* group, not an *advocacy* group representing a large membership. No 'them and us' attitude, but a particular kind of equality, with respect for each individual's abilities and contribution in an atmosphere of mutual learning. We saw ourselves as a '*facilitator for progress*'.[9] Education of the public about research, whilst they are well, was another main objective of the Group.[10]

Groups do not come ready-made, nor with fully articulated aims, objectives, constitution and modus operandi. These had to be drafted and refined from the outset, but not at the expense of getting on with the work we had come together to do at our first meeting.

3. The work of the CAG-CT

The *CAG-CT* began work at its first meeting by commenting on the draft of a feasibility study examining the use of HRT in women with early stage breast cancer. This work shaped development of the multi-centre national trial of HRT in Women with Early Stage Breast Cancer. [ISRCTN 29941643],[11,12] (See INVOLVE website database, Project No. 44. www.invo.org.uk).

We successfully applied for funding from the NHS Research and Development Cancer Programme in 1995 against a call for proposals in their priority area of' 'improving accrual into trials'. Our project: '*Using a Consumers' Advisory Group to increase accrual into trials*'[13] used independently facilitated focus group methods to identify and prioritise[14] the outcomes that patients, researchers and clinicians wanted. This work also identified the specific training needs for those who would be involved in conducting the trial, and the information needs of participants, patients[15] and health professionals. Facilitators from the King's Fund set out clear ground rules and methodology for arriving at prioritisation. This enabled satisfactory and equitable input from a very mixed group of researchers, clinicians, patients and advocates in this project.[16]

4. Addressing general uncertainties

I want to emphasise that, in this project, the CAG-CT's breast cancer patient–researchers undertook this work, not through personal, individual interest in the effect of use of HRT in conjunction with a diagnosis of breast cancer, but because they appreciated the general high level of uncertainty about this. They knew that clinicians, and huge numbers of breast cancer patients, many of them suffering from extreme menopausal symptoms as a result of the treatment itself, were confused and uncertain about the use of HRT, and the effects of Tamoxifen, in these circumstances. Many misunderstandings on the part of both patients and clinicians were exposed: it was mutually educative and beneficial.

Such patient advocates, working very closely with experienced clinicians in a facilitative working group as co-researchers, are able to develop a professional detachment that, although founded on personal experience of the disease, puts aside personal considerations in order to address particular general uncertainties. We did it because we saw enormous potential benefit for improved quality-of-life for many thousands of women.

These principles were modelled again in the Health in Partnership Welsh study of shared decision-making and risk communication.[17] The *CAG-CT* was involved from the pre-trial phase, and throughout. http://www.healthinpartnership.org/studies/edwards.html In this work, a range of pre-trial focus

group work led to a more precise definition of the research question. It is vital to know what citizens value most when they become patients, and to be able to measure this accurately and reliably. It is very important to explore the feasibility, acceptability and relevance of a hypothesis with patients,[18] so as to clearly define the question – or even perhaps reject it altogether.

5. Endorsement for and recognition of our activity

New joint approaches of working together in research endeavours require promotion, endorsement and evaluation if they are to be taken seriously. Endorsement of the *CAG-CT* initiative was given by the *House of Commons Health Select Committee* in their Report on Breast Cancer Services (HMSO July 1995): '*We believe that patient involvement at all stages of a trial, including initial design, is essential, and that initiatives such as the Consumers' Advisory Group for Clinical Trials are to be welcomed*'.[19] They stated that patients should be seen as '*full and active participants*'.

The United Kingdom Co-ordinating Committee for Cancer Research (*UKCCCR*) recognised the *CAG-CT*'s contribution. It received regular reports of our activity. We were urged to devote energy to promoting understanding of trials to the general public.

Two conferences were arranged with *Marie Curie Cancer Care*. 'Towards Public Understanding of Clinical Trials'[20] took place in February 1998 in London, followed by 'Information Provision – how can we get it right?' in October 1999.

6. Patient and public involvement in research today

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 as active participatory researchers.[4,21] Evidence suggests that benefit from their participation outweighs the drawbacks.[22–26]. Clinical research has become more sensitive, more relevant (to the patient), and of greater benefit to society and the NHS as a result.

Users are no longer always viewed as 'outsiders'.[27] It is acknowledged that patients possess unique expertise and experience[28] that can enhance deliberations, provide insights and valuable contributions formally and informally, both in one-to-one exchanges and in structured situations.

7. The future

Patients and clinicians must now work together to shape the therapeutic research agenda,[4,8,16] and to develop and use new models of engagement. Together they must identify and order the priorities for research about topics that matter to patients, to lift them to the top of the agenda. The UK leads the way in promoting collaboration in the research process from pre-trial through to dissemination and implementation: many models are available on the database of *INVOLVE*.[29]

We can now extend this collaboration by encouraging partnerships between organisations representing patients, and organisations representing clinicians, working together to confront important uncertainties about the effects of treatments, within the James Lind Alliance.[30] www.lindalliance.org.

Much involvement and collaboration has resulted from spontaneous patient activity[31,32] embraced by supportive health professionals who identified the potential for mutual learning, improved research hypotheses, more relevant endpoints, and better outcomes for patients and for the health service. This has been taken up, encouraged and supported by DoH organisations.[33,29]

Development and refinement of methodologies, more skilful integration of qualitative research with the quantitative,[34–36] have led to evidence of value leading to provision of better healthcare. At the same time, patients' contribution and the work of multidisciplinary researchers have led to improvements in the process of undertaking research, reporting research, publishing findings and in reviewing, disseminating and implementing evidence within the Cochrane Collaboration.[37]

8. Research governance

Research governance is necessary to protect patients, professionals and organisations, but its introduction and implementation in the UK has been a shambles.[38,39] Everyone must strive for regulatory processes that are sensible, fair, appropriate and adequate.

Adherence to the letter of the law, rather than its spirit, combined with lack of flexibility and common sense, has resulted in unethical and unacceptable delays for researchers in the UK,[40] and loss of morale.[41] A way forward to ensure that all Trusts are working to the same standard is by use of Research Passports for researchers' contracts, now being rolled out in the UK.[42] A similar Research Passport for involved patient/public researchers could well be the way forward.

We must now anticipate and plan for a comprehensive and practical regulatory approach to research that actively involves patients, to avoid it being regulated out of existence by bureaucratic insensitivity and heavy-handedness. Attempts by University Departments to impose unsuitable honorary research contracts, and to deduct tax at source on fees or honoraria of voluntary, un-waged, independent patient-researchers, as I have experienced,[43] are unethical obstacles to testing treatments together.

9. Conclusion

When the composition of any group of stakeholders changes, the power dynamics are altered. As an initiative develops over the course of time, it goes beyond the scope of originators to influence or shape – what Epstein describes as the 'rebounding pathways of influence and engagement'. We have probed into the hitherto closed 'black box of science' in the search for reason and compassion when we test treatments.[10] This is a 'new approach to the study of the politics of knowledge-making' – a place where patient–advocates meet with Science in testing treatments.[44]

Conflict of interest statement

No conflict of interest.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ejca.2006.05.022.

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