

Patient perspective

Why don't health researchers report consumer involvement?

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ABSTRACT

Background The expected influence of patients and the public on the relevance and design of research has yet to be determined. Our aims were to investigate if researchers publishing in international general medical journals had actively involved consumers in their research and the extent to which authors perceived that they had done so.

Methods Two researchers independently identified the extent to which there was consumer involvement in the research process in 200 published papers, randomly selected from each of four international general medical journals. Corresponding authors of the published research papers were surveyed to establish the extent to which they perceived that they had involved consumers in their studies.

Findings Consumer involvement actually occurred in six of the 200 original articles according to our established definitions – two papers in each of the *British Journal of General Practice* and *British*

Medical Journal and one each in *The Lancet* and *New England Journal of Medicine*. One hundred and thirty two (66%) corresponding authors replied, of whom 54 (41%) reported that they had involved consumers in their research. Three-quarters (39) of these thought that involving consumers had had benefits.

Interpretation A minority of researchers are aware of the potential benefits of involving consumers in health-related research. There is a mismatch between researchers' perceptions that they are involving consumers, and an established definition of consumer involvement. This appears to be due to a mix of researchers' lack of knowledge or skills and omission of details about consumer involvement in the published papers.

Keywords: consumer involvement, lay, publication, research

Introduction

New systems for wider involvement of citizens in healthcare are being instituted within the health service in the UK and other European countries.^{1,2} There are calls for such patient and public involvement to be extended to research too.^{3,4} The belief is that research and development that is focused on what is rated as important by patients should

increase the relevance and public impact of health-related research.⁵

We investigated whether researchers publishing in international general medical journals had actively involved consumers in their research and the extent to which authors perceived that they had done so.^{6,7} Our definition of 'consumers' for this study was 'patients and potential patients, carers, organisations representing consumers' interests, members of the public who are the targets of health promotion

programmes and [those individuals and groups who are] exposed to potentially harmful circumstances, products or services'.⁶ Others have adopted this definition too.⁸ The definition of 'involvement' used was that consumers were involved at any or all of the stages of the research process – that is, 'setting the research agenda, commissioning research, undertaking research, interpreting research and disseminating the results of research'.^{6,7}

Methods

Preliminary discussions to shape the purpose and content of the study took place with a variety of consumer representatives from self-help groups, a medical librarian (SS) and a consumer involvement organiser.

Stage 1

We established the extent to which consumer involvement in research was evident in published papers. Two hundred papers were selected from four journals: the weekly *British Medical Journal* (*BMJ*), *New England Journal of Medicine* (*N Engl J Med*) and *The Lancet*, and monthly *British Journal of General Practice* (*BJGP*). Fifty papers were selected from all 'original papers' or 'articles' in each journal. Consecutive papers were extracted from the *BJGP* from 1 January until the end of September 2000, until 50 papers were obtained fitting the inclusion and exclusion criteria. Fifty papers obeying the inclusion and exclusion criteria were randomly selected from each of the other three journals, using a table of random numbers.

- **Inclusion criteria:** original papers of at least 2000 words, published between January and September 2000 inclusive.
- **Exclusion criteria:** systematic reviews or meta-analyses, guidelines or case reports.

Two researchers (LMO and SL) acting independently scrutinised the methodology described in the study papers to define the extent and staging of consumer involvement in the research process. Where there was disagreement RC could act as arbitrator.

Consumer input for *this* study came from SS acting as a 'member of an organisation representing consumers' interests [a medical library] and exposed to... products or services [medical research journals]'.⁶ SS was deemed to be suitable because his background knowledge of scientific publications enabled him to work with the research team. SS critiqued the proposed method and discussed and interpreted the findings of the study.

Stage 2

We posted a questionnaire to the corresponding authors of all 200 study papers in January 2001. We defined 'consumer' and 'consumer involvement' and asked each author to specify whether they considered that there had been consumer involvement in their research study, and if so, what and at which stage(s) in the research process.^{6,7} Authors described the effects any consumer involvement had had on their research, and commented on whether consumers *could* have been involved and the potential value.

Questionnaires were sent out on paper and on disk and could be emailed or posted back on paper or disk. Freepost envelopes were enclosed for return within the UK.

Non-respondents were reminded once by email where contact details were known, and otherwise by post.

Results

The questionnaire was revised following the consumer representatives' comments.

Stage 1

Two hundred and sixty papers were reviewed in order to select 200 which fitted the inclusion criteria. Of those excluded there were 45 short papers (less than 2000 words), 13 systematic reviews or meta-analyses and two case reports.

There was 100% agreement about the extent of consumer involvement between the two independent researchers. Consumer involvement was reported in six of the 200 papers; two each in the *BJGP* and *BMJ* and one each in *The Lancet* and the *N Engl J Med*.^{9–14}

The extent of consumer involvement at specific stages in the research process included: consumers' input into determining health needs and relevance of questionnaire and research design (2); Community Health Council acting as 'patients' advocate' in commissioning research (1); 'local people' collecting data (2); research subjects recruiting controls (1) (see Table 1).

The countries of fieldwork of the six papers reporting consumer involvement were: UK (3), USA (1), Netherlands (1), Thailand (1).

Stage 2

One hundred and thirty two (66%) corresponding authors responded from publications in the *BJGP* (40), *BMJ* (39), *N Engl J Med* (25) and *The Lancet*

Table 1 Extent of consumer involvement in 200 published research papers

Stage in the research process	Papers with consumer involvement ($n = 6^*$) <i>n</i>
Set priorities for health services through needs assessment and other activities	2
Commissioned, funded or reviewed proposals	1
Managed <i>and</i> designed research	0
Recruited participants for research projects	1
Collected data	2
Acted as pro-active participants in research <i>and</i> having some control over the processes of supplying information	0
Analysed and interpreted results	0
Monitored or audited existing health services	1
Reviewed a study or body of work	0
Disseminated results of research	0
Implemented findings of research	0
Looked at ethical issues associated with research	0

*One paper included consumer involvement in two stages of the research process

(28). Authors returned completed questionnaires by email (41) or posted back a paper copy (82) or disk (9).

Countries in which research fieldwork was undertaken were: UK (69), developed countries not UK or USA/Canada (31), USA/Canada (20), under-developed countries (6), mix of UK and USA (3), mix of developed/ underdeveloped (3).

Seventy eight (59%) responding authors did not report including consumer involvement in their published studies; the rest (54 or 41%) indicated that they had involved consumers in at least one stage of the research process, as Table 2 shows.

Responses from the 54 authors who reported involving consumers in their published research

Authors of all six papers rated as having actually involved consumers, reported having done so.⁶ Eighteen other authors volunteered extra information about consumer involvement in their studies that had not appeared in their research reports, that fitted our definitions of consumer involvement.⁶ These included examples of consumers prioritising the topic of research (12), contributing to study design (9), disseminating results (6), enabling funding (3) and

Table 2 Comparison of extent of defined consumer involvement in published research studies with whether authors reported that it had occurred ($n = 132$)^{6,7}

Stages in research process in which consumer involvement was reported	Consumer involvement	
	Actual ^{6,7} <i>n</i>	Reported <i>n</i> (%)
0	126	78 (59)
1	5	15 (11)
2	1	12 (9)
3	0	14 (11)
4	0	2 (2)
5	0	6 (5)
6	0	1 (1)
7	0	1 (1)
8	0	1 (1)
9	0	2 (2)

clarifying the study for other lay people (2). Typical descriptions of consumer involvement given by these authors were:

- 'National Childbirth Trust was represented at advisory group meetings and consulted on aspects of project management'
- 'informal consultation with patient group both identified the topic and informed decisions on methodology'.

Perceived consumer involvement was reported most commonly in *disseminating* the research findings (28 of the 54 respondents) and in *identifying the topic* for research (25), as Table 3 shows.

The descriptions of consumer involvement by 26 respondents fell outside our stated definitions of consumer involvement.⁶ Typical descriptions mistakenly given to illustrate consumer involvement where consumers exerted no influence over any stage of the research process or were merely the subjects of research were:

- 'it was featured in mass media, a radio interview on BBC'
- 'a key element of the research was a questionnaire to elderly people'
- 'many pharmaceutical advisory committees disseminated results'.

Thirty nine (72%) of the 54 authors who believed that consumer involvement had occurred in their study thought it had been beneficial; whilst ten (19%) reported neither negative nor positive effects, as described in Table 4. Examples of benefits attributed to the involvement of consumers included: increased response from subjects (6), help in design (4), additional funding (4), another perspective to research study (3), identified problem for research (3), influence on government to take research findings seriously (2), influence on media campaign (2), conveying of information (1). The majority of authors did not believe that consumer involvement had influenced the outcome of their research, as Table 4 shows; 13 authors considered that involving consumers had influenced the outcome of their research for the better, of whom seven had involved consumers in a way that fitted with our study definitions.^{6,7}

With hindsight, many of these 54 authors perceived that they could have involved consumers in more stages of the research process; an additional 19 thought that they could have involved consumers in 'disseminating' research, 15 in 'evaluation', 14 in 'prioritising' research, 10 in 'analysing and interpreting' findings, 7 in 'managing research' and 7 in 'designing research', 5 in 'identifying' the research topic, 2 in 'commissioning'.

Table 3 Stages of research process in which defined consumer involvement was reported by corresponding authors^{6,7}

Stage of research process in which consumer involvement reported	Corresponding authors who had reported consumer involvement occurring in their research (<i>n</i> = 54)		
	Consumers involved in at least one stage of research process		Don't know
	<i>n</i>	(%)	<i>n</i>
Identifying topic	25	(46)	1
Prioritising	16	(30)	4
Commissioning	11	(20)	3
Designing research	16	(30)	1
Managing research	6	(11)	1
Undertaking research	14	(26)	1
Analysing and interpreting	8	(15)	0
Disseminating	28	(52)	2
Evaluating	16	(30)	1

Non-response rates varied between 7 and 10 for each item

Table 4 Perceived beneficial or negative effects and influence from consumer involvement on research process according to corresponding authors

Perceived effects and influence on outcome of research process attributed to consumer involvement	Corresponding authors who had reported consumer involvement occurring in their research (<i>n</i> = 54)	
	<i>n</i>	(%)
Perceived effect(s) on research process		
Negative effect(s)	0	
Neither beneficial nor negative effects	10	(19)
Beneficial effect(s)	39	(72)
Both beneficial and negative effects	1	(2)
Don't know	1	(2)
No answer	3	(6)
Perceived influence on outcome of research		
Influenced outcome of research for the worse	0	
Influenced outcome of research neither better nor worse	30	(56)
Influenced outcome of research for the better	13	(24)
Don't know	1	(2)
No answer	10	(19)

Similar proportions of responding authors who perceived that they had, and had not, involved consumers, worked in all categories of countries and were funded from all types of sources – research councils, charitable bodies, commercial sources and nil additional funding.

Discussion

There was little evidence of consumer involvement reported at any stage in the research process in the majority of the 200 published papers we studied. According to the definitions we adopted, consumer involvement was reported as being integral to the research undertaken in only six publications.^{6,7}

However, two-fifths of authors responding to our study questionnaire declared that they *had* involved consumers in at least one stage of the research process. Nearly half of these gave examples that fitted with our definition of consumer involvement, but over half gave examples which showed that they did not understand that consumers had to have some influence on the research process to be classed as being 'involved'.^{6,7}

Explanations for the gulf between perceived and actual consumer involvement

Many researchers appeared unaware that actual involvement means that consumers are able to influence the research process in some way. This requires the relinquishing of some power over the research process. We need to train researchers and consumers, if consumers are to be empowered to influence the research process.^{15,16}

Real consumer involvement did appear to have featured in studies where details had been omitted from the research reports. The word limit of a journal paper might have prohibited the inclusion of information about consumer involvement, or such information may have been thought unimportant. Authors may not have prioritised the inclusion of information about how the research topic was identified or may have written up and submitted their report before the study results were disseminated with consumers' help.

Limitations to our study

It is possible that the research published in the four general medical research journals selected may not

have been representative of health-related research undertaken in the UK and worldwide. It could be that research published in specialist journals involves consumers more often, but we have no evidence for that.

Consumers were reported to be involved in the work of one-third of clinical trial co-ordinating centres in the UK in the year 2000 in a study that adopted the same definition as in our study.⁵ Insufficient time may have elapsed since the calls to include more consumer involvement in research and for a response to be made by the research community that is evident in publications.

Advantages of consumer involvement

Most of the respondents agreed in principle that consumer involvement gives added value to research studies whether or not they themselves had incorporated it. But few of those who described involving consumers acknowledged that this consumer involvement had influenced the outcome of their research, although most thought that there had been benefits to the research process. The advantages of consumer involvement in research and development are expected rather than proven, except for some good examples.^{3,5,16,17} Dieppe has warned of the dangers of research 'agenda bias' arising from vested interests dominating the commissioning of new research, and indicated that the views of customers might help to decide what research should be done.¹⁸

Future of consumer involvement in health research

The recent publication of a *Research Governance Framework for Health and Social Care* emphasises that 'participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research'.¹⁹ Education and training for consumers and researchers will need to be a component of the implementation of the research governance framework as our results show that a substantial proportion of world class health researchers do not understand the meaning of consumer involvement nor how to integrate it within their research. Informed and trained consumers might form local networks upon which health researchers could call at any stage in the research process.

REFERENCES

- Mackeeney S, Fallberg L and Andersen T. *Supporting Patients' Rights and Empowering Citizens: emerging systems in Europe*. Copenhagen: European Partnership on Patients' Rights and Citizens' Empowerment, World Health Organisation, 2001.
- Department of Health. *Patient and Public Involvement in the New NHS*. London: Department of Health, 1999.
- Hanley B. *Involvement Works*. Winchester: Standing Group on Consumers in NHS Research, 1999.
- Anon. How consumers can and should improve clinical trials [editorial]. *The Lancet* 2001;357:1721.
- Hanley B, Truesdale A, King A, Elbourne D and Chalmers I. Involving consumers in designing, conducting and interpreting randomised controlled trials: questionnaire survey. *British Medical Journal* 2001;322:519–23.
- Standing Advisory Group on Consumer Involvement in the NHS R and D Programme. *Research: what's in it for consumers?* Wetherby: National Health Service Executive, 1998.
- Oliver S, Milne R, Bradburn J et al. Involving consumers in a needs-led research programme: a pilot project. *Health Expectations* 2001;4(1):18–28.
- Hanley B, Bradburn J, Gorin S et al. *Involving Consumers in Research and Development in the NHS: briefing notes for researchers*. Winchester: Consumers in NHS Research Support Unit, 2000.
- Smith J, Regen E, Shapiro J and Baines D. National evaluation of general practitioner commissioning pilots: lessons for primary care groups. *British Journal of General Practice* 2000;50:469–72.
- Williams SE, Bond CM and Menzies C. A pharmaceutical needs assessment in a primary care setting. *British Journal of General Practice* 2000;50:95–9.
- Hovell MF, Zakarian JM, Matt GE et al. Effect of counselling mothers on their children's exposure to tobacco smoke: randomised controlled trial. *British Medical Journal* 2000;321:337–42.
- Fielder HMP, Poon-King CM, Palmer SR, Moss N and Coleman G. Assessment of impact on health of residents living near the Nant-Y-Gwyddon landfill site: retrospective analysis. *British Medical Journal* 2000;320:19–23.
- Nosten F, van Vugt M, Price M et al. Effects of artesunate-mefloquine combination on incidence of plasmodium falciparum malaria and mefloquine resistance in Western Thailand: a prospective study. *Lancet* 2000;356:297–302.
- Meijer JCM, Tehelenburg WCH, Bourna BN, Bertina RM and Rosendaal FR. High levels of coagulation factor X1 as a risk factor for venous thrombosis. *New England Journal of Medicine* 2000;342:696–701.
- Cleophas RC and Cleophas TJ. Is selective reporting of clinical research unethical as well as unscientific? *International Journal of Clinical Pharmacology and Therapeutics* 1999;37(1):1–7.
- Carter Y, Shaw S and Thomas C (eds). *Patient Participation and Ethical Considerations. Master classes in primary care research. No 5*. London: Royal College of General Practitioners, 2001.
- Chambers R. Involving patients and the public – is it worth the effort? *Journal of the Royal Society of Medicine* 2001;94:375–7.
- Dieppe P. To cure or not to cure, that is not the question. *Journal of the Royal Society of Medicine* 2000;93:611–13.
- Department of Health. *Research Governance Framework for Health and Social Care (2e)*. London: Department of Health, 2003.

CONFLICTS OF INTEREST

None.

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