

Title page:

Public involvement influences a national research agenda

Running title: Public involvement influences national research

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Abstract

Objective: To describe the input and influence of public involvement in setting the agenda for a national research programme.

Data sources/ study setting: The NHS Health Technology Assessment (HTA) Programme, 1999 – 2004.

Study design: A mixed methods evaluation employing document analyses, key informant interviews and structured non-participant observations.

Data collection/ evaluation methods: Routine management records of the HTA programme were examined for public influence of research topics. The nature and influence of contributions from the public were compared with those of other experts. Structured observations of Advisory panel meetings investigated how discussion and decisions related to patient and public perspectives and how panel members responded to public input to the programme. Semi-structured interviews gathered perceptions of staff and Advisory Panel members.

Principal findings: The public provided unique contributions both as external experts and as panel members. The value and influence of many of these contributions are acknowledged by staff and panel members.

Input from external public experts was least where recruitment was passive (through a web site),and where contributions were required in a research question format that may be unfamiliar to non-researchers. However, public influence at this stage was at least in the same order as that of professional suggestions.

Input was most where recruitment effort was greater, where contributions could be made in an open format and responsibility for integrating these into a research question format lay with research programme staff. Public experts contributing at this stage often influenced the research plans. They made some important changes including: making patient and carer perspectives explicit; changing the focus of the research; adding new outcomes; refuting the need for the planned research; providing up-to-date prevalence data; and providing plain English background text.

At their best, public members of Advisory Panels were seen as providing useful comment and encouraging greater sensitivity to patient perspectives amongst other panel members. At their worst they were seen as lobbying for particular patient groups.

Conclusions: Public involvement has influenced decisions about research commissioned by the HTA programme with only relatively minor changes to the procedures and resources for managing the programme. The results in outcomes research that incorporates patients' and publics' preferences and values being freely available for evidence-informed health services.

Key words: Public involvement, patient involvement, consumer involvement, research programme, health technology assessment, outcomes research

Background

Patient and public involvement in health technology assessment is justified by three goals:^[1] better oversight and accountability to those being served and, in the public sector, to those meeting the costs; better quality decisions that reflect patients' and publics' preferences and values; and increased knowledge and capacity through well designed dissemination strategies..

A growing body of literature supports the inclusion of patients, other service users and the wider public in guiding health technology assessment^[2,3,4] particularly in considering the interventions and outcomes for evaluative studies.^[5,6,7] This literature addresses individual studies rather than research agendas for whole programmes despite policies supporting public involvement in national level programmes.^[8,9,10,11]

Diverse research funding organizations now involve patients and the wider public in identifying and prioritising research topics but little is known about the actual effects of this involvement.^[12] A systematic literature review found that the evidence for public involvement in research agenda setting rests largely on descriptive reports with very few reports detailing how decisions were made and revealing relatively little impact on subsequent research.^[13] The review recommended research on collective decision-making, research that records working practices and investigates barriers to the influence of the public on research agendas, and assessments of the impact of such involvement.

A particularly appropriate setting for such an investigation is the commissioned research of the UK Health Technology Assessment (HTA) programme, which produces independent research about the effectiveness of different healthcare treatments and tests for those who use, manage and provide care in the National Health Service (NHS) (emphasis added). It identifies questions that the NHS needs the answers to by consulting widely with these groups, and commissions the research considered most important (see figure 1). This paper reports the evaluation of public involvement in setting the agenda for the HTA programme's commissioned research, now part of the National Institute for Health Research (NIHR).

The HTA programme and its advisory panels, supported by the NIHR Coordinating Centre for Health Technology Assessment (NCCHTA), decide which of the many suggestions received from the NHS and its users should become research priorities. Then the programme commissions research by open competition to address these. Results of the research are published as peer reviewed reports in the HTA monograph series.

Most people contributing to the HTA programme are clinicians and researchers. They may be asked to suggest research topics, or be consulted as 'experts' about particular research needs. Some sit on topic prioritisation advisory panels or the Prioritisation Strategy Group, some peer referee research proposals and some are members of a commissioning board. The

staff at the NCCHTA provide the secretariat support. They collate the research suggestions, present them to advisory panels for consideration, commission the research and publish the findings.

Insert figure 1 about here

HTA priority setting

Effective prioritisation lies at the heart of the HTA Programme. This involves choosing 30 or so priorities out of the hundreds of suggestions received each year that become commissioned research. Suggestions arrive through a number of routes including the HTA website, horizon scanning for new technologies, and research recommendations from systematic reviews.

At the time of the evaluation reported here, topics were prioritised by three HTA advisory panels each addressing a different scope: diagnostic technologies and screening; pharmaceuticals; and therapeutic procedures. Panels were assisted by vignettes, or briefings of research need that reviewed the extent of the health problem, outlined existing or planned research, and clarified the research question. Vignettes included information about the:

- research question (the technology to be evaluated, the patient group, setting, control or comparator treatment, research design, primary outcomes and minimum duration of follow-up)
- cost, and current and projected use of the technology
- quantity and quality of the research so far, and in progress
- potential effectiveness of the technology

Public involvement in priority setting

Public involvement in the HTA programme began in 1997 when people were sought through patient and carer organizations and charities to share the tasks of other experts involved in identifying research topics and refining and prioritizing research questions. It has been developed progressively since^[14,15,16] and has been highlighted on the HTA programme web pages.

The term 'public involvement' has been adopted to describe involvement in collective decisions of people who are: patients; unpaid carers; parents/guardians; users of health services; disabled people; members of the public who are the potential recipients of health promotion/public health programmes; groups asking for research because they believe they have been exposed to potentially harmful circumstances, products or services; groups asking for research because they believe they have been denied products or services from which they believe they could have benefited; and organizations that represent service users and carers (adapted from INVOLVE, a national advisory group also funded through NIHR, which promotes public involvement in NHS, public health and social care research).^[17] In order to maximise public input, the programme seeks people who are linked to peer networks so that they are able to draw on a wide body of patient and public opinion. In order to bring fresh eyes to the work of the HTA programme a patient or member of the public is not normally a health practitioner, manager or researcher.

Procedures for involvement included: encouraging suggestions for research from the public; recruiting and supporting public members of advisory panels; inviting people from peer support and patient charities (collectively known as 'public experts' as distinguished from professional experts) to comment on vignettes; and seeking feedback from them, and those working with them, about their experiences and views of the HTA programme including the procedures and resources that involve them.

Recruitment began with developing a job description and person specification. Organizations likely to know people meeting the person specification were considered to be those with service user leadership, a national scope, local network, and a clear awareness of the purpose of research for health. Relevant organizations were identified from directories of patient organizations, searching the World Wide Web for condition specific organizations, and from personal contacts. Through each organization an individual was sought who matched the person specification and was willing to embark on the task as defined in the job description.

At the time this research was carried out, each panel had two public members. Following each panel meeting, researchers at the NCCHTA prepared about six vignettes to inform the prioritisation process. Where possible, people from peer support groups or charities for service users commented on vignettes in order to highlight issues that were important to service users. They were asked to base their comments on their own knowledge and experience, particularly focusing on whether the research question was the right one, what mattered to service users and whether it looked at the right aspects of the health condition or problem. They were also asked for their views on the important areas in which the research topic should make a difference.

This evaluation was conducted during 2003 – 2004, and aimed to assess whether public involvement since 1999 influenced research commissioned by the HTA programme and, if so, how and to what extent.

Methods

Evidence of public input and influence was gathered from in-depth interviews with key informants, structured observations and document analyses. Key informants with knowledge acquired from working inside the organization were chosen for their perspectives and reflections on that experience.^[18] Structured observation of meetings where the research team is familiar with the organizational setting allowed a quantitative analysis of behaviour without interrupting proceedings.^[19] Records used in routine organizational management provided (a) a contemporary record of events;^[20] (b) an account suitable for analysing the perspectives of the record keepers;^[21] and (c) data comparable with data from other sources, such as interviews or observations. The purpose of documentary analysis in these circumstances was to stimulate thinking about the concepts that emerge from other data and to understand the structure and function of the organization.^[22] Data were initially analysed

from each source separately, and later the findings from structured observations and document analysis tracing input and influence were combined with key informant data to identify barriers to public input and influence.

Interviews

A formative evaluation had previously elicited the views of service users contributing to the programme.^[16] For the current work interviews investigated the influence of contributions from the public as perceived by panel members and the secretariat. Eleven key informants were interviewed: two public panel members, two panel chairs, two members of the commissioning board, and five NCCHTA staff who supported the prioritisation and commissioning programmes. Interviewees were assured of confidentiality and concordance with the UK Data Protection Act (1998)^[23] and their informed consent invited.

Interview respondents were first invited to describe the nature of their work, then about their views of patient and public involvement. Interviews were semi-structured with open-ended questions and respondents were given an opportunity to raise additional issues. Most interviews were conducted over the telephone, some were face-to-face, and one by e-mail.

All interviews were recorded and transcribed. Two researchers (DA and SO) read full transcripts and assigned initial free codes independently before discussing their thoughts and preparing an agreed framework. Using this framework the two researchers coded the transcripts again and selected quotes to describe perceptions of public involvement in terms of: the routes for public involvement, supporting public involvement; how public involvement influenced the programme; reasons for public involvement not influencing the programme; and suggestions for change.

Observations of panel meetings

Two Advisory Panel meetings were observed in order to understand how discussion and decisions related to patient and public perspectives and to learn how panel members responded to public input in meetings and vignettes. A checklist was used to record relevant issues including: who raised each issue; whether it was influential; and which issues were decisive factors in panel discussions.

Document analysis

Public involvement in identifying or prioritising research was identified from a search of routine NCCHTA records of: contact with external experts; vignettes prepared by NCCHTA staff annotated with information sources used to draft the vignette (e.g. research, experts, web sites); comments from experts on early drafts of vignettes; minutes of Advisory Panels and Prioritisation Strategy Group meetings; and records of commissioned research projects.

When a research topic or draft vignette amendment resulted from public involvement, one of the authors (DA) examined the records for the following data: the area of health; who made the suggestion; the organization to which they were associated; whether their organization was service user led, or a

charity run for, rather than by, service users. (Organizations were classified as service user led when it was they, and not health professionals or researchers, who formed a majority on the governing board, or were the majority of members of the organization with voting rights.)

A series of the ten most recent vignettes that were prepared with public involvement was analysed in depth to determine the contributions and influence of public and other experts. The three authors developed an analytical framework through independent coding, discussion of discrepancies and comparison of their work with analyses in three other similar studies^[4,24,25] The resulting framework was applied to comments received on vignettes from the public and from experts by two authors independently (GG and SO) who met to discuss and resolve discrepancies.

Comments from public experts were compared with comments from other experts within the same themes, and with the final version of the vignettes to determine whether they had been incorporated. Vignettes were also inspected for records of the sources used in preparing them.

The minutes of Advisory Panels during 2003 and 2004 (five meetings for each of three panels) were inspected for evidence of attendance by public members and their influence on decisions.

Results

Public involvement in suggesting topics

Public input was least at the stage of making original suggestions for research topics. Twenty-eight suggestions for research topics resulted from public involvement between late 1999 and late 2004 — less than 1% of all suggestions received. Four of these suggestions were merged into a single vignette which subsequently led to a commissioned research project. The remaining 24 suggestions from the public did not lead to vignettes. A minimum estimate of the success of public suggestions is 1 in 28 (3.6%); a maximum is 4 in 28 (14.3%). This compared with maximum success rate of 4.8% of all suggestions (records were not available for calculating how often, or how many, suggestions generally were pooled for single vignettes).

Key informants identified a number of barriers to public involvement in suggesting usable research questions. It is difficult to translate the problems of people's daily lives into a topic that supports a well structured research question. Public and professional members of panels inspecting topic suggestions agreed that research questions should be clear, relevant, well justified and attract wide support; but professionals also considered the likelihood of commissioning good research. Identifying priorities required sifting a large number of suggestions. Most suggestions fell short in terms of the required characteristics, particularly in failing to provide a clear researchable question.

NCCHTA staff and public members alike perceived that public suggestions were often disregarded because they were

too vague or they describe a service provision problem without specifying the research uncertainty which needs to be resolved in order to improve the quality of the service. [NCCHTA staff].

Public suggestions were also discarded because they could not be readily translated into the conventional framework of a research question:

If it were from a voluntary organization, particularly a small voluntary organization... or self help group, it would be hard for you to be seen to have a good question, because of the kind of hoops you have to jump through to make it look good. [public panel member].

There was little opportunity to improve poor suggestions as the procedures to attract them in the identification programme were separated from the procedures to examine them in the prioritisation programme (see figure 1). There was also no opportunity for communication to clarify or justify topics between the people outside of the HTA who made suggestions and people inside the HTA who processed them for priority setting.

This was less of a challenge where NCCHTA staff took suggestions for research from the recommendations of systematic reviews. This resulted in a research agenda that, from the perspective of research commissioning, was 'fine tuning of research need' [NCCHTA staff] after years of filling research gaps. In contrast, a public panel member's interpretation was that the research community suggested more research and was 'feeding the beast' whilst the concerns of patients, or nurses, or registrars [public panel member] were ignored. Staff were concerned that too few good suggestions were offered at the beginning of the process. They indicated a need for 'relationship building' to 'improve our dialogue' with people who might offer research suggestions.

There had already been efforts to formalise working relationships with organizations by 'affiliating' them with the HTA. Three HTA-affiliated organizations were patient organizations. Two members of NCCHTA staff and a panel chair mentioned working with affiliated organizations as one possible way of 'nurturing and fostering' relationships that could lead to better suggestions. Affiliated organizations were already relatively successful, with 8-9% of their suggestions leading to commissioned research — at least twice the usual success rate.

Public involvement in preparing vignettes

The clearest evidence of public input and greatest influence was in the preparation of vignettes. Routine records indicated public involvement in 54 of the 323 vignettes prepared since 1999 (17%). Contributions from peer support groups or charities to the preparation of 41 vignettes came from 34 individuals who were members of 24 different organizations. A further 13 vignettes had comments from charities. Public input at the vignette stage was spread across a range of topics although some broad areas had no public input. For

instance, topics about cancer and vascular research, each with over 30 vignettes, had no public input.

From a series of ten vignettes prepared with public comment, nine incorporated comments from public experts and five led to commissioned projects (see table 1). All five were supported by service users or charity reviewers. Five did not lead to commissioned projects; three of these had attracted skepticism from the public experts.

In-depth analysis of this series of ten vignettes revealed that they attracted a total of 125 public expert comments, 59 of which were incorporated into the vignettes (47%). Between them, other experts (between one and four for each vignette) made 141 comments within the same themes, 92 of which were incorporated (65%). The details of comments from public input and professional experts rarely overlapped. A smaller proportion of the comments from public experts were incorporated into the vignettes. There was no attempt to assess the quality of any comments.

Quite often ... and it's not just [public experts] ... but general experts don't understand exactly what the nature of the research brief is, even though... we've got a standard email.... So they think that perhaps it's the research protocol and then they start sort of going down the wrong line. [NCCHTA staff]

Even though not all public contributions were incorporated or retained, they made some important changes (table 1). These included: making patient and carer perspectives explicit; changing the focus of a vignette; adding new outcomes; refuting the need for the planned research; providing up-to-date prevalence data; and providing plain language background text. Other comments simply endorsed plans for research in the area. Some vignettes incorporated information from the web sites of charities or service user organizations despite public input being sought later than clinical input and with less specific guidance about what was needed in a response.

Public involvement in Advisory Panels

Public members of Advisory Panels were seen, at their best, as providing useful comment and encouraging greater sensitivity to patient perspectives amongst other panel members or, at their worst, as lobbying for particular patient groups. Each Advisory Panel included approximately 15 members, including two public members. There were 15 panel meetings held during 2003 and 2004. Most Advisory Panel meetings were attended by only one public member. Three meetings had two public members present (20%) and one meeting had none.

Only 5 of the 15 meetings had contributions from public members recorded in the minutes, and in only two meetings did these contributions relate to research priorities. Other minutes referred to: a resignation; congratulations to the HTA on its tenth anniversary conference; and public members introducing discussion of vignettes.

The panels observed had two public members each, although only one in attendance when each panel was observed. Table 2 presents themes discussed during these panel meetings. Research methods attracted most comment. Existing studies and relevance to the public were equally frequent discussion topics, followed by lack of evidence, ethics and benefit of intervention.

In one meeting, the public member raised eight points that were about patient relevance, and between them other panel members raised a further seven such points (table 3). In the other panel meeting the figures were two and two respectively. Comments by public members included: the importance of black and ethnic minority people's needs in relation to sickle-cell anaemia; and current recommendations for melatonin use by children.

Key informants described how some, but not all, public members bring a patient and/or public perspective that other members listen to, respect and consider an asset.

The most impressive quality of the best people in this field is that... they [have] influence over the minds of the other decision makers in the room. So they're effective and... an influential participant in the discussion. [and]... there's no doubt that they are conveying authentically the views of the people on whose behalf they are advocating. ... it's very impressive and very powerful. [NCCHTA staff]

It is very very very seldom ever that I find that the lay members actually introduce patient focussed considerations and ideas that have not already been addressed by all these caring people round the table whose job... is to look after patients... It actually is uncommon for them to broach utterly new ground. [Panel Chair]

Some concern was expressed about members' specialist background being inadequate for their generalist role on a panel, and about possible conflicting interests with their organizational role, whether professional or public, voluntary or paid, to advocate for patients in a particular area. Although these issues were not necessarily unique for public members, professionals thought that they might be faced with a greater challenge than other members.

Each individual member of the panel I would expect to contribute in a non partisan way and one of the problems that we've had with public members is that to keep up with the research and to understand the research world enough to be able to contribute they often have a background within a particular specific area... [Some people]... lobby on behalf of individual areas and... are less interested or less engaged in the broad generality, which is what we really want them there for. [Panel Chair]

It might be hard for you to resist the temptation to push [a] topic because your job and your commitment was to people with that condition. And that's very natural and one understood that, and they probably saw other members, the professional members of the committee perhaps doing that as well... paediatricians are very committed to child health issues and... the distinction between informing the committee as an expert in child health and advocating for child health topics is a very fine one, which I'm not sure I could draw. [NCCHTA staff]

An alternative view from key informants was that, over time, skilled public membership may be changing the culture of Advisory Panels, with all members becoming more sensitive to patient/ public perspectives.

Barriers to public involvement and influence

A number of organizational boundaries presented structural barriers to public involvement (see figure II). The scope and profile of the HTA programme and the scope and profile of voluntary sector organizations presented barriers to mutual awareness, understanding and a capacity to work together. A mismatch in interests and priorities, roles and responsibilities, and time scales for effective working were problematic when the HTA programme and people in the voluntary sector tried to work together.

*It's a two way thing in terms of going out there and making ourselves known to people and making use of their enthusiasm... it is a bit of a challenge... Maybe it's the nature of the programme, research and development... the name... 'Health Technology Assessment' programme... doesn't really mean a lot to people and it sounds terribly high tech and perhaps off putting, whereas... we cover all therapeutic interventions.
[NCCHTA staff]*

sometimes they didn't feel able or willing to respond to our invitation. Often because they are very small organizations depending on voluntary staff or very limited resources and this wasn't a priority for them. [NCCHTA staff]

Barriers to early input were the conceptual leap required to translate health problems into research topics; reliance on passive systems and awareness of the HTA programme in the voluntary sector; and the task of data entry via the HTA www pages. These were less of a barrier to suggestions from many other sources, particularly those where NCCHTA staff inspected systematic reviews for research recommendations (thereby avoiding the conceptual leap) and entered the data themselves.

The scope and profile of voluntary sector organizations often prevented quick and easy choices of organizations to approach for comments on vignettes. There may be many relevant organizations, yet they may differ in ideologies relevant to research topics. For instance, when seeking public input for screening, NCCHTA staff anticipate organizations holding conflicting views. An organization representing the general population might not want "to over medicalise" [NCCHTA staff] or support invasive procedures whereas another supporting sufferers might be calling for screening whether it's appropriate or not.

Public input to the programme could also be hampered by boundaries within the HTA which resulted from internal structures and working procedures. For instance, only at Advisory Panels was there the benefit of face-to-face communication. The initial route for research topic suggestions was one-way. Indeed, some suggestions were lost because there was no opportunity to clarify or negotiate refinements with their originator. Similarly, communication between NCCHTA staff and public experts about vignettes usually comprised a request and a response. Rare examples of iterative communication were raised as particularly valuable.

Areas of staff responsibility limited their ability to reflect on the whole process, from the original research suggestion to refinement of the vignette and panel decisions. Barriers were also presented when procedures differed between inviting professional and public input. NCCHTA staff preferred to consult professionals first, to shape the vignette and set the clinical details, before public consultation, thereby restricting the opening for public contributions. Public membership of Advisory Panels was not limited by a timing issue, but by an imbalance of numbers. With only two public members for each panel, there was often only one in attendance, making their role even more difficult.

Conclusion

This small scale study of routine data collected for the purposes of research management provides an in-depth analysis of the influence of public involvement on a research programme. It shows that, despite barriers, members of patient groups and charities have made contributions not available from other sources and influenced decision-making for research commissioning.

Input was least for originating possible research topics. Nevertheless, the success of public suggestions was in the same order as suggestions from elsewhere. In comparison with originating possible research topics, public input into shaping research questions was much greater and more influential. Key informant interviews comparing the challenges at both stages revealed barriers and provided the motivation to address these and enhance involvement by increasing the number of public members of panels, seeking input to vignettes from professionals and public experts simultaneously, and adopting a more targeted approach to inviting comment on the most appropriate vignettes.

Despite evidence of unique contributions and tangible influence, it is not possible from this study to conclude whether public input differs systematically from input of other experts, or whether contributions differ between peer support organizations or other charities. Nor is it possible to conclude whether contributions would be more influential if public involvement was achieved more consistently from the initial identification of research topics to commissioning research or across different research areas.

This is an important addition to a small but growing literature analysing public input and influence in research across a range of disciplines.^[26,27] It is unusual because investigations of research programmes and HTA agencies, rather than individual projects, have so far focused on describing their policies and motivations for public involvement^[1,12], rather than the impact of involvement.

In terms of a framework for public involvement in health technology assessment^[1], this paper describes mechanisms that combine setting priorities for technologies to be assessed with deliberating and characterizing evaluative evidence for specific technologies and applying eligibility criteria and standards to judge the value of specific technologies in relation to

alternatives. This requires contributions to research by people who are experts designated by their experience rather than by qualifications or professional standing^[28].

Having seen the potential for influence, the HTA programme is increasing its public involvement. Completed research projects are published in the programme's journal, *Health Technology Assessment*, which is freely available on the World Wide Web and has an impact factor of 3.87, ranking it in the top 10 per cent of medical and health-related journals. The influence of the programme through public involvement therefore has implications for the research community and evidence-informed health services internationally.

References

- (1) Abelson J, Giacomini M, Lehoux P, Gauvin F. Bringing 'the public' into health technology assessment and coverage policy decisions: From principles to practice *Health Policy*, Volume 82, Issue 1, Pages 37-50.
- (2) Bridges, J. and Jones, C. Patient based health technology assessment: a vision of what one day be possible. *Int J Tech Ass Health Care* 2007; 23(1): 30-5
- (3) Hanley, B., A. Truesdale, A. King, D. Elbourne, I. Chalmers. 2001. Involving consumers in designing, conducting, and interpreting randomised controlled trials: questionnaire survey. *British Medical Journal* 322: 519-523.
- (4) Sakala, C., G. Gyte, S. Henderson, J.P. etal. Consumer-professional partnership to improve research: Experience of the Cochrane Collaboration's Pregnancy and Childbirth Group. *Birth* 2001; (28): 133-137
- (5) Oliver, S, L. Oakley, J. Lumley, E. Smoking cessation programmes in pregnancy: systematically addressing development, implementation, women's concerns and effectiveness. *Health Education Journal* 2001a, (60): 362-370
- (6) Rees R and Oliver S An example from health promotion. In Coren E (ed) (2007) *Collection of examples of service user and carer participation in systematic reviews*. London. Social Care Institute for Excellence; pp15 – 34. 2007. <http://www.scie.org.uk/publications/details.asp?pubID=125> [Accessed 2007 Aug 08]
- (7) Oliver S, Gray J. A bibliography of research reports about patients', clinicians' and researchers' priorities for new research. London: James Lind Alliance, 2006 Dec.
- (8) Best Research for Best Health: A new national health research strategy. London, England: Department of Health, 2006.
- (9) Resnik, D.B. Setting Biomedical Research Priorities: Justice, Science, and Public Participation. *Kennedy Institute of Ethics Journal* 2001; 11 (2): 181-204
- (10) Model Framework for Consumer and Community Participation in Health and Medical Research. Canberra, Australia: National Health and Medical Research Council (NHMRC) Research, 2004
- (11) National Institutes Director's Council of Public Representatives (COPR) (2004) Enhancing Public Input and Transparency in the National Institutes of Health Research Priority-Setting Process. [online]. Available from URL: <http://copr.nih.gov/reports/enhancing.pdf> [Accessed 2007 May 23]
- (12) O'Donnell, M, V. Entwistle. Consumer involvement in decisions about what health-related research is funded. *Health Policy* 2004; 70(3): 281-90
- (13) 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 Technology Assessment* 2004; 8 (15): 1-148

- (14) Oliver, S., R. Milne, J. Bradburn, P, et al. Investigating consumer perspectives on evaluating health technologies. *Evaluation* 2001b; (7): 468-486
- (15) Oliver, S., R. Milne, J. Bradburn, P. et al. Involving consumers in a needs-led research programme: A pilot project. *Health Expectations* 2001(c); (4): 18-28
- (16) Royle, J. S. Oliver. Consumer involvement in the health technology assessment programme. *International Journal of Health Technology Assessment in Health Care* 2004; 20 (4): 493-497
- (17) Hanley, B., J. Bradburn, M. Barnes, C. et al. Involving the public in NHS public health, and social care research: briefing notes for researchers. Eastleigh: INVOLVE. ISBN: 095412152X. Available from URL: <http://www.invo.org.uk/pdfs/Briefing%20Note%20Final.dat.pdf> [Accessed 2008 Aug 08]
- (18) Hammersley, M., P. Atkinson. *Ethnography: principles in practice*. London Routledge, 1995
- (19) Emerson, R. Observational fieldwork. *Ann Rev Sociology* 1981; (7), 351 – 378
- (20) Burgess, R.G. *In the field: an introduction to field research*. London Unwin Hyman, 1984
- (21) Finnegan, R. (1996) Using documents. In *Data collection and analysis*. : Sapsford, R. Jupp, V. editors. London Sage 1996: 138-51
- (22) Strauss, A, Corbin, J. *Basics of qualitative research: techniques and procedures for developing grounded theory*. Newbury Park: Sage, 1990: 35, 52
- (23) UK Data Protection Act 1998 Chapter 29, part IV para 33 (1). Available from URL: http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1 [Accessed 2008 Aug 08]
- (24) Oliver, S. Selai, C. Guidelines for consumers interested in peer reviewing - II. Ideas to help consumers peer-review Cochrane protocols and reviews. London: Social Science Research Unit, Institute of Education, University of London, 2001. 15 pages. Available from URL www.ioe.ac.uk/ssru/reports/ [Accessed 2008 Aug 08]
- (25) Horey, D., G. Gyte, C. Sakala, S. [P-058] What do you mean? Collated consumer feedback on Cochrane reviews and protocols on topics in pregnancy Cochrane Colloquium Proceedings, October 2004, Ottawa, Canada 20041 [Online] 0:0. Available from URL: <http://www.cochrane.org/colloquia/abstracts/ottawa/P-058.htm> [Accessed 2008 Aug 08]
- (26) Boote, J., R. Telford, C. Cooper. 2002. Consumer involvement in health research: a review and research agenda. *Health Policy* 2002; 61(2): 213-36
- (27) Nilsen, E.S., H.T. Myrhaug, M. Johansen,, et al... Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database of Syst Rev* 2006; (3): CD004563
- (28) Collins H.M. and Evans R. The Third Wave of Science Studies: Studies of Expertise and Experience. *Social Studies of Science* 32/2 (April 2002) 235–296

Tables

Table 1: Public input and influence at the stage of preparing vignettes

Vignettes that lead to commissioned projects			
Vignette	Input	Influence	Peer support/ Charity
Arthroscopic debridement of knee	Suggested outcomes of employment prospects; improved personal self-care; life-time change in mobility (quality of life issue)	Outcomes accommodated as 'patient utility'. Prioritised by panel despite doubts about equipoise. Project commissioned with public input and specified outcomes.	peer support
Carers for frail older people	Highlighted need for patient outcomes as well as carer outcomes; and short term, and non-residential care too.	NCCHTA staff used charity www site for numbers needing care. Incorporated charity suggestions about intervention and outcomes. Patient focused outcomes removed before commissioning research	charity
Child height monitoring	Very supportive. Changed to child growth monitoring Recommended annual measurement Outcomes suggested: self-esteem, confidence and victim of bullying Considered treatment options following diagnosis Mentioned screening for obesity as well as lack of growth	More frequent measurement mentioned in vignette Growth monitoring confirmed in vignette, before commissioning research Outcomes of self esteem and confidence added to vignette Treatment options not included in screening vignette	charity
Fracture with juvenile idiopathic arthritis	Gave information about condition; corrected incidence figure; suggested outcomes of increasing muscle strength; stamina; pain; and bone density; and importance of weight bearing and exercise	Information added to vignette. Only pain as an outcome not included, and some details about the condition.	charity
Paediatric psychology in diabetes	Suggested details for psychosocial outcomes	Details from charity expert not incorporated into vignette.	charity

Vignettes that did not lead to commissioned projects			
Metformin for polycystic ovarian syndrome	Public expert very supportive. Gave information about condition, prevalence and demand for metformin	Information about prevalence and demand included in vignette. Vignette was superseded by a Cochrane review and a distillation of that review in the Lancet. No research commissioned.	peer support
Staph aureus in peritoneal dialysis	Described context of self care and need for prevention rather than treatment	Comments included in 'additional comments'.	charity
Zinc and piracetam to prevent sickle cell crises	Corrected incidence figure and gave cost information; Referred to joint lay-led and professional-led charity guidelines for good practice	Most public expert information included in vignette. Researcher also used charity www site to provide background – clear English valuable here.	charity
Self help technologies	Sceptical about the value of research	Panel confirmed charity and professional experts' views and research plans postponed	charity
Exercise for pre and postmenopausal women/ The effect of physical activity on fracture rates and falls in people at high risk	Mentioned frequency of exercise Was generally sceptical about compliance. Suggested falls as an outcome.	Few charity comments included in vignette. Falls as an outcome inserted from professional expert.	charity

Table 2: Discussion themes during panel meetings

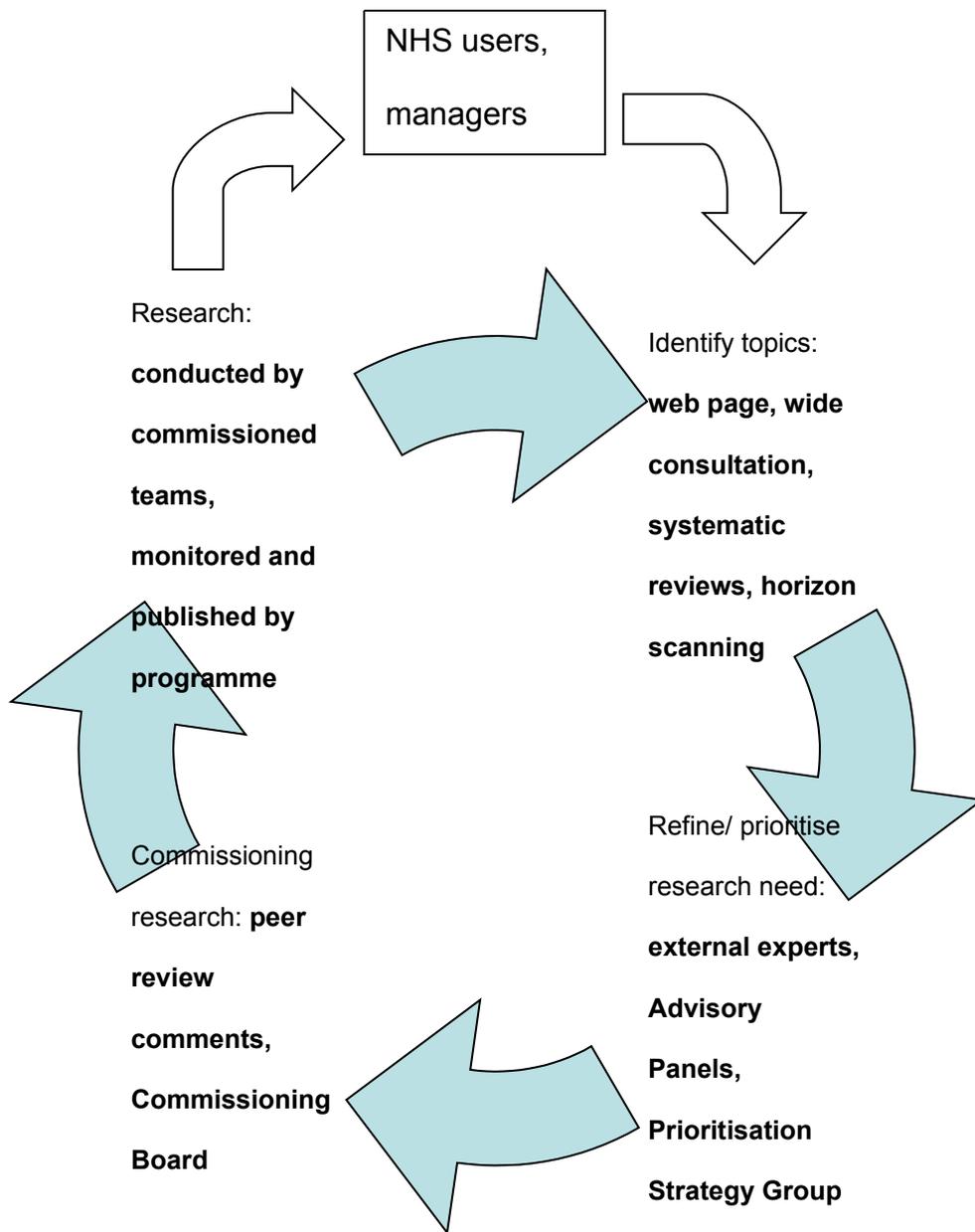
Focus of comments	Number of comments in panel meetings				Average
	Discussing research topics		Discussing vignettes		
	Panel A	Panel B	Panel A	Panel B	
Methods and methodology	15	19	18	14	16.5
Existing studies	4	10	4	3	5.25
Relevance to the public	9	4	6	2	5.25
Lack of evidence	5	6	1	4	4
Ethics	5	2	3	2	3
Benefit of intervention	0	7	0	0	1.75

Table 3: Contributions about relevance to patients/ the public

	Number of comments about relevance to patients/ the public			
	Discussing research topics		Discussing vignettes	
	Panel A	Panel B	Panel A	Panel B
Public member	5	2	3	0
Other members	4	2	3	2

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Figure 1: NIHR HTA programme cycle for commissioning research to meet NHS needs



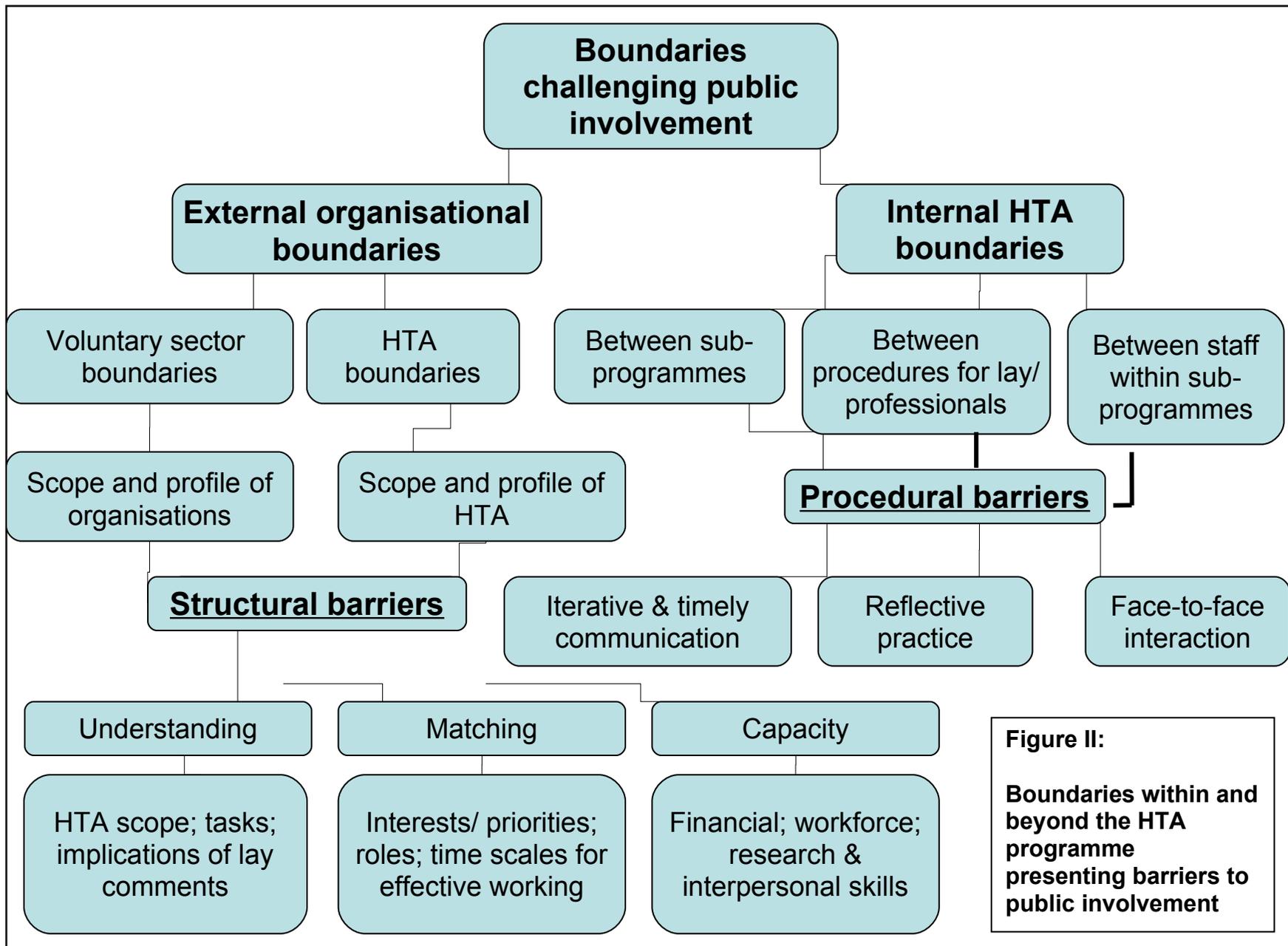


Figure II:
Boundaries within and beyond the HTA programme presenting barriers to public involvement