

# Ensuring public and patient participation in research: a case study in infrastructure development in one UK Research and Development consortium

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There is a policy drive in the UK National Health Services (NHS) towards public involvement in service, education and research, with a number of national initiatives such as INVOLVE that have championed effective user input on research and development (R&D). The requisites of research governance include a balance of professional and public input, and the structures for this now exist at primary care level. There is a need for examples of how such policies can be implemented in Primary Care Trusts, and this article aims to show in detail the way in which a systematic approach to user involvement in R&D has been implemented. The PPIRes (Public and Patient Involvement in Research) project, whose progress over two years from 2003 to 2005 is reported, has been funded by NHS R&D monies allocated through a research consortium in Norfolk, and has been hosted in an NHS – academic partnership between Norwich Primary Care Trust and the Institute of Health at the University of East Anglia. The profile of volunteers, recommendations for good practice in public involvement, and the ‘facilitators and challenges’ to the programme are described.

**Key words:** patient involvement; primary care; public involvement; research development

*Received: November 2004; accepted July 2005*

## Introduction

The National Health Services (NHS) Plan (Department of Health, 2000) promotes a health service where patients have a much enhanced opportunity to make their views known at all levels of the service. This can happen in individual consultations; for example, by better sharing of decision making (Elwyn *et al.*, 2002), or through surveying service user views (Roland, 2000). It can also happen at organizational level, via bodies such as Patients’ Forums, or through the incorporation of lay people

into managerial and governance structures – as in the new UK NHS Foundation Trusts (Klein, 2004). This emphasis on the need for a stronger lay voice has also begun to develop in clinical education (Howe and Anderson, 2003) and research (Boote *et al.*, 2002).

The common assumption underlying this concerted drive for a strong patient voice is that an increased dialogue will improve professional responsiveness and improve quality of care for patients (Anderson *et al.*, 2002). Other drivers include the need to respond to societal changes and public expectations; the potential to prevent and reduce damaging litigation; and a political need to make debate on resource allocation transparent (Brooks, 2001). There is a rich literature on how

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public involvement can influence health services, particularly when focusing on specific areas of clinical practice (eg, Rose *et al.*, 2003). However, to date there are few examples of effective working models of public input to research and its dissemination (R&D), and agreement on good practice guidelines for such involvement is only just emerging (Telford *et al.*, 2004).

Public involvement (here used in the sense of 'inviting, supporting and encouraging people ... to have a say in determining how services are provided, in what ways, when and to whom' – Skelcher, 1993) may range from non-existent to a fully user-led enterprise. Between these extremes professionals may periodically consult with, routinely include, or embed collaboration with members of the public in their organization (Arnstein, 1969). In most current NHS initiatives, the level of public contribution to organizational goals is at the level of routine inclusion for advice, or consultation only (Goodare and Lockwood, 1999; Cooper *et al.*, 2004). One health partnership described the purpose of co-operation between a research team and the public as helping researchers to 'define priorities, resolve ethical issues, refine procedures and interpret results' (Lemka *et al.*, 2000). This expectation, typical of contemporary NHS aims, is an essentially utilitarian goal for public involvement which stops far short of more radical models such as participatory research, where all stages of the research project (including its main aims) are negotiated with and co-owned by the community concerned (Macaulay *et al.*, 1999). Nevertheless, even a modest increase in public involvement is expected to deliver important benefits for patients both through service and research (Chalmers, 1995; Nicolson, 2000), and the onus is now on researchers in the health and social care fields to consider how they can involve the public in an effective and efficient way.

### The national and local context

Nationally there are some excellent examples of organizations who are championing public involvement (INVOLVE, 2004), or who are systematically incorporating users into the creation and operationalization of their R&D programmes (Department of Health, 2003). Fewer examples have been written up as to how such principles are being rolled out at a local level. East Norfolk and Waveney

R&D Consortium<sup>1</sup> includes one Primary Care Trust (Norwich PCT, NPCT) which has a track record in hosting and supporting research, and which was recognized as a lead R&D Primary Care Trust by the Department of Health in 2002. The consortium has a formal strategic partnership with the local university (University of East Anglia, UEA), where several academics in the Institute of Health were keen to develop a more formal partnership with members of the public. These two agencies (NPCT and UEA) proposed that they develop this programme on behalf of the consortium partners. A key step was the commitment of funding by the consortium to pilot such a programme, which allowed a part-time facilitator to be appointed for one year (2003–4): based on the success of the initial stage the funding was made recurrent (financial year 2004 on). This article records the development of the project through its first two years; describes the characteristics and activities of those who have volunteered to assist researchers; shows the key guidance which we have used for management of the researcher–public interface; and considers the implications for the future.

### The project

The original aims of the project were to identify good practice in involvement of the public in R&D, and to incorporate this into a locally owned project. Aims were summarized as FIRM ('Find, Involve, Recruit, Maintain'), and included in this was educating researchers as well as the public. Early on, it became known as the PPIRes project – *Public and Patient Involvement in Research*.<sup>2</sup>

The project followed a plan based on a set of consecutive steps (see Figure 1). The specific programme developed involved a period of initial induction and networking (Figure 1, steps 1–7), followed by working out a 'marketing' campaign. We accessed members of the public via media adverts (radio, local papers), and by direct contact with

<sup>1</sup> The consortium includes the Norfolk and Norwich University Hospital Trust (Norwich), James Paget Hospital (Great Yarmouth), Norfolk and Waveney Mental Health Partnership NHS Trust, the local general practitioner research practice consortium SAND, and seven local Primary Care Trusts including Waveney in East Suffolk.

<sup>2</sup> PPIRes will be used as a short acronym for the rest of this article.

1. Proposal submitted to secure funding from consortium.
2. Two lead partners develop post and appoint project facilitator, employed within R&D office of the Primary Care Trust.
3. Review literature.
4. Identify and review other national examples of user involvement in R&D.
5. Develop specific programme for pilot year.
6. Describe good practice in public involvement.
7. Make contact with local charities, advocacy groups, NHS staff working at public interface.
8. Plan and advertise specific information events for the public ( $\times 3$ ) and researchers ( $\times 1$ ).
9. Develop a database for volunteer details.
10. Evaluate number and areas of interest.
11. Disseminate availability of volunteers to researchers and promote project.
12. Review and consider next phase of project.

**Figure 1** Steps in the PPIRes pilot project

local voluntary organizations representing specific user groups (eg, Age Concern, Royal National Institute for the Blind). Interested volunteers were invited to three free information events (step 8), which were held in well-known local city centre public venues with reasonable transport and good physical access. Out of pocket expenses for travel, childcare and carers were reimbursed on the day.

The initial events (2003–4) were a mixture of small group work, short keynotes, questions and discussion, and some input from people who had already played a role as lay people in various R&D settings. Numbers were limited to 25 per event, and there were six experienced staff (NHS and university) to support the group work and to host the visitors. Attendees were invited to complete an evaluation and an application form for ongoing involvement in the ‘Research Panel’ (see Figure 2). One meeting in each year was also held to introduce the research community of the consortium to the PPIRes project.

## Who responded?

Sixty-six lay attendees came to the three initial public events, of whom around a third (23) had been recruited directly via their membership of organizations, and the rest responded to the media adverts. This resulted in 36 initial volunteers for the

Surname	Email address
Title	Present occupation
First name	Previous occupation(s)
Address	Research experience
City	Qualification(s)
Postal code	Emergency contact
Home phone	Medical factors
Fax	Age
Work phone	Specific needs/preferences for involvement
<i>Interests</i>	
Older people	Younger people
Women's health	Men's health
Dementia	Mental health
Rehabilitation	Chronic pain
Social deprivation	Arthritis/osteoporosis
Substance abuse	Stroke/heart
Physical disability	Terminal illness
Public health issues	Respiratory problems
Hearing	Vision
Learning difficulties	Community health issues
Hospital services	Trauma
Other	

**Figure 2** Specification of database fields for volunteers

database: 27 of these were female, with a preponderance of older people (aged 55+). Mental health users were well represented as there had been a prior user initiative around R&D involvement in the local Mental Health Trust. Young people, ethnic minorities and people with physical disabilities were relatively under-represented at the initial meetings, although arrangements had been made for people with special needs, and some advocacy group representatives from these sectors did attend.

As recruitment has continued, the current Research Panel (May 2005) membership stands at 41 total (six male, 35 female), plus 10 named organizations who have joined the panel. Volunteers' ages range from 36 to 80, the majority being newly retired. Eight people have formally dropped out of the panel and a further six have not been in contact despite several letters and emails. The areas most frequently cited as of interest are musculoskeletal disease, including osteoporosis (49%, 20 individuals) and women's health issues (44%, 18 individuals).

The initial researcher meeting had 16 attendees, a second meeting attracted 14, and presentations have also been given to the R&D research consortium and at regional R&D meetings.

1. Named link researcher on each project to whom the volunteer can refer.
2. Boundaries of the volunteers' roles to be agreed and respected, taking account of time and other commitments.
3. Volunteers' ideas and suggestions to be taken seriously and incorporated wherever possible.
4. Volunteers be reimbursed appropriately for personal expenses and costs of attendance, including any costs to carers and supporters.
5. Allow volunteers to renew their commitment periodically and recognize they can withdraw at any time.
6. Volunteers to be treated with respect and understanding.
7. Information given to volunteers should be in familiar language, clear, in an acceptable format and with sufficient time given to respond. Issues of access and method of communication should be addressed. Where face-to-face attendance at team meetings is difficult, access to alternative ways of communicating with other team members will be found.
8. Research team keep the volunteer up to date on the progress of the research project.
9. PPIRes Project Facilitator to provide ongoing support to volunteers including advice from mentors, additional training and enabling volunteers to meet other people doing the same work to increase their understanding and support over time.
10. Personal details will be kept confidential and will not be disclosed to third parties, without prior consent. This will include other researchers interested in the volunteers' experiences and knowledge.

**Figure 3** Good practice for researchers in dealing with lay volunteers. Modified from Telford, R., Boote, J. and Cooper, C. 2004: *Health expectations*, 7, 209–20.

## Who has used PPIRes?

There was a time-lag of around four months between the creation of the Research Panel and its first uptake by researchers, but in 2004–5 the requests have become more active, and this has been helped by the consortium research governance committee prompting researchers who do not have a named lay person on proposals to approach PPIRes. To date (May 2005) there have been over 40 requests and enquiries regarding the service. These have ranged from general enquiries as to what the service has to offer an individual researcher, to requests for ongoing involvement on committees involved in, for example, research governance. The most common request is for the review of research proposals and patient information sheet/consent forms. The skills of most individuals from the Research Panel have already been utilized: 71% have been involved in one project and 51% in more than one project.

A set of guidance principles were produced by which the volunteers could expect the researchers involved to abide (Figure 3). These were derived from the work of Telford *et al.* (2004), but were discussed and moderated for the PPIRes project during the initial information days. They now form the basis of the statement of agreement between new volunteers and researchers, and have proved non-contentious with both sides.

## Further developments

Since the completion of the pilot year (2003–4), there has been a commitment from the consortium to make the funding recurrent. The PPIRes facilitator has implemented a programme of optional training events, which covers medical terminology, assertiveness, effective meeting skills, and communication skills. These sessions are supported by the Norwich Primary Care Trust Training Department as standard courses which are open to any public volunteers.

The planned programme to incorporate new volunteers now includes:

- *Induction session*: An induction session which looks in more detail at what is expected of panel members and utilizes the NHS CD-ROM *Introduction to today's NHS*. The session follows the journey of an individual from the moment he suffers a cerebrovascular accident in a shopping mall through the first year of his treatment and recovery. Whilst the CD is intended for new staff into the NHS it offers the opportunity to view a wide range of aspects of the health care services and facilitates discussion about possible research at different cross-sections along the journey.
- *Beginning the research process*: Looking at identifying topics for research through consultation with the public and collaboration with researchers, follows the work of one researcher in setting the research question for a PhD.

- *Research methods – how to answer questions:* Defines qualitative and quantitative research and leads the group through all a range of research methodologies from documentary evidence to action research.
- *Examples of good practice:* Encompasses the experiences of several researchers in carrying out research – with and without public involvement and leads to a discussion of the advantages and disadvantages of involvement.
- *Research governance and ethics:* Leads the Research Panel logically through the processes involved in obtaining the appropriate consents and permissions for research and on to discussion about confidentiality.
- *Turning research findings into practice:* How to write or review a lay summary of a piece of research and where and how to get a paper published and a lay summary into the public domain.

Each of these sessions is repeated to ensure as many of the group as possible have the opportunity to attend. Sessions vary in their timings – morning, afternoon or evening – to ensure that those people who work or have caring commitments have the chance to attend some of the sessions. Invitations are now being made to people from other Primary Care Trusts in the R&D consortium, and the model has been discussed with them in detail.

All sessions to date have been well attended. Twenty-four volunteers came to the general induction, and 26 in total have come to the programme of research meetings. ‘Medical terminology’ has been particularly well taken up and appears to have given panel members a useful battery of knowledge in preparation for reading research proposals. A medical dictionary has been offered to all panel members. In addition one-off sessions on communication skills, quality and diversity have been offered, plus places for PPIRes volunteers to attend a half-day Research Seminar organized by the R&D Department of the local hospital trust (taken up by 10 members).

### Qualitative evaluation of the project

In terms of our aims, we managed to find, involve, recruit and maintain as described above. The key reasons given by members of the public for their recruitment were a desire to influence the research

agenda, and to share one’s own experiences for the benefits of others. The evaluation sheets from the first information day showed that greater clarity was needed with respect to the role and time commitment of volunteers. This was improved in the last two, resulting in take-up rising from 43% on the first day to 59% on the second and 73% on the third.

Each training session is subject to an evaluation carried out by the PPIRes facilitator. This is both formal and informal. Written comments have included:

‘I have enjoyed all the courses I have attended’

‘I felt helped with confidence building eg, silence is ok sometimes and that it is not always possible to have a solution to a problem or to help everyone.’

‘Assertiveness ... gave me a lot to think about how I deal with various situations’

‘Medical terminology is essential for research volunteers.’

‘I especially gained invaluable knowledge in the role play of effective meetings’.

Both Panel members and researchers are asked for feedback on their involvement in any research project. The format is based on that used by the Academic Palliative Medicine Unit at the University of Sheffield<sup>3</sup> and includes:

- In what ways do you feel the member influenced or changed the research process?
- What is your general view about service users being involved?
- Do you feel the professional staff present were fully aware of your role?

Considerable data has emerged from the project on facilitators and barriers, and the following overview reflects the findings in the end of pilot year report, summarizing feedback from project staff, volunteers, and researchers which is routinely collated by the facilitator:

- Volunteers and researchers express theoretical concerns about the contribution ‘non-academic’ volunteers can make to a research team, but this

<sup>3</sup> As presented at 2004 INVOLVE fourth national conference, permission given to cite. [www.conres.co.uk/Conference2004.asp](http://www.conres.co.uk/Conference2004.asp)

appears to be allayed once they engage with the PPIRes volunteers.

- Researchers may not initially be convinced that the additional effort and resources required by them to work with volunteers is worthwhile, again improving once service is in use.
- Researchers need to appreciate there may be a ‘cultural’ gap between their established ways of working and those of some volunteers, and this may form a barrier to full volunteer participation. Researchers should be aware of these and encourage approaches acceptable to all.
- Volunteers may be wary about becoming involved in ‘research’ where the agenda is set by commercial industry.
- Payments to volunteers (over and above out of pocket expenses) is a complex issue particularly for volunteers in receipt of benefits. Useful guidance documents have been produced locally and nationally. Regular payments may raise issues with employment legislation. Lack of payments was seen as a deterrent to further involvement by two interested members of the public.
- There may be limits on what the volunteer can do in terms of their knowledge and experience. It has been accepted that some laboratory-based studies may present limited opportunities, but that those with patient contact can benefit from lay input.
- The principle has been adopted that the volunteer chooses what study they feel comfortable with and what contribution they would like to offer.
- The single biggest issue raised by volunteers is their desire for feedback about how their involvement has helped the study, the progress of the study and the outcome of the study in terms of improving services. Good practice guidance seeks to address this, and the facilitator takes responsibility for checking this occurs.
- One barrier, which might deter further service to research groups, is the low level of perceived benefits to the volunteer. It is clearer what the benefits are to the researcher. The project has therefore been keen to explain to the volunteer what they might take from their involvement, and to offer something back via training. The monitoring process will address this issue.
- Project notes in the first year also show the interesting observation that the PPIRes initiative has created a new interface between the hosting organizations and the public, by which related enquiries are made: for example, PPIRes

has been contacted by people in the health economy with research ideas who want to speak to someone in the Primary Care Trust, or a person who wanted to know how to donate their organs for research.

## Discussion

The progress towards a substantive public involvement in R&D through a robust infrastructure funded by a consortium of NHS Trusts makes the PPIRes project likely to be sustainable and to have a long-term impact (Cooper *et al.*, 2004). By its commitment to finance, and to making public involvement a priority on its governance ‘checklist’, the East Norfolk and Waveney consortium has already taken significant steps towards making public involvement part of the routine R&D culture, and have adopted a proactive approach to implementing change by assuming that this requires engagement at multiple organizational levels (Denis *et al.*, 2002).

Threats to the project are likely to come from the issues outlined in the evaluation above; for example, lack of suitable volunteers or loss of altruistic motivation. Nationally a change in policy away from public involvement in research governance would alter the ‘obligation’ to include the public (Coast and Donovan, 1996), and might see a gradual loss of commitment from the researchers and the consortium. Another tension might come from any demand by members of the public for research to be user led rather than researcher led; a push to play a more autonomous role which may not accord with the wishes of the professional research community.

Particular efforts were made to contact under-represented groups but a tentative conclusion from this is that one size does not fit all – for example, seeking ‘representatives’/individuals from more marginalized sociodemographic groups appears from initial contacts to work better on a project-by-project basis rather than expecting individuals to put themselves forward as a volunteer. This may be because media and direct advertising is not picked up by these groups: some initial confidence building may be needed for people from ‘hard to reach’ backgrounds (socially deprived, ethnic minorities, people with disabilities) to perceive themselves as able to be effective in such a setting, or because their lives do not afford them the

leisure for volunteering. By supplementing individual volunteers with organizational links to the Panel, the need for named individuals to come forward has been avoided, as the relevant voluntary groups will take a request, 'vet' it with their own user group, and come back to the PPIRes facilitator with potential contacts whom both sides can then support. However, the training programme is offered to individuals, and so the relevant expertise will need to be offered to multiple organizations if this approach is to be effective in the long term.

The national picture for R&D is changing with the creation of the UK Clinical Research Collaboration, and there may be pressure from disease-specific networks such as cancer or mental health to recruit their own expert patient input at a local level. While this hopefully may complement rather than compete with local structures, it is important that the value of locally owned initiatives is recognized, and that public involvement is well supported. Bracht and Tsourous (1990) note that when implementing a community programme, health project leaders/managers must have profound understanding of factors such as the public's perceived needs, resources, social structures, values and experiences. It may be that projects such as PPIRes will prove invaluable to topic-specific research initiatives, and achieve an involvement which cannot be replicated at a national level.

With any innovation, the need for sustainability arises. It appears important to interface the PPIRes initiative with other public involvement initiatives, so that each Trust takes some responsibility for their local volunteers as part of a coherent (rather than fragmented) approach to public involvement in their organization's activities. However, the funding stream for PPIRes is separate from other public involvement initiatives.

Some of the strength of PPIRes lies in the combination of 'hands on' (Primary Care Trust and university involvement, consortium funding and accountability) and 'hands off' (autonomy, experimentation), where development has been facilitated within the context of a contemporary need. However, if there were a weakening in the organizational support for PPIRes, funding could be withdrawn, and the volunteers would have no power to prevent this change. The project does not have full consumer control, and readers may like to consider what might be the relative advantages

and disadvantages of greater public control over the research enterprise.

## Conclusion

At a pragmatic level, the PPIRes project has proved effective in its ability to find, inform, recruit and develop members of the public to become more involved with research and its dissemination. Its progress reflects the literature on diffusion of innovation (Greenhalgh *et al.*, 2004) insofar as it has required some champions, startup funding, policy linkage, shared values, and a balanced view of the likely benefits and constraints to take it forward.

The project will continue to be evaluated by the assessment of uptake of the opportunity by both volunteers and researchers; by satisfaction with role of both parties; and over time, by evidence of increased user involvement in ongoing teams on a substantive rather than occasional basis; and also their citation and inclusion in publications.

Our main reason for describing it in detail is to allow others to consider using a similar approach to create a genuine infrastructure investment in user involvement in R&D, and we would be interested in similar experiences.

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