Involving users in the research process

A 'how to' guide for researchers

What is user involvement in research?

User or public and patient involvement in research means doing research 'with' patients and the public so they are not just participants in the research. This requires users to have a say in the decisions made about the research, so that the methods and outcomes are more appropriate to research participants and patients.

Who are these guidelines for?

These guidelines have been created to assist researchers to fulfil the National Institute for Health Research (NIHR) and the comprehensive Biomedical Research Centre's (BRC) requirement for public and patient involvement in research.

Who are users?

The term user refers to patients, their carers and family members, as well as to members of the public and representatives from patient and charitable organisations. Other terms for users include service users and consumers.

What is the relevance of user involvement in research?

'The contributions of patients provide alternative views from the usual NHS staff perspective. Users are able to make judgements and observations based on their understanding of the condition and may have a different take on what health outcomes are important, that health care professionals and researchers may not have considered.' [1]

Several funding streams (such as the NIHR Research for Patient Benefit funding stream and Programme grants in particular), require researchers to show how they plan to involve users in their research. The National Research Ethics application form also asks for this information. Where users have not been involved researchers must show clear justification for not including them.

The stages of involvement

The NIHR identifies five principal stages of research where user involvement should be considered in all studies. These five stages are:

- The development of the grant application
- The design and management of the research
- The undertaking of the research
- The analysis of the research data
- The dissemination of research findings

When completing grant or ethics application forms you will need to indicate at which stages you have already involved users or where you intend to involve them.

The levels of involvement

In addition to identifying the stage(s) at which you plan to involve users, you will need to define the level of involvement users will have in your research project.

The three levels are:

Consultation – This means that researchers ask users for their views and advice on aspects of the research. For example, researchers might ask users to comment on the research proposal, and the researcher would choose whether to make any suggested changes.

Collaboration – This means that the researchers and the users work together to make decisions, for example on a study steering group. This could include working together to identify research questions or which research methods to use. Essentially the decision making is shared between users and researchers.

User led or controlled – This means that the users make the decisions about research, for example what is researched and how the study is carried out. In this scenario the users would lead the research project, perhaps as the main applicant or lead researcher, and the researchers would work alongside or for them.

Consultation is currently the most common example of user involvement in research, with user led being the least common.

Within one research study it is possible to have different levels of user involvement at different stages of the research.

Implementing user involvement

The following information describes how users could be involved at the five stages. Each stage is accompanied by a real example of user involvement in research along with some of the key issues you will need to consider when implementing user involvement. The design and the management of the research have been separated to show the different role users can have at each of these stages.

User involvement activities are not defined nor restricted to certain methods. Researchers should think about the appropriate type of involvement for their study and be clear on the objectives for involving users prior to recruiting them.

Please note: users can be involved in other areas of research other than the five stages outlined here, for example identifying research questions and prioritising research topics. For more information on these other stages please refer to the Biomedical Research Centre website – www.biomedicalresearchcentre.org – and the suggested reading list at the end of this document.

1. Development of the grant application

The BRC recommends that all new research is reviewed by one or more users as part of the peer review process.

At this stage of the research process users can:

- discuss the research idea and help to focus the question to one that reflects patients' needs and will benefit patients

- review the research proposal and offer suggestions from a patient perspective

- help identify where users could be involved in other areas of the research project

- be named as a co-applicant for funding and ethics approval.
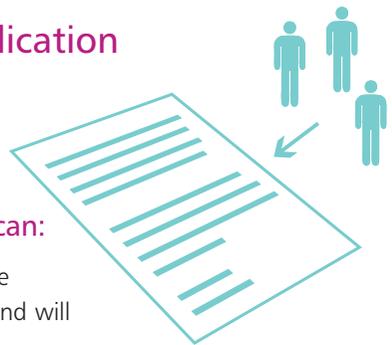
Issues to consider:

- Users will need to understand the research topic. Consider providing them with information and training. The BRC provides one day training for patients and the public which informs them about the research process. Contact the BRC User Involvement Manager, Sophie Auckland, for more details. See page 14 for contact details.

- All potential users including patients, their families, patient groups and charitable organisations can be considered for inclusion at this stage.

- Give users time to discuss queries with the research team, and to provide feedback.

- Users must be informed that the application process can be lengthy and that not all proposals are successful.

How to involve users:

- Find out if there is an existing patient group or research advisory panel related to the research topic who you can ask to review your idea or research proposal. You can contact the BRC User Involvement Manager, the Research Design Service London or one of the Clinical Research Networks for this information. See page 14 for contact details.

- Invite patients via staff at relevant clinics to attend an informal session to discuss your ideas. It is particularly useful to involve users who are local to where the study will take place as they may have relevant information which you can use to identify and recruit potential study participants.

- For rare conditions you may need to approach national or international organisations for representatives who can comment on your proposal.

- Another option is to establish a reference panel of people who can review all the research proposals related to the specific condition. This could include patients, family members, health professionals and organisation representatives. See the Stroke Research Patients and Family Group example overleaf.

Examples:

1. The King's College London Stroke Research Patients and Family Group brings together researchers and patients and carers from South London. The group meets every six weeks and provides a forum for dialogue between stroke researchers and stroke survivors and their family members. Researchers are invited to attend meetings to get feedback on planned research (including methods of data collection), to develop lay summaries of studies and to present interim and final findings from studies.

2. After collaborating with patients with Rheumatoid Arthritis on an article for the British Medical Journal, Dr Heidi Lempp approached one of the patient representatives to see if she was interested in promoting patient involvement in relation to service improvements, teaching and research. Dr Lempp invited the patient representative to become a co-applicant for a number of grant applications, one of which was successful in obtaining funding from Guy's and St Thomas' Charity. Dr Lempp sent the patient representative drafts of the application, and together they discussed the content in person, by telephone and email. The patient provided useful feedback from a patient perspective in relation to relevance and feasibility.

   The patient representative said: *"I found being involved with grants intellectually stimulating as I was able to present my views from the perspective of a person who has an in-depth understanding of the illness. I was also able to use my professional skills as a former manager by becoming a co-applicant."*

2a. Design of the research

The involvement of users at this stage can help to:

- identify areas where users could be involved in the research

- inform the design of communication materials to better suit participants, for example:

  → by helping to make patient information sheets and consent forms more understandable,

  → by reviewing questionnaires and other data collection methods.

- identify possible participant recruitment strategies

- consider the ethical implications of the research and help researchers to understand patient concerns and suggest ways to address these

- provide an idea of what it is like to take part in research.
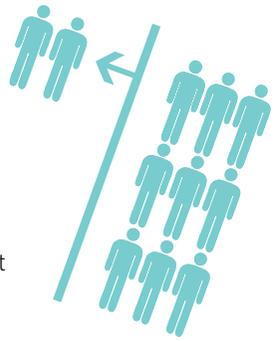
Issues to consider:

- Users will need to understand the research process and research methods to comment on study design.

How to involve users:

- Again you could approach existing patient groups or advisory panels to either review patient communication materials or to help you develop them.

- Create a study specific patient panel to advise on further user involvement in the research, the study design and communication materials.

- Recruit user representatives to become members of the project steering group. Be clear about what they will and will not be able to contribute to, and provide a role description or discuss the role with them.

2b. Management of the research

The involvement of users at this stage can help to:

- Identify ways to resolve problems in relation to recruiting or retaining participants, for example where to advertise and in what format.

Issues to consider:

- Users will need to understand the obligations placed on researchers, for example recruitment guidelines and targets.

How to involve users:

- Recruit user representatives to be members of the project steering group or a patient panel.

- Create a role description detailing what tasks user representatives will undertake, what skills or knowledge they require and the type and level of commitment they will need to make eg how many meetings they will need to attend and for how long.

- Ask users to provide input at specific stages of the study eg patient related tasks such as patient information sheets and the participant recruitment strategy.

Example:

The Centre for Evidence Based Dermatology (CEBD) at the University of Nottingham has been informally involving patients and their carers for several years. In 2009 they took the decision to make user involvement a formal and key function in their research with the creation of the CEBD Patient Panel. A role description and terms of reference for the patient panel were created and were circulated with an advert nationally via dermatology-associated patient support groups, charitable organisations, consultants and GPs and patients connected to CEBD. 20 people responded and were invited to an initial meeting in Nottingham (all travel expenses and accommodation costs were reimbursed). Users were introduced to key staff, provided with an overview of the research done by CEBD and research methodology and terminology, and took part in a discussion with staff about what the role of the patient panel would be.

The CEBD Patient Panel has involvement in the following:

- prioritising research topics
- reviewing all research proposals associated with CEBD
- acting as co-applicants on grant applications
- helping design research methods and patient information materials
- advising on the dissemination of research findings.

In addition, one user representative has led a Cochrane Review into their condition.

The panel meets twice a year in person and also communicate via telephone and email on a regular basis. Some user representatives are co-opted onto other research project steering groups.

3. Undertaking the research
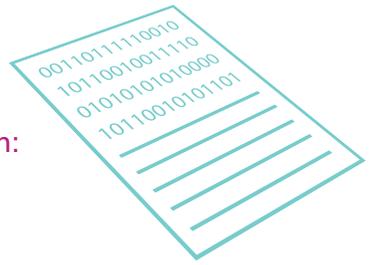
Users involved at this stage of the research can:

- Undertake data collection.

Issues to consider:

- Users will need to understand how to collect data. This will require training and/or a previous knowledge of conducting research.
- This will also require researchers to acknowledge users' involvement as a member of the research team.
- Seek advice from the **BRC User Involvement Manager** (see page 14 for contact details) regarding the protocols associated with involving users in data collection.

How to involve users:

- Seek the opinion of users already involved in the project as members of the steering group or advisory panel, about the appropriateness of having users collecting data.
- Ask for volunteers from those already involved in the project steering group.
- Recruit specifically for users interested in undertaking data collection. This allows you to stipulate certain requirements and skills for the role.
- Liaise with the **BRC User Involvement Manager** (see page 14 for contact details) about training for users in data collection techniques.

Example:

A cancer research study investigating the experience of women undergoing treatment for breast cancer had patient representatives from the Humber and Yorkshire Coast Consumer Research panel on its steering group. During discussions about the data collection methods, an issue that was raised was that some of the proposed questions and topics could be upsetting and very personal for some participants. It was suggested that the users, who had experience of having been treated for breast cancer, might be better placed to lead discussions. Two users received training in research methods and how to carry out focus groups and interviews. They were then supported to carry out the data collection, with a researcher assisting them when needed. This is turn led to some of the research participants becoming involved as users in other research projects.

4. Analysis
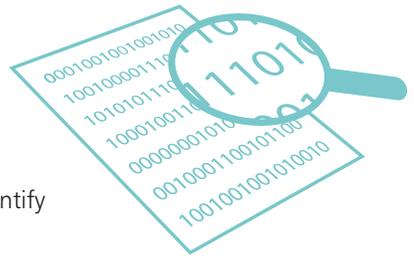
Users can help to:

- Suggest gaps in the data which can help identify further research questions
- Provide their interpretation of the data which may be different to that of the research team.

Issues to consider:

- Users may need training to analyse research data depending on how the data is presented and their previous experience.

How to involve users:

- Present raw data to a group of users and/or representatives of topic-related organisations. Initiate a discussion and ask people to feedback their thoughts on the data presented. Be prepared to offer explanations and answer questions on aspects of the data that people do not understand.
- User representatives as members of a steering group should be given the opportunity to comment on the data and receive a lay summary if required.
- Create a lay summary of the data. This is particularly useful if it is statistical data.
- Circulate a lay summary of the initial findings to patient groups, charitable organisations, and patient forums or chat sites for comments and interpretation.
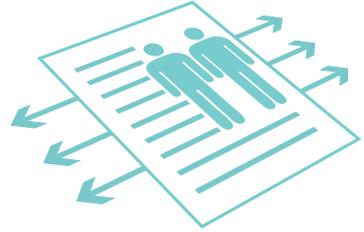
Example:

Professor John Bond at the University of Newcastle invited patients and carers to an informal workshop and presented them with an overview of the findings from a study called *'Boundary Work, Normal Ageing and Brain Pathology'*.

"The workshop was attended by older people, advocates of older people, informal carers, clinicians, dementia researchers and social scientists. The panel was invited to discuss changes in the understanding of cognitive ageing, possible scenarios for dementia research and care coming out of various debates identified in the research and to reflect on the role the diverse stakeholders could play in the debate." [2]

This allowed users to ask questions about aspects they did not understand and then to provide the researchers with a patient and carer interpretation of the data. In addition to this, attendees at the workshop were also asked to *"decide future research topic priorities."*

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[2] Research-user workshop: Project Initiated Programme Event, Research Beehive, Newcastle University, Friday 5th May 2006.

5. Dissemination of research findings

Users can help to:

- advise and develop reports on the research findings that are understandable to the public

- provide suggestions on where to disseminate the findings; who will be interested, how to reach them and in what format. For example, there may be a website forum where you can make your research known, or a patient group you could present to

- participate in presenting the findings of the research and talk about their experience of being involved in the process.

Issues to consider:

- You will need to help users understand the research outcomes in order that they can create a plain and easy to understand summary.

- Depending on their skills users may need further training to be able to write reports aimed at people with a non-clinical/scientific background.

- If presenting to an audience, users may also need practice and training as this can be daunting for some people.

- Creating findings in different formats may involve additional costs. Include this in your budget when planning your research.

How to involve users:

- Work with users on the project steering group to create an easy to understand report about the research for the general public. By asking users to identify what they can and cannot understand, you can work together to create a library of suitable terms and phrases to explain medical and research processes and procedures.

- If users were not represented on the steering group, ask a local support group or the Trust readers group to review the lay version.

- Liaise with local patient support or community groups to seek advice on the appropriate methods for circulating the report.

- Invite patient groups and/or members of the public to informal events that showcase the research and invite discussion and feedback. The meeting facilities in the Biomedical Research Centre on the 16th floor of Guy's Tower can be booked for this purpose.

- Engage people through web forums and Trust events such as the summer Open Day.

- Work with the Trust R&D communications manager, contactable through the Trust communications team on 020 7188 5577. They can help you to reach the wider public through the media, and can advise on the use of users as 'case studies' in media activities.

Example:

King's College London supports a Stroke Patients and Family Research Group to produce a six monthly newsletter covering updates on research findings, new projects and opportunities to get involved as a user or research participant. The newsletter also includes information about support groups, reviews of books relating to stroke and interviews with staff and users. The newsletter is circulated to all patients on the South London Stroke Register and people have the choice to receive a paper or email version.

Principles of user involvement

- Plan user involvement as early as possible

- Be clear about what users will be able to do

- Be clear about what users will not be able to do

- Ensure all staff understand the reasons for involving users and attend training where necessary

- Support users with training and information

- Identify a key person within the research team for users to contact

- As a minimum reimburse users' travel expenses

- Where possible offer childcare or carer expenses and cover other incurred costs such as telephone calls and stationery

- Acknowledge users' input and be sure to feedback on the research and what you feel their contribution meant

- Ask for users' feedback on their experience of being involved so you can make improvements for next time

- Ask users if they would like to remain involved if other opportunities are available

Budgeting for user involvement

Where possible, researchers should plan for the additional cost of user involvement and account for this in their grant applications. This will ensure there is support to involve users, and hopefully enable them to stay committed to the study. Occasionally there are funds available to support user involvement in research. The **BRC User Involvement Manager** (see page 14 for contact details) will have information about current opportunities.
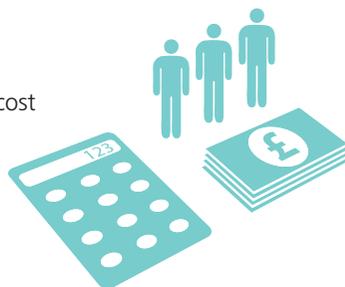
The amount it will cost to involve users will vary depending on factors such as:

- how many users you involve

- where they travel from

- childcare and carer support

- if you facilitate user involvement through meetings then how many meetings there will be and how meetings are conducted (eg in person or by telephone) will all effect the overall cost

- the level and extent of users' involvement

- what you expect the users to do and how often.

You will also need to consider items such as room hire, refreshments, training, stationery, telephone calls and the production of extra documents such as lay versions of reports.

For further support and guidance please contact:

Suggested Reading

The following documents are available on the Biomedical Research Centre website **www.biomedicalresearchcentre.org**

'Involving patient and the public in medical research'

'Guidance on recruiting and retaining users'

Exploring Impact: Public involvement in NHS, public health and social care research. October 2009. INVOLVE. **www.invo.org.uk**

Senior Investigators and Public Involvement. INVOLVE **www.invo.org.uk**

The INVOLVE website also has additional resources and examples of user involvement in research.

Public and Patient involvement: How to guide. Research Design Service North West. **www.rds-nw.nihr.ac.uk**

With thanks for contributions to:

Professor John Bond, University of Newcastle

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Dr Carron Layfield, Centre of Evidence Based Dermatology, University of Nottingham

Dr Heidi Lempp, King's College London

Dr Chris McKevitt, King's College London

Guy's and St Thomas' NHS Foundation Trust and King's College London's
comprehensive **Biomedical Research Centre**

Working together to deliver better health through research

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