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# Public involvement in clinical trials:

## Supplement to the briefing notes for researchers

Supporting public involvement in NHS, public health and social care research

# About this supplement

This supplement provides advice for researchers who design and conduct clinical trials. It is a specialist supplement to support the general information on how to involve members of the public in research which can be found in the **INVOLVE Briefing notes for researchers: public involvement in NHS, public health and social care research** and should be read alongside the Briefing notes (see www.invo.org.uk/resource-centre/resource-for-researchers).

INVOLVE commissioned **Claire Vale** of the Medical Research Council Clinical Trials Unit to develop and write this supplement. She was supported by:

**Jim Fitzgibbon,** volunteer Research Partner Coordinator (supported by Involving People, National Institute for Social Care and Health Research (NISCHR), Clinical Research Centre) at the Cancer Research UK Wales Cancer Trials Unit, Cardiff University

**Bec Hanley**, Co-Director, TwoCan Associates

**Delia Muir**, Patient and Public Involvement Officer at the Clinical Trials Research Unit, University of Leeds

**Claire Murphy**, Clinical Trial Manager at the Medical Research Council Clinical Trials Unit (MRC CTU)

**Annmarie Nelson**, Deputy Director of the Marie Curie Palliative Care Research Centre, based at the Cancer Research UK Wales Cancer Trials Unit, Cardiff University

**Richard Stephens,** a patient representative on two Lymphoma trial management groups (TMGs) and on National Institute for Health Research and other national committees and bodies in cancer and health research

**Bridget Young**, Professor and Director of Communication Skills in the Institute of Psychology, Health and Society, University of Liverpool

Further information on those involved can be found on page 14.

INVOLVE is funded by and part of the National Institute for Health Research (NIHR) (see www.invo.org.uk).

## Terms used

INVOLVE defines public involvement in research as research being carried out **'with'** or **'by'** members of the public rather than **'to', 'about'** or **'for'** them. This includes, for example, working with research funders to prioritise research, offering advice as members of a project steering group, commenting on and developing research materials and undertaking interviews with research participants.

When using the term 'public' we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services.

In the examples the terms reflect those used by the authors such as, research partner, consumer or lay member instead of public.

An explanation of some of the terms used can be found in the INVOLVE online jargon buster (see www.invo.org.uk/resource-centre/jargon-buster).

This supplement is one of a series edited by Helen Hayes at the INVOLVE Coordinating Centre, details of other titles are in the further reading section on page 13.

# Introduction

This supplement provides general advice about public involvement in the research design and conduct of clinical trials covering key issues, such as how best to access members of the public; when and in what ways to involve them and how to support their involvement as the trial progresses. It also includes a section on further reading and resources. It describes involvement of the public in clinical trials at three distinct levels:

1. **involvement in an individual trial (including membership of a trial management group (TMG))**
2. **involvement in a group or programme of related trials (for example focused on a single disease)**
3. **involvement with a clinical trials unit or research department responsible for running many trials.**

This is not to say that these are the only ways (or indeed the best ways) to involve people in clinical trials. As for any research study, the involvement needs to be appropriate to the specific needs of the trial(s) as well as the needs of those getting involved.

> "Our research partner brings a different point of view to our meetings. We can get caught up with the design and running of the trial so it's useful to have a report back on how our decisions on the running of a trial will impact on someone with cancer."
>
> A lung cancer trial manager at the Wales Cancer Trials Unit (WCTU)

> "Our research partner recently enquired whether using the trial drug and tamiflu together may present a potential safety issue to trial participants, and how a recent decision by NICE might impact on the trial. Neither of these topics had been picked up on by the WCTU or other members of the TMG."
>
> A bladder cancer trial manager at the Wales Cancer Trials Unit

# Where should I start?

Ideally, involvement should begin as early in the trial process as possible. There are examples of patients and the public being involved in helping to define the research priorities of programmes of clinical trials and developing trial ideas. However, it is (almost) never too late to involve patients and the public in a trial for example in the dissemination of results after the trial.

It is important to follow good practice in public involvement (See Briefing note five: How to involve members of the public in research www.invo.org.uk/posttyperesource/before-you-start-involving-people) at whatever point in the trial you initiate involvement. It may also be appropriate to use different approaches within the same trial or group of trials, involving different people in different ways at different stages.

It should be noted that unlike recruiting participants to enter into clinical trials, involving people in clinical trials in a research advisory, consultative or collaborative capacity does not require specific ethical approval (National Research Ethics/INVOLVE 2009 see www.invo.org.uk/resource-centre/publications-by-involve)

## Public involvement at different levels of trial conduct

The following sections describe involvement at different levels of trial conduct together with key benefits and challenges of each approach, and are illustrated with examples. It is worth considering in advance the purposes and circumstances of the involvement whether, for example, involvement should be across a program of related trials, as well as or rather than in an individual trial. Or you may want to initiate public involvement to help with specific issues or problems that arise during the course of a trial such as poor recruitment. We have covered a broad spectrum of experiences and examples to illustrate how involvement in clinical trials can work, although there are many other examples that are not included here.

## 1. Involvement in individual trials

This type of involvement is what many people think of when they consider involvement in clinical trials. Probably the most common form of involvement within an individual trial is as a member of a trial management group (TMG), although this is not the only way to involve people in individual clinical trials.

### Potential benefits

- establishes strong working relationships between individuals on the TMG
- ensures that the members of the public who are involved understand fully the specific trial and its value
- gives different perspectives to other members of the trial team for example on specific problems that may crop up within a trial
- assists with dissemination of results for example via charities or patient groups, or by providing a patient story or perspective
- furthers the professional development or training of members of the trial team
- helps with future or other ongoing trials for example in establishing standard wording or structure for patient information.

### Potential challenges

- asking for a long-term commitment to a new trial expected to take many years to complete may be hard, for example for people living with a life-threatening condition
- identifying individuals who are best in a position to contribute
- ensuring that people's opinions are heard and valued by the trial team
- providing individualised training and support for members of the public, which could be time and resource intensive
- retaining the interest of individuals during periods when there may seem to be little or nothing happening with the trial
- maintaining involvement and avoiding disappointment when trials do not get funded.

### Involvement in trial management groups

At the Medical Research Council Clinical Trials Unit (MRC CTU) (see www.mrc.ac.uk), the most common approach to involving members of the public in clinical trials is as members of trial management groups (TMGs). At a workshop for patients involved in the MRC CTU cancer trials, the patients suggested that they would benefit from clear guidance about:

- the role of the TMG in the running of the trial
- the roles of different TMG members
- the format of TMG meetings and the frequency of meetings
- explanation of the anticipated role of the consumer on the TMG
- a glossary of technical terms likely to be used by TMG members

This led to some of the patients working with trial staff to develop a TMG pack (see www.trialsjournal.com/imedia/1292821605618248/supp1.doc). The pack covers the issues above, as well as providing clear information on payment and reimbursement of expenses people to contact who may be able to answer further questions or direct them to information they might find helpful. The aim of the pack was to inform and support patients involved to contribute fully to TMG meetings.

Its also important to consider that as involvement is a two way process, it may be necessary to ensure that the professionals members of TMGs are prepared for working in partnership with members of the public, for example ensuring that the chair is able to effectively involve people and that the expertise of all members of the TMG – patient or professional are recognised.

Having more than one member of the public on a TMG is one way of providing additional peer support, however some members of the public may never feel comfortable in this formal role, so it's important to find appropriate people and possibly provide other opportunities for involvement.

"The main questions you should always ask yourself as a consumer are: Is the research going to benefit patients in the short or long term? If not is there some possibility that the research will contribute to the knowledge base that will make further research a possibility? And, will the results of the trial change the way doctors do things, for the better?"

**Dave Ardron**
a consumer member of the TMG for the MRC CTU Quartz trial on being involved in a TMG

**Patients and carers across England contributed significantly to the protocol for a large UK-based multicentre NIHR Health Technology Assessment-funded study (MUSTARDD-PD) researching the management of people with mild dementia associated with Parkinson's disease.**

The MUSTARDD-PD study steering committee already included two lay people. However, the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) Coordinating Centre was keen to widen the input of service users/public into the development of the study because of the particular sensitivity of this research topic.

DeNDRoN therefore circulated the draft patient & carer information sheets & consent forms to members of PPI patient/carer panels across all of DeNDRoN's Local Research Networks.

Lay people provided constructive ideas around how to raise the subject of dementia with this target population, and suggested alternative wordings to make all the study practicalities much clearer.

Derek Stewart 2011

**Patient involvement in the Medical Research Council (MRC) Clinical Trials Unit (CTU) RADICALS trial**

The involvement of patients in the RADICALS Trial Management Group (TMG) has had an impact on recruitment rates. When the trial opened to recruitment, there were initial problems in recruiting enough patients. Through TMG meetings, it was suggested by the consumer that potentially eligible patients could be found outside of the usual urological clinics. The consumer was a member of PCaSO, a prostate cancer support group. He was able to flag up the trial to members of the group who might then mention the trial to their consultant or to other men affected by prostate cancer. The trial was discussed at group meetings, the Chief Investigator was invited to speak to group members about the trial and the trial was featured several times in the group's newsletters, which have wide circulation.

The TMG also addressed low recruitment rates by producing and distributing patient information DVDs to eligible patients. A consumer member of the TMG made a crucial contribution to this. He reviewed and commented on the scripts developed by the TMG and the production team and made sure the DVD would be clear to potential trial patients. The DVD also featured a Questions and Answers section with the Chief Investigator. The consumer, along with members of a patient support group, prepared questions that would be relevant to men thinking of joining the trial. Anecdotally, this has helped with recruiting patients who weren't sure about joining the trial until they watched the DVD.

The RADICALS Trial is funded by the Medical Research Council and Cancer Research UK (see http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-radiotherapy-and-hormone-therapy-after-surgery-for-prostate-cancer)

## 2. Involvement across a group of clinical trials

Another way to involve the public in clinical trials is at the level of a programme of research, for example trials of hormone therapy in prostate cancer, or trials of interventions for pressure ulcers. This is a useful approach in that it can:

- help develop a coherent programme of clinical trials in a given area
- draw on the experiences and expertise of people who best understand the condition
- ensure involvement throughout the trial process
- develop strong working relationships between the public and the trial team.

### Potential benefits

- working with people who have first-hand experience and knowledge
- establishing and building relationships that potentially lead to regular collaboration with people with knowledge and expertise throughout all stages of research
- providing an opportunity for people to develop more strategic roles within the trial program as they become more experienced for example influencing the design of new trials; becoming co-applicants on trial grants and so on
- giving members of the public a chance to build their skills over time through their involvement in a programme of research.

### Potential challenges

- finding appropriate people – especially in under-researched areas
- providing training and ongoing support for those involved which may have time and resource implications
- sustaining involvement over a prolonged period, especially if there are periods when no trials are happening.

"In 10 years of research, the few hours spent with the service user network has been some of the most valuable time of my career."

**Jane Nixon**
Professor of Tissue Viability
and Clinical Trials Research
Leeds Clinical Trials Research Unit

"Involvement in Trial Steering Committees (TSC) opens up to lay people a different, broader perspective on medical research. It also requires different, more strategic skills compared to involvement in Trial Management Groups (TMGs). Although time consuming – the paperwork can be very substantial and mentally very demanding – sitting on a TSC can be very rewarding and can often raise generic questions to take back to individual TMGs."

**Jim Fitzgibbon**
Research Partner Coordinator
Wales Cancer Trials Unit

### The Pressure Ulcer Research Service User Network UK (PURSUN UK), University of Leeds

The PURPOSE (Pressure Ulcer Programme of Research) team at the Leeds Clinical Trials Research Unit (CTRU) identified a need to further develop patient and public involvement (PPI) in their studies and in the field generally. The team had found the pressure ulcer community to be a seldom heard group due to the lack of an existing service user/carer group and the complex health needs of many people in the community.

Therefore, we formed PURSUN a small network of service users, carers and family members with some personal experience of preventing or living with of pressure ulcers. Recruitment for this network has been challenging and we have needed to cast the net as wide as possible to reach people for example patient forums, carer groups, tissue viability nurse specialists, local press, INVOLVE.

We have taken a flexible, "asset based" approach to involvement, which allows network members to take on various roles depending on their skills, needs and the level of commitment they feel able to give. Preparation workshops, based on the Patient Learning Journey Model[1], support this process by enabling network members to reflect upon their experience and expertise. This can then be matched to appropriate research roles.

Research opportunities are sent out to the network as they arise. PURSUN is supported by a PPI officer who acts as a point of contact and is responsible for members' ongoing development. As well as being part of the PURPOSE steering committee, we also hold less conventional, informal research meetings, focusing on service user input. The aim is to put people at ease and create a dialogue between service users and researchers. We also offer opportunities for people to contribute to things from home, allowing input from people with work/carer commitments or mobility issues.

Morris P, Dalton E, McGoverin A and Symons J.(2009). **Preparing for patient-centred practice: developing the patient voice in health professional learning**, In: Bradbury H, Frost N, Kilminster S, Zukas M. Beyond Reflective Practice, Routledge, Oxford.

The PURPOSE Programme is funded by the National Institute for Health Research (NIHR).

## 3. Involvement at a unit level

The third approach to public involvement in clinical trials is involvement at a unit or departmental level. This type of involvement is similar to that employed by the National Institute for Health Research (NIHR) Clinical Research Networks (for example Medicines for Children, Mental Health, Primary Care), where patient/public panels advise the Networks on forthcoming studies, help in the prioritisation of research and participate in different aspects of dissemination. This type of involvement is useful in that it can:

- ensure a consistent or strategic approach to public involvement throughout a unit
- promote public involvement in a broad range of trial activities
- lead to initiation of public involvement at the earliest stages of trial design
- support researchers and the public involved in clinical trials.

### Potential benefits

- places involvement at a strategic level
- ensures consistent involvement in all trials conducted within a Unit
- builds familiarity between researchers – who may feel more confident approaching members of the public who they know and vice versa
- facilitates quick responses to specific issues – by drawing on existing expertise and skills of involved people
- coordinates involvement across many trials – by helping individuals to feel less isolated and providing support and mentorship.

### Potential challenges

- excludes input or experiences from people who may be put off at the thought of becoming involved at a strategic level in a large organisation or department
- overlooks important issues that may be specific to the disease or subject area
- relies on the input of a small, group of individuals that may not be benefiting from the opinions of others
- increases the burden of responsibility on individuals who are involved.

### Involvement at the Wales Cancer Trials Unit (WCTU)

The WCTU is strongly committed to public involvement and for the past three years, has involved research partners within its workstreams. Involvement focuses on professional working partnership with the volunteers, in collaboration with Involving People, Wales (see www.involvingpeople.org.uk).

To identify volunteers who are able to contribute effectively and confidently at often challenging and technically complex meetings, a formal recruitment process was established. So far, more than 20 research partners have been recruited this way, some of whom work across multiple trials and sit on strategic panels. Trials staff are involved with the selection and training of new volunteers and the mentoring of existing ones.

We have developed Standard Operating Procedures (SOPs) to cover, financing, recruitment, training and mentoring Research Partners. Trial Managers contact the volunteers at least once per month, as volunteers had complained about lack of contact in slow times. It was also felt that a point of contact and coordination of the volunteers was needed and so we liaised with Involving People for their support in placing a volunteer at the Unit for two days per month.

The volunteer came into 'post' in January 2011. His role includes:

- recruiting research partners to trials
- supporting both research partners and trial managers
- reviewing current support systems
- identifying development opportunities for research partners
- ensuring links with the Involving People network.

A recent early review identified good progress. Crucial to longer term success will be gaining the trust and confidence of both research partners and trial managers.

WCTU is funded by Cancer Research UK and Marie Curie, it is a National Cancer Research Institute accredited and UK Clinical Research Collaboration (UKCRC) registered trials unit.

### Involvement in a Protocol Review Committee (PRC) at the Medical Research Council Clinical Trials Unit (MRC CTU)

The PRC reviews new protocols for trials (and other type of research). This includes the patient information sheet, the consent form and any appendices. The PRC may comment on any aspect of the protocol – including the underlying science, the clarity of presentation, formatting, look and feel.

The specific role of the lay member is to read and comment on protocols submitted to the PRC, focussing in particular (but not exclusively) on patient information sheets and consent forms. There also is a more general role to contribute to the discussions of the PRC about any proposal, especially from the perspective of patients and/or potential participants.

"I thought I might be out of my depth on a committee of researchers looking at all sorts of trial protocols, but whenever I ask for more detail or more clarity about patient benefit, people are always happy to explain the science or statistics in ways I can understand. That in itself is good practice for everyone in making the proposal, protocol and patient information much more patient-friendly. I have to work hard to try to be as professional as the professionals, but the protocol review committee is very much a team process. Everyone asks questions and offers views, and all views carry equal weight. Being part of that team is both challenging and also very rewarding. It's just such an amazing thought that my suggestions might improve the quality of health research – and of treatments and outcomes – for hundreds of patients in the future. It's a huge feel-good factor on the train home afterwards!"

**Richard Stephens**
of the MRC CTU protocol review committee

**The UK Dermatology Clinical Trials Network** is dedicated to involving patients in their research wherever possible from the design of the trial right through to the dissemination of the results. The Centre of Evidence Based Dermatology where the network is based has a Patient Panel with members sitting on the Steering and Executive Committees of the Dermatology Trials Network to represent the views of patients and carers. Panel members take part in focus group discussions on the development of trials and join trial steering committees to ensure that the needs of patients are considered throughout the study (see www.ukdctn.org/home).

# Advice to researchers:

To help you plan public involvement in your clinical trial we suggest you consider the following points:

- Be flexible in your approach. For good reasons, clinical trials are managed in quite a rigid way. However if you want to make these processes accessible to members of the public, patients and carers then a degree of flexibility is needed. There is a balance to be had. This may mean being open to running meetings in a different way.
- Don't be too prescriptive about what you want people to do – otherwise there is a risk that you will always get the same people coming forward who fit that role. Perhaps try an asset-based approach – take some time to identify the skills and experiences of the people you are working with and build on what they already bring to the table.
- Consider when to involve people. In general, this should be as early as possible in the development and design of your trial, for example, consider involvement in grant applications or in developing the protocol. One way to ensure this is by involvement across a programme of research, or at a departmental level.
- The people selected may be involved in the trial over a long period of time and so the working relationship between researchers and members of the public is very important. Therefore, think about different options for recruitment. Is a"formal" interview the best approach – is it likely to identify the best people for the role, or would a different method be more appropriate? (see INVOLVE Briefing note six: Who should I involve and how do I find people www.invo.org.uk/resource-centre/resource-for-researchers)
- Develop terms of reference and role descriptions for members of the public and try to establish ways of working that suit all members of the team from the beginning. (see INVOLVE resource for researchers www.invo.org.uk/resource-centre/resource-for-researchers)
- Be honest about what aspects of the trial design can and cannot be changed and clearly explain the reasons for this. You should try to be open to new suggestions and to doing things in new ways when possible and appropriate.
- Think about designating a mentor – perhaps a member of the research team – who people know they can approach with questions about the trial, for clarification about the process, or who can provide support as required. Over a programme of research more experienced patients may be able to take on a mentoring role with newer members of the public.
- Trials are complicated so people need to be well supported.
- Think about people's personal development. It is important to consider what the people involved in the research are getting from the experience as well as the impact on the research. Developing people will also benefit future trials that they are involved in.
- Establishing and maintaining good communications is vital for successful involvement, and bear in mind the advice about flexibility. Some people prefer phone calls, some like emails. Some will be comfortable with teleconferencing but for others this may be an extremely ineffective way for them to contribute.
- Plan to provide feedback to the people you involve to let them know how their contribution has helped – or be able to explain where you haven't been able to take their views on board. People feel they are often consulted, without seeing any change as a result.

# Further reading and resources

## Public involvement in clinical trials

### National organisations

**The Centre of Evidence Based Dermatology**
www.nottingham.ac.uk/scs/divisions/evidencebaseddermatology/index.aspx

**UK Dermatology Clinical Trials Network**
www.nottingham.ac.uk/scs/divisions/evidencebaseddermatology/aboutcebd/ukdermatologyclinicaltrialsnetwork.aspx

**Leeds Clinical Trials Research Unit**
http://ctru.leeds.ac.uk/

**Medical Research Council Clinical Trials Unit**
www.ctu.mrc.ac.uk/

**NIHR Evaluation, Trials and Studies Coordinating Centre**
www.netscc.ac.uk/getting_involved

**NIHR Clinical Research Network Coordinating Centre**
www.crncc.nihr.ac.uk

**Wales Cancer Trials Unit**
www.wctu.org.uk

**Involving People, National Institute for Social Care and Health Research Clinical Research Centre (NISCHR CRC)**
www.involvingpeople.org.uk

### Resources

Boote,J., Baird, W., and Sutton, A. (2011). Public involvement in the design and conduct of clinical trials: a review. **International Journal of Interdisciplinary Social Sciences**, Volume 5, No. 11.

**Making the Difference: actively involving patients, carers and the public. Patient and public involvement. The Way Forward: Examples and evidence from the Clinical Research Network. Derek Stewart ( 2011)**
www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/PPI/Documents/Making%20the%20difference%20May%202011.pdf

**Medical Research Council (MRC) Clinical Trials Unit (CTU) Trial Management Group (TMG) pack**
www.trialsjournal.com/imedia/1292821605618248/supp1.doc

**Guidance for trial managers in the MRC CTU cancer group**
www.trialsjournal.com/imedia/1489272765658534/supp3.doc

**Role description for MRC CTU Protocol Review Committee (PRC) member**
www.invo.org.uk/wp-content/uploads/2012/04/MRCCTURoledesclaymember.pdf

**Terms of reference and role descriptions for the PURSUN project**
Pressure Ulcer Research Service User Network UK (PURSUN UK) Aims of the network and structure:
www.invo.org.uk/wp-content/uploads/2012/03/PURSUNnetworkstructureandaims.pdf

PURSUN Description of roles and responsibilites for patient and public involvement
www.invo.org.uk/wp-content/uploads/2012/03/PURSUNPPIrolesandresponsibilities.pdf

For further information on the **Wales Cancer Trials Unit Standard Operating Procedures (SOPS**) please contact: Dr Annmarie Nelson, Deputy Director, Marie Curie Palliative Care Research Centre, Wales Cancer Trials Unit, School of Medicine, Cardiff University
nelsonA9@cardiff.ac.uk

# Public involvement in research resources

**INVOLVE Briefing notes for researchers: public involvement in NHS, public health and social care research. INVOLVE 2012**

www.invo.org.uk/resource-centre/resource-for-researchers

Other titles in the series of supplements to the briefing notes:

- different ways of involving members of the public in research
- how to find people to involve in research
- strategies for diversity and inclusion
- public involvement in systematic reviews

**Staley K., (2009) Exploring Impact: Public involvement in NHS, public health and social care research, INVOLVE, Eastleigh**

www.invo.org.uk/posttypepublication/exploring-impact-public-involvement-in-nhs-public-health-and-social-care-research

**Patient and public involvement in research and research ethics review. Joint INVOLVE and National Research Ethics Service (NRES) statement 2009**

www.invo.org.uk/resource-centre/publications-by-involve

**INVOLVE Evidence library – an online database of references on the impact, nature and extent of public involvement in research**

www.invo.org.uk/resource-centre/evidence-library

**INVOLVE Putting it into Practice database – an online database of references of reports and articles on guidance and the practice of public involvement in research**

www.invo.org.uk/resource-centre/putting-it-into-practice-database

**Involving Users in the Research process – leaflet produced by Guy's and St. Thomas' and King's College London Biomedical Research Centre**

www.involvinglondon.co.uk/RDSPPI/media/PPI-PDFs/A-how-to-guide-for-researchers.pdf

**People in Research – resource to help members of the public find opportunities to get involved in research and for research organisations / researchers to advertise involvement opportunities.**

www.peopleinresearch.org

For further information and resources on public involvement in research please visit the resource centre on the INVOLVE website (see www.invo.org.uk/resource-centre)

# Further information on the people who developed the Clinical Trials Supplement

**Jim Fitzgibbon** is the volunteer Research Partner Coordinator (supported by Involving People, National Institute for Social Care and Health Research (NISCHR), Clinical Research Centre) at the Cancer Research UK Wales Cancer Trials Unit, Cardiff University. He has been involved in clinical research for a number of years and has been a patient representative on many clinical trial management groups and trial steering committees. He is also a patient representative on the Operational Steering Group of the National Institute for Social Care and Health Research (NISCHR) in Wales.

**Bec Hanley** has worked for fifteen years to promote and support patient and public involvement (PPI) in research. She has a particular interest in clinical trials, and works as an adviser to the Medical Research Council Clinical Trials Unit on PPI. She is co-director of TwoCan Associates, which helps voluntary and statutory organisations involve people who use services in their work, through which she has carried out a wide range of projects, including: development of guidance for PPI for the Research for Patient Benefit Programme; evaluations of PPI for the UK Clinical Research Collaboration and providing training and support for PPI for the National Institute for Health Research (NIHR) Clinical Research Network Coordinating Centre (CRNCC) and INVOLVE.

**Delia Muir** is the Patient and Public Involvement Officer at the Clinical Trials Research Unit, University of Leeds. She recently set up the Pressure Ulcer Research Service User Network (PURSUN UK), a network of patients and carers with personal experience of pressure ulcers who work in partnership with researchers in the field. Delia has also worked extensively within healthcare education. She has a background in the arts and community engagement.

**Claire Murphy** is a Clinical Trial Manager at the Medical Research Council Clinical Trials Unit (MRCCTU) where she has gained considerable experience in managing large, international trials particularly in prostate cancer. Claire is a member of the MRC CTU Consumer Involvement Group through which she was involved in developing guidance on involvement for trial managers and a trial management group induction pack for consumers.

**Annmarie Nelson** is the Deputy Director of the Marie Curie Palliative Care Research Centre, based at the Wales Cancer Trials Unit (WCTU). She is a member of the National Cancer Research Institute (NCRI) Psycho-oncology Clinical Studies Group, and sits on the Marie Curie research board. Annmarie is interested in the patient experience at all levels and, as such, has initiated a range of qualitative studies linked to existing clinical trials, and works closely with Involving People to develop an active consumer group at the WCTU.

**Richard Stephens** has a background in journalism, education and local government. In the 1980s he lost both parents to cancer, and then in 1998 was himself diagnosed with Hodgkin's Lymphoma. Richard sits as a patient representative on two Lymphoma trial management groups (TMGs) and on several national committees and bodies in cancer and health research. He is a member of the NCRI Consumer Liaison Group, and Independent Cancer Patients' Voice, a patient-led charity promoting the patient voice in cancer research. He is a member of the Medical Research Council Clinical Trials Unit (MRC CTU) Protocol Clinical Trials Unit Protocol Review Committee.

**Claire Vale** is a Senior Research Scientist in the Meta-analysis Group at the Medical Research Council Clinical Trials Unit (MRC CTU) where she has been involved in systematic reviews and meta-analyses in cancer for the last 10 years. She has recently led a project involving a group of women in a systematic review of treatment for cervical cancer. Claire currently chairs the Consumer Involvement Group at the MRC Clinical Trials Unit, where she has been involved in developing advice and guidance on involving consumers in trials.

**Bridget Young** is Professor and Director of Communication Skills in the Institute of Psychology, Health and Society, University of Liverpool. Her research focuses on communication in clinical settings, particularly in paediatrics and cancer care; clinical trial methodology, including recruitment to clinical trials, patient and public perspectives on clinical research; measurement of health outcomes in children and the use of qualitative methodologies for informing the design, conduct and interpretation of work to evaluate healthcare interventions.

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