



*National Institute for  
Health Research*



# **Senior Investigators and Public Involvement**

# **INVOLVE**

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

## About this paper

This paper was written by Sarah Buckland and Karen Postle, from the INVOLVE Coordinating Centre, drawing on information provided by the Senior Investigators included in the paper.

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# Contents

- i) Introduction
- ii) How the paper is organised

## A. Stages in the research process

- 1. Systematic review
- 2. Setting the research agenda (identifying topics, shaping the research agenda)
- 3. Project design
- 4. Undertaking research
- 5. Writing and disseminating
- 6. Clinical Research Networks (Topic Specific, Comprehensive and Local Research Networks)

## B. Nature of involvement

- 7. Co-applicants and user researchers
- 8. Steering groups - membership of research project steering / advisory groups and funding committees
- 9. Service user reference groups and user networks

## C. Concluding comments

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# Senior Investigators and Public Involvement

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## i) Introduction

This paper has been produced by INVOLVE on behalf of the National Institute for Health Research (NIHR) for the Senior Investigators Conference, November 2009.

The first 100 NIHR Senior Investigators were appointed in April 2008 and a further 63 were appointed in April 2009, with further rounds of annual appointments planned to yield a full complement of over 200 NIHR Senior Investigators. Senior Investigators are selected by an international panel of judges through open competition. They are selected for the contributions they are making to research and are considered fundamental to the NIHR Faculty.

The information provided in this document about the work of the Senior Investigators was taken, with their consent, from the applications for membership of 31 of this first wave of appointments. The information has been checked with all those whose details have been included in this paper. The language used and the detail included reflects the variations in the information provided in the applications and includes various research, medical and scientific terms.

We have selected these examples to illustrate the wide range of activities and the different ways that Senior Investigators are involving the public across all stages of the research process. However other Senior Investigators, not included in the paper, also cited examples demonstrating how they were involving the public.

We believe that this document will be of interest to researchers, both to highlight the potential for greater public involvement amongst other researchers, as well as providing an understanding of why researchers are increasingly valuing public input.

## **INVOLVE**

INVOLVE is a national advisory group which promotes and supports greater public involvement in NHS, public health and social care research. INVOLVE is funded by the National Institute for Health Research.

By public involvement in research, we mean the active involvement of the public (e.g. patients, informal unpaid carers, service users) in research processes, so that research is carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. For example, being a co-applicant on a research grant or as a member of a research project steering committee.

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## ii) How the paper is organised

We have grouped the examples into two main sections:

- Section A covers the different stages in the research process and provides examples of how the Senior Investigators are working with the public at these different stages. We have included involvement in the Clinical Research Networks in this section as they cover several of the different stages of the research process.
- Section B describes three types of involvement, highlighting some of the different roles that the public are carrying out. For example as co-collaborators, or as members of advisory or steering groups.

Some Senior Investigators provided examples of involvement across a range of different stages or types of involvement. This information has been collated under the most relevant headings. However, this was not practical in some instances where examples briefly referred to a range of stages or types of involvement. In these circumstances we have cross-referenced the entries with the relevant sections. E.g. at the end of Section 2, Setting the research agenda - 'For other examples of involvement in setting the research agenda, see also sections 1.3 and 9.3'.

We have also included a number of verbatim comments from the Senior Investigators, to help convey their experiences of patient and public involvement.

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## **A. Stages in the research process**

### **1. Systematic review**

The Cochrane Collaboration and the Centre for Reviews and Dissemination have a history of public involvement in undertaking many of their systematic reviews. Several of the Senior Investigators highlighted reviews they had undertaken involving the public. These covered topic areas such as cystic fibrosis, skin, cancer and wounds. In one example a service user led the review team.

#### **1.1 Cochrane Reviews: Wounds**

*Professor Nicky Cullum, Department of Health Sciences, University of York*  
Professor Cullum established the Cochrane Wounds Group and is the Coordinating Editor. The Cochrane Wounds Group benefits from the input of 17 health care users around the world as peer reviewers who also help to prioritise reviews for completion and updating.

#### **1.2 Cochrane Reviews: Cancer**

*Professor Janet Dunn, Warwick Medical School, University of Warwick*  
Professor Janet Dunn worked with a very enthusiastic consumer who accompanied her on the systematic review course at the NHS Centre for Reviews and Dissemination in York. This led to a successful registration with Cochrane to undertake a systematic review assessing the recruitment and retention of people from ethnic minority groups to cancer, diabetes and stroke clinical trials. Despite going through Cochrane registration this was not pursued due to lack of funding and has subsequently been restricted to cancer clinical trials using Warwick Medical School funding.

#### **1.3 Cochrane Reviews: Cystic Fibrosis, Children, Chronic fatigue**

*Professor Rosalind Smyth, Institute of Child Health, University of Liverpool, Alder Hey*

In 1995, as Co-ordinating Editor of the Cochrane Cystic Fibrosis (later Cystic Fibrosis and Genetic Disorders) Group, Professor Smyth initiated processes of partnership with consumers to ensure relevance and quality of reviews. Within the Group, all protocols and reviews are independently peer reviewed by consumers, using consumer checklists, developed in collaboration with consumers. This has involved the engagement of 24 consumers in 9 countries, with experience of 7 different diseases. The Group is in regular contact with consumer groups throughout the world. Consumers are also invited to comment on and contribute to the list of priority titles for future Cochrane reviews.

#### **1.4 Centre for Reviews and Dissemination (CRD): Cancer**

*Professor Lesley Stewart, Centre for Reviews and Dissemination,  
University of York*

User engagement and involvement is embedded within the Centre for Reviews and Dissemination (CRD) work. Advisory groups for their research projects may include clinicians, consumers and other relevant stakeholders with specialist knowledge or experience in the field. User views also feed into individualised dissemination strategies and help to guide decisions about target audiences, and appropriate forms of communication.

At the Medical Research Council (MRC) Professor Stewart's research team was the first to directly work with healthcare users in an Individual Patient Data (IPD) meta-analysis. In the team's systematic review of concurrent chemo-radiation for cervical cancer they recruited a number of patient research partners who were encouraged to contribute to the research project in whatever capacity the partners felt best able. This included examining data alongside researchers, contributing to documentation, helping make arrangements for and attending their international collaborators meeting. Both researchers and the women involved learned much from each other. This healthcare user involvement element of the project was funded through a Department of Health post-doctoral award in evidence synthesis. It has been used as a model for involving the parents of children who have been treated for cancer in a further IPD analysis, currently being carried out at the Centre for Reviews and Dissemination (CRD). This aims to develop a clinical decision rule to help identify those children most at risk of developing serious consequences when they develop a fever. The parents are helping define which outcomes are most important to children and families, and how to balance risks against benefits.

#### **1.5 Cochrane Reviews: Skin**

*Professor Hywel Williams, Centre of Evidence Based Dermatology,  
University of Nottingham*

Consumer involvement has been prominent in the Cochrane Skin Group right from the start after a dedicated meeting of users in 1999. The research team's policy is to include consumers as referees and co-authors in all of their reviews. Consumers comment on the relevance of outcome measures and on the readability and scope of the reviews. Some have even led a review team to full publication.

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## 2. Setting the research agenda

The following examples illustrate how user groups have been involved in contributing to the research priorities in two areas - antiretroviral therapy and stroke treatment.

### 2.1 HIV/AIDS

*Professor Deenan Pillay, Department of Infection, UCL*

The Development of Antiretroviral Therapy in Africa (DART) Steering Group includes community activists. As Principle Investigator of the DART Virology work, Professor Pillay believes that the controversies surrounding many areas of Antiretroviral Therapy (ARV) rollout in Africa must be addressed prior to engaging in a research plan. There is active and vibrant discussion within and outside the DART team involving a large range of user groups. This discussion very directly informs research priorities, in particular the ethics of specific antiretroviral approaches in an African setting.

### 2.2 Stroke Treatment and Prevention

*Professor Helen Rodgers, School of Clinical Medical Sciences, Newcastle University*

Professor Rodgers' local stroke service seeks the experience and views of patients and carers to inform their research priorities, clinical practice and service developments. Users identified the limited availability of services for carers as a priority for research. Professor Rodgers is Associate Director for patient, carer and public involvement (PCPI) for the Stroke Research Network.

**For other examples of involvement in setting the research agenda, see also sections 1.3 and 9.3.**

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## 3. Project design

The Senior Investigators highlighted numerous ways in which they had involved service users and carers in the design of research projects. People have been involved in influencing the initial design of studies, advising on ethical issues, ensuring that the methods being adopted are reasonable from the patients' perspective as well as advising on outcome measures.

### **3.1 Creutzfeldt-Jakob Disease (CJD)**

Professor John Collinge, Department of Neurodegenerative Disease, Institute of Neurology, National Hospital for Neurology and Neurosurgery, London

At the request of the Chief Medical Officer (CMO), the NHS National Prion Clinic (NPC), together with the Medical Research Council's (MRC's) Prion and Clinical Trials Units established the first UK clinical trial in CJD – the MRC Prion-1 study. This study involved detailed consultation with individual patients, their carers and patient groups which resulted in significant changes to the study design. The MRC PRION-1 trial steering committee had a lay chairman who lost his son to variant CJD. This work has established the framework and expertise to allow trials of future therapeutics and is being followed by the National Prion Monitoring Cohort of which Professor Collinge is the Principal Investigator. This is being overseen by an independent oversight committee with a lay member who has an affected relative. Professor Collinge directs the National Prion Clinic.

### **3.2 Brain Injury in Newborn Children**

Professor David Edwards, Division of Clinical Sciences, Imperial College London

Professor Edwards' research requires the close participation and active involvement of parents. His team seeks parents' consent to participate in research at a time of great stress and emotional insecurity, and often ask parents to return to the hospital for follow-up. Professor Edwards believes that the deep commitment they ask of families cannot be justified without the research being important and the clear communication of its value to the parents. In addition, the demands made on families means that for practical reasons it is essential to minimise the burden and difficulties caused by participation in the research.

*"We have therefore taken several steps to involve parents in the planning of our research programme, regarding this as particularly important as there are important issues of ethics and parent satisfaction involved in research with sick infants, especially when brain injury is involved and rapid decisions are needed."*

### **3.3 Inflammatory Bowel Disease and Nutrition**

Professor Alastair Forbes, Department of Gastroenterology and Clinical Nutrition, University College London

Professor Forbes is a "professional member" of Patients on Intravenous and Nasogastric Nutrition Therapy (PINNT), the patient support group for those on long-term nutritional support. He believes it was crucial to involve this group in the design of his studies of glutamine and GLP-2 to ensure that the demands the researchers made on study patients were reasonable and sustainable for the 6 and 12 month study periods involved.

### **3.4 Aphasia**

Professor Matthew Lambon Ralph, Neurosciences and Aphasia Research Unit, University of Manchester

In forging previous applications for specialist funding from the Tavistock Trust for Aphasia and also from CONNECT (The Communication Disability Network), a group of potential users was integral to the planning and design of the proposed university-based specialist clinic/aphasia support groups.

**“This input and feedback was critical in order to ensure the effectiveness and appropriateness of the clinics and how these might most readily link with our research programmes.”**

### **3.5 Mental Health**

Professor Shôn Lewis, Department of Psychiatry, University of Manchester

In terms of specific research projects, a carers' organisation for Severe Mental Illness (Making Space) was involved in the design and execution of a family intervention trial. Professor Lewis included user-focused outcomes for the first time in the UK in an antipsychotic drug trial: Cost utility of the latest antipsychotics in severe schizophrenia (CUtLASS).

### **3.6 Breast Cancer and Colorectal Cancer**

Professor David Mant, Department of Primary Health Care, University of Oxford

Professor Mant took an early lead in involving health care users in the design and execution of clinical research in primary care when the research team set up the breast cancer follow-up trial in the late 1980s. They recruited women with breast cancer into a series of user groups to discuss both the content of the intervention and the conduct of the trial.

Since that time Professor Mant has routinely involved users both by recruiting lay members/ patient representatives onto trial steering groups and by setting up focus groups to help the researchers to develop interventions or sort out particularly difficult design issues, particularly related to participation. In the ongoing Follow up After Colorectal Cancer (FACS) trial, they sponsored an external qualitative study to explore attitudes of health care users to participation on the advice of the lay member of the steering group.

### **3.7 Prostate Cancer**

Professor David Neal, Department of Surgery / Oncology, Cambridge University

Along with the other two Principle Investigators in the Prostate Testing for Cancer and Treatment Trial (ProtecT), Professor Neal involved men in a qualitative research project to help them design the protocol. This was successful in that this work led to a new protocol that increased recruitment. Our work with these

patients was instrumental in working out the best form of words to describe accurately the uncertainties over the benefits and dis-benefits of screening and treatment for prostate cancer without alarming men, but being absolutely honest. They found out that patients' perceptions were very different from their own. There is continued involvement with men recruited to the study through a website and a regular newsletter.

**"The term watchful waiting has long been used to describe a conservative approach with appropriate intervention but to men the term meant "you watch whilst I die". This had a profound effect on our approach to recruiting patients to clinical trials involving treatment arms of different degrees of invasiveness."**

### **3.8 Drug Safety and Alcohol Misuse**

*Professor Munir Pirmohamed, Dept of Pharmacology and Therapeutics, University of Liverpool*

Professor Pirmohamed communicated with APRIL (Adverse Psychiatric Reactions Information Link), a patient organisation focusing on adverse psychiatric reactions, in order to get patients involved in his research into drug safety issues. He is also developing a research proposal with APRIL on depression associated with isotretinoin (a drug used to treat severe acne), to be submitted for funding to the Lotteries Commission.

### **3.9 Breast Cancer**

*Professor Anthony Swerdlow, Section of Epidemiology, Institute of Cancer Research*

Most of Professor Swerdlow's research for the last 15 years has involved individual patient data collected by questionnaire and/or personal interview from patients with illnesses or from members of the public. In all of these studies the views of the patients/public taking part were an important component in designing the study and in refining the questionnaires and procedures.

For instance, in the Breakthrough Generations Cohort Study, which has been joined by over 100,000 women in Britain, and for which Professor Swerdlow is the epidemiological principal investigator (with a laboratory co-principal investigator), the Committee who advise on the design and conduct of the study includes women who have taken part in the study. One of these participants helped with the design of the initial study and attended the ethics committee with him. Furthermore, the first 900 participants included in the study completed a questionnaire about their views of the study and its design, which was then used to alter the design to improve it from the women's viewpoint. The researchers send annual newsletters to all study participants, and act as appropriate on their feedback.

Professor Swerdlow has since started a national case-control study of the aetiology of breast cancer in men, and has been consulting with men with breast cancer in order to refine and improve the design and questionnaire - for instance, with regard to their concerns and views on the methods and questions.

*“The patients have proved extraordinarily helpful, and the designs of the studies have been improved as a consequence.”*

### **3.10 Eczema**

*Professor Hywel Williams, Centre of Evidence Based Dermatology,  
University of Nottingham*

The Health Technology Assessment (HTA) funded Softened Water Eczema Trial (SWET) seeks to answer whether water softeners improve eczema symptoms. In addition to providing useful practical suggestions on design, logistics and readability, their consumer panel persuaded the researchers to change the research design to ensure that all study participants had an opportunity to try the device out in their homes.

*“This decision [to change the research design] made the study significantly more attractive to recruitment. The study has since recruited to target and on time.”*

### **3.11 The Patient Oriented Eczema Measure (POEM)**

*Professor Hywel Williams, Centre of Evidence Based Dermatology,  
University of Nottingham*

Professor Williams’ research fellow had shown that there were a profusion of poorly tested scales for eczema that measured things that were interesting to doctors. The researchers therefore sought to develop an outcome that measured something important to patients, and worked with patients and the local support group to scientifically develop items that would capture the “bother” associated with eczema.

**For other examples of involvement in project design, see also sections 4.3, 4.5, 4.7, 6.1, 7.1, 8.1, 8.8, 9.1, 9.4, 9.6, 9.9.**

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## **4. Undertaking research**

Senior Investigators reported a variety of ways in which the public had contributed to the undertaking of research projects, including assisting with recruitment and analysis of the findings. One of the main ways that the Senior

Investigators reported involving the public in undertaking research was through advising and contributing to the patient information and consent forms. This is an area where patients can help to ensure that the information provided to patients is pitched at the right level (not too complicated but also not too simple) and provides the information that is important to patients. Involvement in this way can potentially help with the recruitment to trials by providing patients with a clearer understanding of the trial and what would be involved. In addition, one Senior Investigator also reported on how a voluntary organisation had assisted in directly encouraging recruitment to a study. Later, in Section 9, we highlight how the establishment of user groups provide a mechanism through which the public can contribute to all aspects of research within a unit or department.

The first example in this section is of a specific initiative where members of the public were involved in interpreting the data from a study. In Section 7, we provide examples of how Senior Investigators have worked alongside service users as co-applicants or through employing user researchers. In these instances the service users and carers are invariably also involved in data collection and analysis.

#### **4.1 Ageing**

*Professor John Bond, Institute of Health and Society, Newcastle University*

Professor Bond has engaged actively with patients and the public through workshops. For example in a project looking at normal ageing and brain pathology, he held workshops with the public to present raw qualitative data and obtain interpretations of the data from the participants.

#### **4.2 Cancer**

*Professor Janet Dunn, Warwick Medical School, University of Warwick*

Professor Dunn works closely with her local patient support groups for assistance with the development of patient information sheets and consent forms for all trials. Examples have been the herceptin duration trial (PERSEPHONE) and Positron Emission Tomography (PET-NECK) trial development. In addition, consumers initiated a 'Patient day at Warwick' to discuss the problem of follow up for breast cancer patients; this formed the basis of the *iBreast* follow up trial proposal.

#### **4.3 Midwifery, Birth and Breastfeeding**

*Professor Mary Renfrew, Department of Health Sciences, University of York*

In 1989 Professor Renfrew was Principle Investigator for a Medical Research Council (MRC) funded randomised controlled trial (RCT) in which users were actively engaged in recruiting, randomising and following up participants. This was the first RCT that she is aware of to involve users in such roles. Professor Renfrew has since ensured that all her studies formally involve users in planning, conduct, review, dissemination, and co-authorship. Users sit on the Advisory Group that oversees her research programme.

#### 4.4 Stroke Treatment

Professor Helen Rodgers, School of Clinical Medical Sciences, Newcastle University

Patients helped to develop recruitment strategies, assessment tools, patient information sheets and consent forms for a multi-centre study undertaken by Professor Rodgers to evaluate botulinum toxin in the treatment of upper limb spasticity after stroke. A lay member is on the Steering Committee.

#### 4.5 Children

Professor Rosalind Smyth, Institute of Child Health, University of Liverpool, Alder Hey

Professor Smyth reported that grant applications and parent information documents for studies of infants with bronchiolitis have been improved by comments from a parent whose child had suffered from severe bronchiolitis.

#### 4.6 Eczema

Professor Hywel Williams, Centre of Evidence Based Dermatology, University of Nottingham

Users from the National Eczema Society have also supported Professor Williams in publicity and recruiting into a study which occupied a prominent position on their homepage [www.eczema.org](http://www.eczema.org)

#### 4.7 Cancer

Professor John Yarnold, Department of Radiotherapy and Oncology, Royal Marsden Hospital

The early involvement of healthcare users is routine in all Professor Yarnold's trials, with volunteers recruited via the National Cancer Research Institute (NCRI) Consumer Liaison Group. The volunteers' role involves commentary and questioning of trial design, eligibility and implementation, including all patient information materials.

**For other examples of involvement in undertaking research, see also sections, 1.4, 6.1, 6.2, 7.1, 7.4, 8.1, 9.1, 9.3, 9.4, 9.9.**

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## 5. Writing and disseminating

This section provides examples of how Senior Investigators have worked with the public in writing and disseminating research findings. These include talks, presentations, writing information booklets, open days and producing web based

information. The public were not always actively involved in communicating the research findings, and so some of these were more examples of how the Senior Investigators engaged with the public rather than of active involvement. However, these methods did appear to provide some opportunities for the public to influence both current and future research.

### **5.1 Creutzfeldt-Jakob Disease (CJD)**

*Professor John Collinge, Department of Neurodegenerative Disease, Institute of Neurology, National Hospital for Neurology and Neurosurgery, London*

Professor Collinge's team hold an annual open day at which their research is discussed with patients, patients' representatives, carers and health professionals and at which they actively invite feedback. The team provide teaching and study days for patients, at-risk individuals, health professionals and carers as well as providing web-based information. A lay summary of their entire research portfolio has been made available on the web. Professor Collinge continues to have a major commitment to public communication via frequent interviews in national and international print and broadcast media.

### **5.2 Inflammatory Bowel Disease and Nutrition**

*Professor Alastair Forbes, Department of Gastroenterology and Clinical Nutrition, University College London*

Professor Forbes has a personal group of 20 patients and ex-patients who help him to fund raise and raise awareness of research issues and who keep his thoughts closely focused on patient needs.

### **5.3 Aphasia**

*Professor Matthew Lambon Ralph, Neurosciences and Aphasia Research Unit, University of Manchester*

The Neurosciences and Aphasia Research Unit (NARU) gives regular talks and presentations to both groups of people with aphasia (e.g., stroke clubs, etc.) as well as specialist aphasia therapy special interest groups. This provides a mechanism not only to disseminate research findings to patients and their carers but also to receive feedback from them about current and future research plans.

### **5.4 Dementia**

*Professor Martin Rossor, Department of Neurodegeneration, Institute of Neurology, London*

In 2005 Professor Rossor introduced "Patients' Choice" in the Journal of Neurology, Neurosurgery and Psychiatry. An article is identified in each issue by a lay person independently of the editors, which is deemed to be of particular relevance to patients. This is highlighted on the cover and provided as a free download.

## 5.5 Disability / Biomedical research

Professor Alan Thompson, Dept of Brain Repair and Rehabilitation, Director, Institute of Neurology, UCL

Within the Comprehensive Biomedical Research Centre, Professor Thompson is helping to drive a strong programme of patient and public involvement to enhance levels of engagement and ensure that the research they carry out and the outputs from the Comprehensive Biomedical Research Centre have maximum value for patients and the public. They have established a research patients' and carers' support network which has launched a series of lectures and produced a summary of the research activity being carried out within University College London Hospitals / University College London.

**"Patient involvement is fundamental to my research areas of rehabilitation and outcome measurement and in my role as Deputy Director of the University College London Hospitals (UCLH) University College London (UCL) Comprehensive Biomedical Research Centre (CBRC)."**

**For other examples of involvement in writing and dissemination, see also sections, 1.4, 4.3, 7.2, 7.5, 8.4, 8.8, 9.1, 9.9.**

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## 6. Clinical Research Networks (CRN)

The NIHR Clinical Research Networks consist of six Topic Specific Clinical Research Networks, the Primary Care Research Network and the NIHR Comprehensive Clinical Research Network. They were established to provide an infrastructure to support research in all areas of disease and clinical need in the NHS. The Clinical Research Networks are increasingly involving the public in their work. This has in no small part been influenced by the commitment of the Senior Investigators who are in influential positions within these networks.

### 6.1 Stroke Research Network – Thames (SRN)

Professor Martin Brown, Institute of Neurology, National Hospital for Neurology, UCL

The Thames Stroke Research Network, which Professor Brown leads, incorporated the Stroke Association as one of its constituent partners. The research team also has an independent patient and carer representative on the Network's Steering Committee, who provides them with independent advice from healthcare users on the priorities for the network, the choice of research studies within the portfolio of the network, and on the design and execution of the individual research studies, where relevant.

## **6.2 Diabetes Research Network (DRN)**

Professor Nishi Chaturvedi, National Heart and Lung Institute, Imperial College

In her role as Associate Director for the UK Diabetes Research Network, Professor Chaturvedi has helped to devise a strategy that enables and supports patient and public participation in research. As an example, the network was approached to assist with a study of early drug intervention shortly after diagnosis of type 1 diabetes. This is a relatively new treatment, whose long term effects are unknown, but potentially offers a cure for type 1 diabetes. Professor Chaturvedi has helped to organise a patient and public advisory group to discuss the study and in particular, to advise on the content of patient information sheets and the optimal approaches to recruitment.

“This work highlighted important questions and misconceptions about the value of clinical trials, and reassured us that approaching people shortly after diagnosis would not be viewed as intrusive, if performed by the team directly involved in that individuals' care. This information was used to revise study materials and was viewed as being very valuable by the study sponsors.”

## **6.3 National Cancer Research Network (NCRN)**

Professor Janet Dunn, Warwick Medical School, University of Warwick

The National Cancer Research Network involves consumers on all their clinical study groups and as such is a rich environment for involving patients and carers in all aspects of trial design and conduct. A recent example has been the development of the breast cancer follow up trial (*iBreast*) and the Chemospare breast cancer trial with two consumers who are members of the National Cancer Research Institute (NCRI) Breast Clinical Studies Group and ‘independent cancer patient voices’. Consumer representatives are named co-investigators on the grant applications and will play an integral part in assessing the acceptability of these trials to newly diagnosed patients.

## **6.4 Mental Health Research Network (MHRN)**

Professor Shôn Lewis, Department of Psychiatry, University of Manchester

As the chair of the organising committee for the UK Mental Health Research Network's (MHRN's) Annual Scientific Conference, Professor Lewis works with service users to ensure full representation on the programme.

## **6.5 Dementias and Neurodegenerative Diseases Research Network (DeNDRoN)**

Professor Ian McKeith, Institute for Ageing and Health, Newcastle University

Professor McKeith is co-director of DeNDRoN. The DeNDRoN Coordinating Centre is establishing a working party that will be responsible for overseeing the development and monitoring of the progress of patient and carer participation. One of the initial objectives of the working party is to establish and support a network of people who have dementia, Parkinson's Disease, Motor Neurone Disease or Huntington's Disease; their carers and the public.

**"The views and perspectives of older people, particularly those with age-related disorders and disability, their carers and the wider public are important drivers of both DeNDRoN and the Newcastle Biomedical Research Centre".**

## **6.6 Dementias and Neurodegenerative Diseases Research Network (DeNDRoN)**

Professor Martin Rossor, Department of Neurodegeneration, Institute of Neurology, London

Professor Rossor is Director of the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN). DeNDRoN, in common with the other topic specific clinical research networks, has a dedicated patient and public involvement Director and the research team has recently completed a major scoping exercise involving patients and carers to establish how they wish the patient involvement initiative to develop.

## **6.7 Medicines for Children Research Network (MCRN)**

Professor Rosalind Smyth, Institute of Child Health, University of Liverpool, Alder Hey

Professor Smyth is Director of the MCRN. The bid for the tender for the Coordinating Centre was from a consortium which included the National Children's Bureau (NCB), representing the views of children. The MRCN were the first network to appoint a full time consumer liaison officer and its resources also support the involvement of an Associate Director for Consumer Involvement from the NCB.

**"Involvement of children and families at all points in the research process is fundamental to the work of the MCRN."**

**For other examples of involvement in Clinical Research Networks, see also sections 1.3 and 9.9.**

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## **B. Nature of involvement**

### **7. Co-applicants and user researchers**

This section gives examples highlighting how Senior Investigators reported involving the public as co-applicants on grant applications or as user researchers. Such involvement potentially provides a far greater opportunity to work alongside others to contribute to studies from the very outset and throughout the life of a project.

Five Senior Investigators in this report cite examples of the involvement of service users or voluntary organisations as co-investigators, four of these being on NIHR funded grants. In addition to involvement as co-applicants, several Senior Investigators report involving user researchers. A user researcher is someone who uses or has used health and / or social care services because of illness or disability, who is also a researcher.

#### **7.1 Primary Care**

*Professor Richard Baker, Department of Health Sciences, University Hospitals of Leicester, member of INVOLVE*

In Professor Baker's National Institute for Health Research Service Delivery and Organisation (NIHR SDO) funded study of continuity in primary care, a patient representative was a co-applicant who contributed as a full collaborator to study design, management of the study and interpretation of the findings. The patient representative also chaired a patient advisory group that was asked for advice on the design of study instruments and other aspects of the study.

#### **7.2 Mental Health and Primary Care**

*Professor Christopher Dowrick, Division of Primary Care, University of Liverpool*

Involvement of user led and voluntary care organisations is crucial to the success of Professor Dowrick's NIHR R&D Programme to increase equity of access to high quality mental health services in primary care. They have identified as a co-applicant someone who represents Anxiety UK, the UK's leading charity for people with anxiety disorders. During the lifetime of the programme Professor Dowrick and his team will bring in service users already working within the research's target groups, with the aim of enhancing their capacities in research, development and dissemination. The service users will be encouraged to participate in the delivery of relevant interventions, for example working as user-trainers or lay health workers. The service users will also form an integral part of the research dissemination phase, developing key educational materials and enabling delivery of these across the broad primary mental health care economy.

Anxiety UK are working on the development of a user led primary care mental health service, which will offer a guided self help clinic. This service will include people presenting from the programme's exemplar groups. This clinic will therefore provide substantial opportunities to implement findings from the programme.

### **7.3 Mental Health**

*Professor Robin Murray, Institute of Psychiatry, Kings College*

In Professor Murray's study developing and evaluating the use of a better way of assessing quality of care among patients with psychotic illness, service users from Service User Research Enterprise (SURE) have been involved from the start and a researcher who has experienced severe mental illness has held a half time post.

In the ten year follow up of the Aetiology and Ethnicity of Schizophrenia and Other Psychoses (AESOP) study funded by the Medical Research Council (MRC), Dr Diana Rose, a service user, is an adviser.

In the research team's NIHR Programme grant to study ways of improving physical health and decreasing drug abuse, two service users are part of the management team, and there is regular input from service users and carers.

### **7.4 Stroke Treatment and Prevention**

*Professor Helen Rodgers, School of Clinical Medical Sciences, Newcastle University*

In collaboration with her local carers' centre, Professor Rodgers established and evaluated a service for carers. A member of the carers' centre was a co-applicant on the proposal which was funded by the Stroke Association and he was a member of the project steering committee. The stroke information service subsequently won an award from the Strategic Health Authority.

### **7.5 Schizophrenia**

*Professor Nicholas Tarrier, Division of Clinical Psychology, School of Psychological Sciences, University of Manchester*

Since the early 1980s Professor Tarrier has been involved with carers in his research on schizophrenia and serious mental illness. This involved writing an information booklet for Making Space (a carer and voluntary service organisation - previously NWF) and working in close collaboration with this organisation over many years both in designing and collaborating in treatment research. This has included a jointly held research grant to train family support workers and the inclusion of carer and service user representatives on the management committees / teams of all recent research projects. The NIHR funded RECOVERY programme has two service users as co-applicants and a service user reference group.

## 7.6 Mental Health

Professor Graham Thornicroft, Health Service and Population Research Department, Institute of Psychiatry

Professor Thornicroft's Department has established and developed the first service user research team in mental health - the Service User Research Enterprise (SURE) co-directed by Dr Diana Rose and Professor Til Wykes. SURE is a team of service user researchers conducting research from the perspective of mental health service users. Dr Rose, a service user herself, has been involved in several stigma and discrimination projects at the Institute of Psychiatry. She has ensured that the voice of service users is clearly heard with respect to problems of stigma, prejudice and discrimination. The SURE team ensures that public and patient involvement in research projects has elements of all three of the INVOLVE levels of public and patient involvement - consultation, collaboration and user-led research.

**"Service user involvement is now an integral part of the research of our department and much of the research of the Institute of Psychiatry as a whole."**

Professor Thornicroft has been awarded a Department of Health NIHR Programme Grant for Applied Research in Stigma and Discrimination in Mental Health (the Social Inclusion: Research Evaluation (SAPPHIRE) Programme). User participation is an integral part of the programme. The participation of staff from SURE as Co-Investigators, with Judi Chamberlin from the National Empowerment Center in Boston, and Vanessa Pinfold from Rethink, demonstrates the research team's commitment to genuine user involvement in this research programme. The team's partnership approach to this work is also illustrated by the fact that its (i) school student, (ii) police, (iii) medical student, and (iv) trainee psychiatrist intervention studies have been carried out as joint ventures with the charity Rethink.

**For other examples of involvement as Co-applicants and user researchers, see also section 6.3.**

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## 8. Membership of research project steering / advisory groups and funding committees

Membership of steering groups, advisory groups and funding committees / panels is a common way through which researchers seek advice and contributions from the public. The following are a few examples of the types of projects where the public have been involved. In some cases these are people

drawn from relevant voluntary organisations and in other instances they are individuals with personal experience of a condition. Two examples in this section are where the public have been involved in advising on funding decisions for voluntary organisations.

### **8.1 Stroke**

*Professor Martin Brown, Institute of Neurology, National Hospital for Neurology, UCL*

Professor Brown involved patients in providing feedback on the design and execution of two randomised controlled trials.

### **8.2 Leg ulcers**

*Professor Nicky Cullum, Department of Health Sciences, University of York*

Professor Cullum reports that although the research team makes every effort to engage service users in their primary research this is not easy in the field of chronic wounds - possibly because patients tend to be quite elderly, are often quite socially isolated, and (in the case of pressure ulcer patients) extremely ill. Nevertheless, both of their recent trials: Larval Therapy Venous Ulcer Study (VenUS II) and Ultrasound Venous Ulcer Study (VenUS III) have consumer involvement on the Trial Steering Committees.

### **8.3 Primary Care**

*Professor Christopher Dorrick, Division of Primary Care, University of Liverpool*

The major clinical trials on which Professor Dorrick is currently a principal investigator (MUST, FINE and THREAD), all have service user representation on their Trial Steering Groups. (MUST - Randomised controlled trial of teaching general practitioners to manage patients with persistent medically unexplained symptoms; FINE - RCT of nurse led self help for patients in Primary Care with chronic fatigue syndrome, and THREAD - Randomised controlled trial to determine the cost effectiveness of Selective Serotonin Reuptake Inhibitors (SSRIs) for mild to moderate depression with somatic symptoms in Primary Care).

The Mersey Primary Care R&D Consortium has primary care user representatives on its executive board, and a work stream dedicated to assessing ways in which service users can be enabled to participate in all aspects of the primary care research process.

### **8.4 Brain Injury in Newborn Babies**

*Professor David Edwards, Division of Clinical Sciences, Imperial College London*

A representative of Scope was formally involved in Professor Edwards' Medical Research Council (MRC) funded trial of neuroprotection after asphyxia. Neonatal imaging is run by a board which Professor Edwards chairs, and which has from

the outset included a parent representative who is actively involved in reviewing projects and process. Professor Edwards and his colleagues believe that proper involvement for families requires more background information than can be given in a single discussion. As a result they have invested in the educational route which allows parents to become familiar with the process and outcomes of research using a variety of media, including graphical written and web based approaches, all of which have included parental involvement in the planning stage.

### **8.5 Inflammatory Bowel Disease and Nutrition**

*Professor Alastair Forbes, Department of Gastroenterology and Clinical Nutrition, University College London*

Professor Forbes collaborates closely with 3 key charities in his field and until last year, he was the medical director of Core – the Digestive Disorders Foundation. Core has its roots in the medical profession and was relatively slow to adopt direct patient involvement, despite a long history of information leaflets for patients and the general public. However, with his active support – this has now changed, and there are lay members on all Core committees, including the research awards committee.

### **8.6 Mental Health**

*Professor Robin Murray, Institute of Psychiatry, Kings College*

In Professor Murray's NIHR Programme grant, funded to study ways of improving physical health and decreasing drug abuse, two service users are part of the management team, and there is regular input from service users and carers.

### **8.7 Prostate Cancer**

*Professor David Neal, Department of Surgery / Oncology, Cambridge University*

As Chair of the UK's first research collaborative for prostate cancer research, Professor Neal has incorporated ideas from prostate cancer survivors in the design of meetings for the collaborative, and has invited two prostate cancer survivors to sit on their advisory board for the use of tissue and other bio-materials. This continues with advice from men over the use of tissue and other biomaterials having an input as to how these are used in research.

### **8.8 Children**

*Professor Rosalind Smyth, Institute of Child Health, University of Liverpool, Alder Hey*

Professor Smyth's applications and clinical research studies have involved consumers in the design, conduct, interpretation and dissemination of results of research studies. For example the Calories In Cystic Fibrosis—Oral (CALICO) trial involved a parent of a child with cystic fibrosis on the Steering Committee.

## 8.9 Multiple Sclerosis (MS)

Professor Alan Thompson, Dept of Brain Repair and Rehabilitation, Institute of Neurology, UCL

As Medical advisor of the Multiple Sclerosis (MS) Society and the MS International Federation, Professor Thompson has been involved in a number of initiatives to inform and increase involvement of patients in research. The MS Society now involves people affected by MS as members of the review and grant award panel and he was involved in providing the necessary support and education to facilitate this exciting initiative.

## 8.10 Cancer

Professor John Yarnold, Department of Radiotherapy and Oncology, Royal Marsden Hospital

Professor Yarnold engaged early on with the patient advocate group Radiotherapy Action Group Exposure (R.A.G.E.), who lobbied for compensation following the development of severe late adverse effects of radiotherapy for early breast cancer. In 1996, Professor Yarnold invited two members, including the Chairman, to be members of the National Cancer Research Institute (NCRI) Standardisation of Breast Radiotherapy (START) Trial Protocol Working Party and subsequently, the Trial Management Group.

**“Their involvement has contributed to a profound change in attitude by healthcare users and professionals alike, with mutual respect replacing earlier antagonism.”**

**For other examples of involvement in advisory groups, see also sections, 1.4, 2.1, 3.1, 3.6, 3.7, 3.9, 4.3, 4.4, 6.1, 7.3, 7.4, 7.5, 9.2, 9.4.**

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## 9. Service user reference groups and user networks

This section illustrates some of the ways that Senior Investigators have been instrumental in establishing service user reference groups or user networks. These groups are sometimes part of a specific research project but can also be separate from individual research projects, contributing to and advising a range of projects at different stages.

### 9.1 Prostate Cancer

Professor Richard Baker, Department of Health Sciences, University Hospitals of Leicester, member of INVOLVE

In Professor Baker's National Institute for Health Research Service Delivery and Organisation (NIHR SDO) funded study to develop measures of patients'

experiences of prostate cancer care, a patient advisory group was established to advise on study instruments, design and associated issues. Within the department, he has supported the creation of a Forum to advise on issues of importance to the local community, helped ensure studies are conducted in ways acceptable to patients, facilitated involvement in design and conduct of studies, and promoted the transmission of the findings to local people, many of whom have participated in research.

**"I have learnt that patient involvement in research studies can improve study design, improve the quality of the findings, and help ensure that the preferences of the patient participants are understood and acted on. I have also learnt that patient involvement can facilitate implementation of research findings, for example through patient involvement in guideline groups and contact with national and local patient groups."**

## **9.2 Ageing**

*Professor John Bond, Institute of Health and Society, Newcastle University*

Professor Bond describes how he has always respected and included the views of citizens in his work. Informal consultation with 'patients' has occurred in the majority of his 'patient' focused studies since the 1980s but it was only in the mid nineties that he began to invite more formal participation of patients and the public through involvement in advisory and steering committees.

**"From the 1980s my research group has led the way in seeking involvement of patients and public within expert lay panels. We empowered members to influence the course of research more than traditional 'token' membership on project steering committees may allow."**

## **9.3 Heart and lung**

*Professor Nishi Chaturvedi, National Heart and Lung Institute, Imperial College*

In the preparation stage of the programme grant to follow up a multi ethnic cohort, Professor Chaturvedi created a participant and public advisory group, drawn from previous study participants, clinic attendees, spouses and friends, with representation of the three ethnic groups to be studied (European, Indian Asian and African Caribbean), to discuss research priorities and the acceptability of the investigations they proposed to do. Some of the priorities were then included in the proposal. This group has continued to meet now that the grant has been awarded, and have advised the researchers on the questionnaire, mode of follow up visits to participants, presentation of information sheets, dissemination of previous findings and encouragement to participate through the

media. As the study continues, this group will be provided with regular information on progress with the study, and will be encouraged to perform regular site visits to advise from a participant perspective.

#### **9.4 Aphasia**

*Professor Matthew Lambon Ralph, Neurosciences and Aphasia Research Unit, University of Manchester*

The Neurosciences and Aphasia Research Unit user group sub committee, oversees all aspects of the preliminary phase of the trial including recruitment procedures, information sheets, quantitative and qualitative assessment, trial design and health economic measures. In moving to the full trial, the user group sub committee reviews implementation of the trial plan, recruitment, issues arising in the study and future publications. User representatives from the group sit on the trial management team.

People with aphasia have given feedback on the activities and functions of their NHS specialist aphasia clinic (East Lancashire. Primary Care Trust). and have also advised on maximising clinical recruitment for research studies.

#### **9.5 Dementia and Neurodegenerative Diseases**

*Professor Ian McKeith, Institute for Ageing and Health, Newcastle University*

Professor McKeith is clinical co-director of Newcastle NIHR Biomedical Research Centre on Ageing. The Biomedical Research Centre is addressing involvement through a 'Patient and Public Advisory Group' (PPAG) recruited and supported through the North East Regional Forum on Ageing – 'Years Ahead' (<http://www.yearsahead.org.uk/index.html>) and other local organisations such as Age Concern Newcastle, Disability North, Newcastle Elders Council and similar bodies. 'Years Ahead' was established in January 2005 to bring together organisations operating at regional level with interests in ageing, demographic change, and the health and well being of older people. It consists of an open network of organisations managed through a Partnership Board made up of older people's groups providing geographic coverage across the North East, together with representatives from regional organisations which include Age Concern, Alzheimer's Society, Arts Council NE, Association of NE Councils, Department of Works and Pensions, Equality and Diversity Forum, Government Office North.

#### **9.6 Drug Safety and Alcohol Misuse**

*Professor Munir Pirmohamed, Dept of Pharmacology and Therapeutics, University of Liverpool*

Professor Pirmohamed and colleagues are interested in the epidemiology of alcohol related admissions in the NHS, and improving clinical services to this patient group. This has led to the development of a nurse led service that improves inpatient detoxification and outpatient support, which has in turn led to reduced length of stays and decreased rates of re-admissions (unpublished

data). In order to further develop this, the research team has recruited patients with a history of alcohol misuse to act as advisers for a randomised controlled trial of brief interventions in patients with alcohol dependency. This has been funded by the NIHR Research for Patient Benefit Programme. The user group will be expected to provide active input into the running and interpretation of this trial.

### **9.7 Schizophrenia and Mental Health**

*Professor Nicholas Tarrrier, Division of Clinical Psychology, School of Psychological Sciences, University of Manchester*

Professor Tarrrier and colleagues have created a large data base of service users and lay members who are willing to comment or collaborate on areas of their own interest, including research into psychosis and mental health. The Psychological Treatments Network, which Professor Tarrrier chairs, held a seminar/workshop (Oct 2007) on service user participation in research. The aim of the seminar was to examine practice and guidelines for good practice, and establish a network of service users, individuals and organisations, to collaborate with the research network. The NIHR funded RECOVERY programme has a service user reference group.

### **9.8 Communicable Diseases and Genito-Urinary Medicine (GUM)**

*Professor Jonathan Weber, Faculty of Medicine, Imperial College*

Since 2004, the Jefferiss Wing at St Mary's Hospital (the HIV/AIDS GUM outpatient and day care facility) has had an active patients' forum, where clinical research plans and trials are discussed as a regular agenda item, allowing patients to be involved in the selection of trials, and to offer suggestions for research topics. The forum is currently meeting quarterly, is widely advertised, and includes patients who have participated in clinical trials.

### **9.9 Stroke Patients and Carers**

*Professor Charles Wolfe, Public Health Sciences, School of Medicine, Kings College London and Guy's St Thomas' NHS Foundation Trust*

As part of a £5m Stroke Modernisation Programme locally, Professor Wolfe identified a group of stroke patients and carers from the stroke register who edit and produce, with the assistance of the research team, a Newsletter outlining current research of the group and proposals for the future. The group has developed and executed a pilot project on the family costs of stroke and plan to develop this further. Patients have reviewed the consent forms for the programme's studies and listened to and made suggestions on proposals from the research team. The Local and National Stroke Research Networks and the Comprehensive Biomedical Research Centre are adopting learning from this group.

**For other examples of service user reference groups, and user networks, see also sections, 5.5, 6.2, 7.1.**

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## C. Concluding comments

This paper contributes to the development of the evidence base on public involvement in health and social care research. The examples drawn from 31 Senior Investigators cover a wide range of ways that people have been involved in a diversity of research areas. It illustrates how public involvement in research is making a difference to recruitment to clinical trials, to improved research design and outcome measures. Crucially, this paper highlights recognition of the value of public involvement by some of the nation's foremost researchers in people based research. This paper should enable others to draw on their leadership in promoting public involvement.

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