

# 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



## **Making the Difference**

### **Involving patients, carers and the public in the NIHR Clinical Research Network**

This is the first formal gathering of a few stories, examples and evidence that are specific to the NIHR Clinical Research Network (NIHR CRN). It clearly shows that the involvement of patients, carers and the public is making the difference in research.

As part of The Way Forward review we have been keen to illustrate the breadth and strength of activity that is taking place and this document forms part of that process.

It also offers the opportunity as a discussion document initially amongst Network colleagues and other stakeholders as to how we might continue to collect and share such examples.

It is very evident from this collection that all of this work is enhanced and supported by a number of dedicated individuals who lead on behalf of Patient, Carer and Public Involvement (PPI) with additional advice from the Associate Directors with that responsibility. Thank you for all your work.

The sections in this document are based on the Topic Networks (Diabetes, Mental Health, Cancer, Dementias, Stroke and Medicines for Children). These will be added to in time with further information from the Comprehensive and Primary Care Networks.

Each example listed here uses the same format:

- Factfile – some basic facts and information
- Case Study Number and Impact – as a basic reference
- Keywords – identifying certain phrases
- Summary – single sentence describing the activity
- Description of the activity – maximum of 500 words
- Web link if available

The index at the back of this booklet is a first attempt to cross-reference the different areas of involvement and only refers to those that are illustrated in this document.

Thank you

Derek C Stewart, OBE

## Diabetes

### Making the Difference with the Diabetes Research Network (DRN)

#### **Diabetes Factfile** (Source DRN)

**2.8 million** people in the UK with diagnosed diabetes. Someone is diagnosed with diabetes every 3 minutes in the UK.

Estimates suggest **0.5 million** people have Type 2 diabetes without knowing it (and therefore may unknowingly be developing associated complications (which can affect the heart, kidneys, circulatory system, eyes, feet, mental health, sexual health, nervous system, and increase the risk of stroke or heart attack)).

**1 in 10** has **Type 1 diabetes** – onset usually in the younger population (often in adolescence) and requiring daily insulin infusions for life. This often has a huge impact on young people, and their parents who are often driven to seek the best for their children.

#### **Case Study 1: IMPROVING RECRUITMENT**

Keywords: recruitment, advocacy, service delivery, charities

**By using their patients network to assess attitudes to new treatment delivery recruitment rose significantly.**

The NIHR Diabetes Research Network used its network of patients to help recruitment to a study capturing attitudes to new insulin delivery methods, seeking to avoid multiple daily injections, especially concerning for parents of young children with Type 1 diabetes. The study had struggled over its first 6 months, but DRN patient advocates and their contacts helped to more than double recruitment into the survey arm of the study in less than 4 weeks, with more than new 500 people participating. This has helped to inform and shape the early-stage development of a new type of “artificial pancreas” that has just hit the headlines at Diabetes UK: [http://www.diabetes.org.uk/About\\_us/News\\_Landing\\_Page/New-approach-to-the-artificial-pancreas-announced/](http://www.diabetes.org.uk/About_us/News_Landing_Page/New-approach-to-the-artificial-pancreas-announced/)

#### **Diabetes Factfile** (Source DRN)

**9 out of 10** people with diabetes have **Type 2 diabetes** – traditionally striking the over 40s, with slow onset. Estimates suggest **0.5 million** people have Type 2 diabetes without knowing it (and therefore may unknowingly be developing associated complications which can affect the heart, kidneys, circulatory system, eyes, feet, mental health, sexual health, nervous system, and increase the risk of stroke or heart attack)).

**South Asian** and **African Caribbean** communities are between **2-6 times** more likely to develop Type 2 diabetes than white European populations – yet some of these communities rarely participate in clinical research.

### **Case Study 2: GATHERING CULTURALLY APPROPRIATE EVIDENCE**

Keywords: Questionnaires, raising awareness, Black and Minority Ethnic (BME) communities.

#### **Information was gathered and health checks were provided by knowing where to reach particular groups within their communities**

The NIHR Diabetes Research Network attended the Baishakhi Mela (celebrating the Bangladeshi New Year) in May 2010 in the Brick Lane area of East London. 110,000 people attended from across London and the South East – DRN staff offered blood glucose checks. They ran a questionnaire about people's awareness of diabetes and their attitudes to clinical research along with any cultural or religious barriers that might prevent communities taking part. More than 500 responses received on the day – and the questionnaire is being taken to events for other Black and Minority Ethnic communities, helping us shape ways of engaging in future. More on the Mela visit in our recent newsletter:

<http://www.ukdrn.org/documents/UKDRN-Update-4.pdf>

### **Case Study 3: DEVELOPING THE PATIENT/CARER VOICE**

Keywords: lay panels, getting involved, study design

#### **Inviting people to get involved and register their interest provides a resource for future activity.**

As researchers are told they need to include PPI in their studies, the DRN is forming lay panels to assist access to patient and carer perspectives, from the **1,900** people who have said they are willing to get more involved in DRN research. These national and regional lay panels are engaging with researchers to help study design and materials, and to guide researchers about recruitment methods that target populations may find more acceptable.

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## **Mental Health**

### **Making the Difference with the Mental Health Research Network (MHRN)**

In many disease areas the interests of patients and their relatives are the same. In the field of mental health, there may be strong disagreement between people who use mental health services and their carers – the relatives and friends who support them. This is the context for public involvement in mental health research; we have outlined some examples below.

#### **Mental Health Factfile**

1 in 6 people in the UK currently have a problem with their mental health  
GPs spend a third of their time with patients who have mental health issues  
Around 5000 people kill themselves in England every year  
Annually A&E departments in England deal with around 140,000 attempted suicides  
In 2007 the estimated amount of earnings lost because of the thousands of people unable to work because of mental health problems was £26.1 billion

MHRN publication October 2009 (*leaflet: Mental health problems affect all of us*).

#### **Carers**

Around a quarter of all caring in the UK relates to a mental health or learning disability: 62% of carers look after someone with a physical disability, 6% care for someone with a mental disability and 18% for someone with both a physical and a mental disability

(Carers UK, 2009, Facts about carers. Policy Briefing).

A study by the Office of National Statistics (Singleton et al., 2002) found that carers were twice as likely to have mental health problems if they were the spouse or partner or child, if they were providing over 20 hours of care, if they were providing personal or physical care (compared to practical help), if they were living in the same household as the person they supported, or if they were the sole or main carer.

*Singleton N et al (2002), Mental health of carers. Office of National Statistics*

## **Case Study 4: CARERS IMPROVING RECRUITMENT**

Keywords: Disability, carers, barriers to recruitment, Black and Minority Ethnic (BME) communities

### **Carers help researchers in a particular study (IMPACT) to break down barriers to recruitment**

A UK Disability Rights Commission investigation found people with mental health problems were more likely to experience major illness, and develop serious health conditions earlier than others, yet they are less likely to receive some important health checks.

Previous research has shown those from black and ethnic minority communities face even more inequalities concerning both their physical and mental health, and have not only higher rates of psychosis, but also higher rates of diabetes. About one in 10 patients with established psychotic illness already has diabetes; this is about twice as many as in the general population. Regular cannabis use increases the risk of schizophrenia up to six-fold, but there are, as yet, no established practical treatment programmes to reduce substance use in people with severe mental illness.

The IMPACT study led by Professor Robin Murray aims to address this problem by developing evidence-based, culturally appropriate and innovative health promotion programmes to help people with severe mental illness make healthier lifestyle choices to reduce the risk of major physical health problems including diabetes, and to decrease illicit drug use. The research will also establish a better understanding of the role of cannabis in the onset and relapse of psychosis; the prevalence of the metabolic syndrome (cardiovascular risk factors including obesity, high blood pressure and high blood sugar) in people with severe mental illness, and the role played by antipsychotic medication in precipitating it.

The IMPACT team wanted to hear from people who had first hand knowledge and experience. They asked FACTOR, the carer involvement project run by the Mental Health Research Network, to involve carers in the research.

The researchers asked for input from carers about a trial testing a Health Promotion Intervention to help people with psychosis take better care of their physical health and cut down on cannabis and alcohol. A group of family carers has been meeting regularly to discuss practical aspects of the research, focusing particularly on motivation.

Participants in the study will need to complete an initial assessment consisting of number of physical measurements and questionnaires; these will be repeated at 3 months, and 12 months during their participation in the Health Promotion Intervention which addresses substance use, exercise, and diabetes control.

Care coordinators will use motivational interviewing to encourage their clients to take part. This randomised controlled study will be demanding for service users, not only because of the time and effort of participating in physical and mental assessments, but also because many people with schizophrenia lack motivation.

As a result of discussing this issue at length with the carer group, IMPaCT researchers decided to set up small groups of family carers to give them a better understanding of the study. If carers know more about the research, they can encourage the relative or friend they are supporting to take part in the research and to change to healthier lifestyles.

### **Case Study 5: IMPROVING STUDY DESIGN**

Keywords: Study design, patients carrying out research, recruitment

**By involving people throughout the planning and delivery can have wider impact on individuals.**

The WISE Study (led by Professor Sonia Johnson)\*

\*University College London

Employment rates of people with severe mental health problems are very low and have fallen over the past few decades. Individual Placement and Support (IPS) helps people find and keep jobs. Studies have shown that IPS is successful in increasing employment, but UK studies suggest possible difficulties in finding people willing to make use of the scheme.

The aim of WISE study is to find out how much difference IPS makes when it is introduced to a mental health catchment area and how to maximise its uptake and success. It includes interviewing 80 service users, 15 employers, 4 IPS workers and 18 community mental health team workers. An accompanying service evaluation based on 1400 service users will provide information to compare employment experiences of those in the London borough of Camden's Community Mental Health Teams (CMHTs), which offer the employment and support services, and those that do not. The London borough of Camden has one of the highest rates of mental illness in the country. The study had heavy patient involvement from the outset. Patients were heavily involved in the design of study through a local group called the Service User Research Forum and one was a co-applicant when funding was applied for from NIHR. Patients were also involved in the design of study documentation. The MHRN supported a consultation event for the study.

Importantly the study has patients carrying out parts of the research. People with mental health problems were recruited and trained to become study interviewers. This potentially benefits everyone. People with mental health problems are far more likely to talk and trust someone with a shared experience facilitating recruitment to the study.

The study has recruited well with the support of MHRN staff. Baseline quantitative data have been collected for a complete cohort of CMHT service users. A large team of user-researchers has been recruited and trained: their work on the study has recently begun with 12 out of 80 patient interviews complete. By these, interviewers have already benefited. They have gained: new skills; genuine work experience; income, and increased self esteem. One patient interviewer said "I feel better about myself".

## **Case Study 6: IMPROVING OUTCOMES**

Keywords: Outcome measures, questionnaires, expert panels

### **Involving service users seen as essential in deciding what is a good outcome**

Researchers routinely use a variety of standard questionnaires to assess people's mental health, their symptoms, side effects of medication and quality of life. Questionnaires are used in studies to gauge the success of new treatments and packages of care, and also in evaluations that may determine future funding of NHS services. The Mental Health Research Network tasked a team led by Dr Mike Crawford at Imperial College London to find out what people who use services for mood disorders and psychosis think of questionnaires designed to assess their state-of-being, and whether, in their opinion, they do the job they are supposed to do accurately.

As with all aspects of MHRN work this project had a high level of patient involvement throughout; Dr. Diana Rose, a senior lecturer in user-led research worked closely with Dr Mike Crawford. Several organisations including the MHRN, MIND, and Rethink collaborated and recruited patients for the expert panels. Two expert panels, people with experience of mental health problems, discussed and analysed a sample of two-dozen questionnaires commonly used in research studies, and increasingly by mental health professionals working with people with psychosis and people with mood disorders.

*“There is widespread agreement that the development of effective treatments for health-related problems requires active input from people who use services”, said Mike Crawford. “One of the areas where active service user involvement is essential is in deciding which measures should be used to examine the effectiveness of new treatments. ‘Funding of health services is often linked to ‘outcomes’ – so the choice of what constitutes a good outcome and way of measuring it is important for health services as well as trials and studies. We believe it is essential that service user views are taken into account when outcome measures are selected”, he said. The results of this work showed some of the most widely used outcome measures are those least valued from a patient point of view. The Health of the Nation Outcome Scale is an example of such a measure.*

The results of this project are of potentially huge significance to the NHS and patients. Without user involvement this work could never have taken place.

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## Cancer

### Making the Difference with the National Cancer Research Network (NCRN)

#### Background

Whole system working is a key part of the way that NCRN operates and patient and public involvement (PPI) is a central theme to this approach. Partnerships, to improve the quality and relevance of research for patient benefit, have been developed with key stakeholders, including clinical trials units (CTUs), local research and service networks, consumer research panels (CRPs), experimental cancer medicine centres (ECMCs), universities, funders, research design services (RDS) and patient/user groups.

#### **Cancer Factfile** (Source: Cancer Research UK)

There are more than 200 types of cancer, each with different causes, symptoms and treatments.

There were around 297,990 new cases of cancer diagnosed in 2007 in the UK. Every two minutes someone is diagnosed with cancer in the UK. More than 1 in 3 people will develop some form of cancer during their lifetime. Breast, lung, bowel and prostate cancers together account for over half of all new cancers each year.

Cancer can develop at any age, but is most common in older people. Around three-quarters of cases occur in people aged 60 and over. Around one per cent of cancers occur in children, teenagers and young adults (up to age 24). Overall cancer incidence rates have increased by more than a quarter since 1975 but have remained fairly stable over the past decade.

<http://info.cancerresearchuk.org/cancerstats/keyfacts/Allcancerscombined/>

#### **Case Study 7: INFLUENCING STRATEGY**

Keywords: Funders, charities, partnerships, RCTs, supporting strategic involvement

#### **NCRI and NCRN work in partnership to support involvement in their strategic groups and projects**

The NCRN works in partnership with the National Cancer Research Institute (NCRI) to support a programme of patient and public involvement in cancer research, not only as research participants but also as partners working closely with research teams to help shape the design and delivery of trials that are more likely to recruit and retain participants and be of future patient benefit.

The NCRI is a UK-wide partnership between the government, charity and industry which promotes co-operation in cancer research among its 21 member organisations for the benefit of patients, the public and the scientific community.

PPI is of key importance to both organisations based on the premise that the value and quality of cancer research can be improved through meaningful PPI.

PPI in NCRI and NCRN has been driven by the NCRI Consumer Liaison Group (CLG) with over 60 patient and carer members across the UK. As well as contributing to the work of the NCRI Clinical Studies Groups (CSGs) consumers (patients and carers) are also encouraged to take part in many of the NCRI and NCRN's strategic planning groups and projects. The CSGs are a central component of the framework for cancer research in the UK, providing the primary route through which new ideas for clinical trials are developed.

Patients getting involved in research with NCRN and NCRI are supported through training and mentorship programmes to assist them in carrying out their roles as research partners. Many also act as champions to raise awareness about cancer research and the importance of Randomised Controlled Trials (RCTs). RCTs are the gold standard in research providing vital evidence about treatments and therapies. By taking part in research patients are helping researchers to improve NHS cancer treatment for all.

### **Case Study 8: MAPPING INVOLVEMENT**

Keywords: Involvement activity, mapping, skills and expertise

#### **Survey shows evidence of patient and public involvement across the research cycle in NCRN.**

In a recent national survey undertaken by NCRN of patient and public involvement (consumer) activity in cancer research nearly 34% said they were involved in helping to prioritise research topics, over 17% were directly involved in commenting on the design of clinical trials, whilst just under 44% said they were involved in the management and delivery of trials through their involvement with trial steering groups. Key findings from the survey were:

- Consumers bring a wide range of skills and expertise to their roles in addition to their experiences as cancer patients and carers
- In addition to providing a patient perspective, many are also involved in collaborating to develop research, some are involved in leading research
- Consumers are actively involved across a broad range of research organisations and groups
- Consumers are actively involved across all areas of the research cycle

The NCRI and NCRN continue to support PPI in all of its strategic research groups. This includes the **NCRI Clinical Studies Groups** which are a central component of the cancer research framework in the UK, providing the primary route through which new ideas for clinical trials are developed.

### **Case Study 9: IMPROVING RECRUITMENT**

Keywords: Recruitment, terminology, qualitative research

#### **Listening to patients' views improved recruitment to a prostate cancer clinical trial and recruitment rates increased from 40% to 70%.**

This project involved carrying out qualitative research in parallel with the recruitment to a clinical trial for prostate cancer. The researchers carried interviews with potential participants and listened to tape recordings of the recruitment appointments in order to evaluate the recruitment process. The initial findings showed that recruiters found it difficult to explain the uncertainty about treatment and did not present the different options equally. They also unknowingly used terms that were misunderstood. For example the term 'watchful waiting' was used to describe the non-treatment arm of the trial.

The researchers listened to patients' views about terms used as part of the recruitment process and as a result of making a number of simple changes to the terms used and the order in which the different treatments were presented; recruitment rates for the trial were increased from 40% to 70%.

### **Case Study 10: INFLUENCING WHAT RESEARCH IS UNDERTAKEN**

Keywords: Research portfolio, breast cancer, influencing

#### **Patient advice results in local research network including a trial on their portfolio**

*"The consumer (patient)... members who sit on the (network's)... Clinical Trials Executive have influenced decisions relating to the addition of new trials to our portfolio. One (breast cancer) trial being discussed... was thought by clinical staff to be unattractive to patients and would be hard to recruit to. However... consumer members stated the converse, and in their opinion patients would want to participate. It was on this advice that the meeting agreed to approve the trial. The trial has since opened and recruited well."*

A Cancer Research Network Manager

### **Case Study 11: IMPROVING TRIAL MANAGEMENT & DESIGN**

Key words: Diagnosis, trial management, trial design

#### **Patients work with research team to enhance trial management and design**

The POETIC trial has since gained an established place in the NCRI/NCRN Breast cancer trial portfolio and is open in over 80 UK centres, recruiting 100 new patients per month.

This trial required researchers, clinicians, cancer networks and patients to work closely together to overcome the challenge of ensuring informed patient consent to take part in the trial at the same time as breaking bad news about a cancer diagnosis.

The patient members of the **NCRI Breast Clinical Studies Group** and **Surrey, West Sussex and Hampshire Consumer Research Partnership Group (CRPG)** worked closely with the research team throughout the development of the study to ensure its design and management was patient friendly. They did this by contributing as members of the trial management group by:

- Ensuring the initial approach to patients used by research staff was well-designed from a patients' perspective
- Contributing to the content and language used in the study information sheets and consent form
- Providing evidence to the National Research Ethics Committee that patients were likely to accept an approach from research staff about the study at the time of diagnosis and would feel able to take a decision, providing they had flexibility about the time they needed to reach a decision about trial participation
- Producing a patient pathway flow chart which helped research staff in the set up of the trial
- Providing reassurance to research staff that patients were comfortable with the introduction of a research study at a sensitive stage in their cancer journey and that it was essential that competent adult patients were offered the chance to participate in clinical research

### **Case Study 12: RESEARCH INFORMING SERVICE DELIVERY**

Key words: Quality measures, informing services, commissioning, patient care, patient experience

#### **Patient and carer representatives contribute to review of cancer research and service networks**

PPI representatives have contributed to each of the local research network (LRN) reviews conducted over the last 3 months as part of the combined NCRN annual reporting and National Cancer Peer Review (NCPRI) process. The NCPRI programme, managed by the National Cancer Action Team, involves self-assessments by cancer service teams and external reviews of teams conducted by professional peers, against nationally agreed quality measures. In undertaking these independent reviews of services; the Programme aims to improve care for people with cancer and their families by:

- ensuring services are as safe as possible
- improving the quality and effectiveness of care
- improving the patient and carer experience

The resulting quality indicator scores generated for Cancer Research Networks will inform the Cancer Commissioning Toolkit developed to assist commissioning of quality cancer services in the NHS, as well as contributing to the review process of the LRNs.

The NCRN is unique in having this external NHS service review process with which to partner for its review of LRNs, and is determined to use this to provide broader performance review of its 32 networks.

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## **Children - Patients & Families**

### **Making the Difference with the Medicines for Children Research Network (MCRN)**

For several years the Medicines for Children Research Network (MCRN) have established both National and regional panels that involve parents/carers and more importantly children and young people in research activities. We work alongside researchers to assist with the development of research from the initial idea, prioritising research, and designing and managing research in order for the research to meet the needs of children and families involved.

**Factfile:** There are over 6 million children in England.

MCRN is there to facilitate the conduct of randomised prospective trials and other well-designed studies of medicines for children, including those for prevention, diagnosis and treatment.

And by this, it is the intention to:

- Improve the care of children and their families
- Improve the coordination of research
- Improve the speed of research
- Maintain and enhance the quality of research
- Improve the integration of research
- Widen participation in research

### **Case Study 13: INVOLVEMENT THROUGHOUT PROCESS**

Keywords: Research process, information, recruitment, feedback

#### **Parents helping to optimise chances of success of a priority Department of Health pandemic influenza vaccine trial.**

The Medicines for Children Research Network (MCRN) South West Local Research Network established a families network comprised of 35 parents and young people to assist with the development of research studies, working alongside researchers.

One key achievement has been the success of involving these parents and young people from start to finish in the DH Priority swine flu vaccine study, advising on logistics, information provision, recruitment, and obtaining feedback about participation.

Even when working to a tight timescale, simple steps made a big difference. During the trial work up, families were phoned and detailed feedback was captured to influence how and when the study was run. This was then back to the investigators. Within 1 month the trial had recruited over 255 children.

### **Case Study 14: INFORMATION FIT FOR PURPOSE**

Keywords: Ethics, Patient Information leaflets (PIL), workshop

#### **Working with the National Research Ethic Service (NRES) to inform and improve patient information leaflets.**

Young people from the MCRN young persons' advisory group had the opportunity to run a workshop as part of a Children's Research Ethics training event on how to provide information for children and young people to encourage participation in research. The main aim of the workshop was to:

- Influence NRES Guidance for researchers and for ethics committee members on developing Patient Information Leaflets for children and young people
- Facilitate delegates to develop and advocate best practice for developing child friendly information

The young person's guidance document has now been revised to incorporate views from the day and is now accessible via the MCRN website:

<http://ctuprod.liv.ac.uk/mcrnweb/images/stories/consumer/revised%20guidance%20documents%20for%20patient%20information%20leaflets.pdf>

Note: We are exploring ways to get the guidance document linked to the NRES site.

### **Case Study 15: INFORMING THE RESEARCH AGENDA**

Keywords: Dermatology, Young Persons Advisory Group, research ideas,

#### **Making research that is important to young people actually happen**

Earlier this year the Young Persons Advisory Group was contacted by the UK Dermatology Clinical Trials Network (UK DCTN) for advice on whether or not young people would be prepared to take part in an acne prevention study.

Dermatology is the branch of medicine dealing with the skin and its diseases. The purpose of the UK DCTN is to develop ideas for independent dermatological clinical trials that will benefit patients and qualify for NIHR CRN support.

Network members propose research ideas which are reviewed against set criteria. If an idea is successful a study team will be put together to take the research idea forward.

Carron Layfield is the UK DCTN Network Manager and is responsible for coordinating the involvement of patients and the public in the research process.

When a study looking at acne prevention was put forward to the UK DCTN Carron knew that they would need to find out if young people would be prepared to take part in such a study.

Carron contacted MCRN for advice on the best way to go about gathering young people's views and after learning about the YPAG designed a survey about the study to see if young people would be prepared to take part?

*“The answer was a resounding ‘yes’. Forty young people completed the survey and 70% said they would be happy to participate in this acne prevention study. If the response had been ‘no’, we wouldn’t have taken the idea any further so it was absolutely essential that we had input from young people at such an early stage of the project. Not only were they helpful but the turnaround was quick too. We’re still at the development stage of the project but we’re looking forward to working with the young peoples group again as we develop this research idea further”, says Carron Layfield.*

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## **Dementias and Neurodegenerative Diseases**

### **Making the Difference with the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN)**

Patient and public involvement is a central element of DeNDRoN's collaborative approach, with patients and carers working alongside researchers in the development and delivery of clinical research in the NHS. The aim of involving patients and carers is to ensure that research undertaken is relevant to people living with dementias, Parkinson's disease, motor neurone disease, Huntington's disease and other neurodegenerative diseases.

Lay people are actively involved across DeNDRoN's Local Research Networks and in the collaborative development of new research grant applications through Clinical Studies Groups and Writing Groups.

#### **Factfile:** Dementias and neurodegenerative diseases

Neurodegenerative diseases are characterised by degeneration of neurons in the nervous system and are a major cause of morbidity and mortality. The pattern of loss of cells characterises the different neurodegenerative diseases.

Loss of cells in the cerebral cortex is associated with dementia, ie a loss of cognitive function such as memory, language, planning and thinking. Dementias affect over 700,000 people in the UK, including one in six over the age of 80. Overall a third of people who survive to 65 end their life with a form of dementia. The most common cause of dementia is Alzheimer's disease, affecting 465,000 people in the UK, but there are many other causes such as Lewy body dementia and frontotemporal dementia. In addition to neurodegeneration, vascular and other diseases can cause dementia.

The commonest of the other neurodegenerative diseases is Parkinson's disease, affecting around 120,000 people in the UK. Most people who get Parkinson's disease are aged 50 or over but younger people can also be affected. One in 20 is under the age of 40. The loss of cells is predominantly in the basal ganglia and causes a slowness of movement and tremor. Some patients may develop a dementia late in the disease.

Huntington's disease also affects the basal ganglia to cause abnormal movement and the cerebral cortex to cause dementia. It is a dominantly inherited disorder affecting about 7,000 people in the UK.

Motor neurone disease (MND) affects the nerves controlling muscles and leads to limb weakness and difficulties with speech, swallowing and breathing. Most forms of the disease are rapidly progressive. About 5,000 people have MND in the UK. In addition there are many other neurodegenerative diseases such as progressive supranuclear palsy, multisystem atrophy and spinocerebellar degeneration. These share many of the clinical features described above and although less common comprise a significant number of patients.

## **Case Study 16: CARERS PROVIDING TRAINING**

Keywords: Dementia, carers, training, interviews

### **Carers are training and mentoring researchers in skills around informed consent for dementia research**

In Thames Valley DeNDRoN, carers of patients with dementia have been leading in study-based scenarios with research colleagues in a series of innovative training sessions around the critical issues of informed consent and mental capacity.

These workshops in Oxford involve carers role-playing as potential study participants. The impact has been to help researchers to assess mental capacity in busy 'real-life' situations, meet the practical challenges that they will face when obtaining consent from potential study participants with conditions such as Alzheimer's disease, and understand what patients and carers experience during research interviews.

This ongoing training model has been very positively evaluated by individual clinicians involved, and carers say they welcome the opportunity to contribute their personal expertise to helping improve researchers' skills.

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## **Case Study 17: IMPROVING STUDY RECRUITMENT**

Keywords: Recruitment, focus groups, primary care,

### **Regional patient and carer focus groups have identified solutions for a major study (DOMINO-AD) which was failing to recruit sufficient patients.**

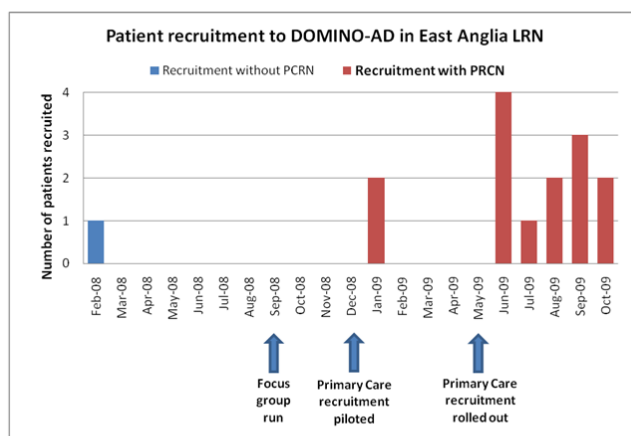
The study, funded by the Medical Research Council (MRC) and the Alzheimer's Society, looks at medication effectiveness in moderate to severe stages of Alzheimer's disease.

Two DeNDRoN local research networks (in South West England & East Anglia) ran patient and carer focus groups which raised ideas for improving recruitment and retention. Both networks showed a consequent marked increase in their recruitment rates, and significantly faster than elsewhere.

The impact of the involvement of people is particularly illustrated in East Anglia, where a major recommendation from their patient and carer focus group was to promote the study more effectively in primary care.

This recommendation made the network confident that embarking on a lengthy process of developing recruitment with the primary care research network would bear fruit. The local network therefore rolled the study out to local general practices, and experienced a sustained increase in recruitment to the study.

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## Case Study 18: FACILITATING RECRUITMENT PROCESSES

Keywords: Recruitment, carers,

### Developing a recruitment and feasibility tool for motor neurone disease clinical researchers

The input of lay people has been pivotal to enhancing the feasibility of conducting clinical research in the UK into this low incidence, high impact disease.

Patient and carer members of the DeNDRoN's Motor Neurone Disease (Clinical Studies Group (CSG) developed a new method for bringing together researchers and potential volunteer participants in MND research. Patients can now volunteer to provide details in the form of a registry which will enable DeNDRoN, in conjunction with the Motor Neurone Disease Association, to identify suitable participants to take part in future research.

One patient on the Clinical Studies Group played a particularly key liaison role with other lay & professional members of the group, and with the Motor Neurone Disease Association.

This strongly collaborative approach secured quick approval for this research tool, and highlights the benefit of identifying and involving appropriate lay people in developing our research infrastructure. Feedback received since, from motor neurone disease clinical researchers, has confirmed the tool's effectiveness in assisting them to recruit to MND studies.

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## **Case Study 19: INFORMING PROTOCOL DEVELOPMENT**

Keywords: Protocol development,

**Patients and carers across England contributed significantly to the protocol for a large UK-based multicentre HTA-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 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/carers 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.

The study team reported that the suggestions were “really helpful, practical and illuminating” and they would “definitely incorporate many suggested changes and amend the documents accordingly”, making the study literature more accessible to the target study population.

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## Stroke

### Making the Difference with the Stroke Research Network (SRN)

The NIHR Stroke Research Network undertakes studies to evaluate acute stroke care, rehabilitation, long term support and secondary prevention. The impact of involving patients and carers at all stages of the research process has meant that research undertaken is relevant and impact can be seen in the development of ideas as well as recruitment targets being met.

The examples reflect on a patient initiated idea for research to influencing research design.

**Stroke Factfile:** Stroke is one of the top three causes of death in England and a leading cause of adult disability. Approximately 110,000 people have a stroke and a further 20,000 have a transient ischaemic attack (TIAs) in England every year.

One third of people who have a stroke die, one third make a full recovery, and one third remain disabled. There are at least 300,000 people in England living with moderate to severe disability as a result of stroke.

Stroke care costs the NHS about 2.8 billion a year in direct care costs and costs the wider economy some 1.8 billion more in lost productivity and disability.

### Case Study 20: IDEAS FOR RESEARCH

Keywords: Sequaelae, research ideas, workshop,

#### Drawing upon patient experiences as a source of ideas for research

Research has shown that patients and carers often feel that stroke care focuses upon the physical consequences of stroke and does not pay sufficient attention to the psychological and emotional reactions (sequaelae).

There is a lack of research into effective interventions to improve psychological care following stroke. Following a meeting of the SRN Rehabilitation Clinical Studies Group and having attended the UK Stroke Forum, one of the lay members of this group wrote a discussion paper for the CSG members to consider, emphasising the need for more research in this area.

This discussion paper resulted in a workshop being held involving researchers and lay members with an active interest in this area. Over 20 people attended. There was consensus that this area lacked a substantial evidence base to inform clinical management of stroke survivors.

The impact of this has been that two protocol applications were submitted to NIHR partner organisations for funding. These applications are currently being considered for funding.

### **Case Study 21: INFLUENCING TRIAL DESIGN**

Keywords: Trial design, care givers, patient information leaflets, recruitment

#### **Using a lay panel helped change trial design and improve the patient information sheets.**

The Training Care Givers after Stroke (TRACS) trial, sought help from the Yorkshire lay panel to refine their trial design and develop their patient information sheets.

The study received funding from the Medical Research Council and is now the world's largest stroke rehabilitation trial having recently recruited to its target of 930 participants.

### **Case Study 22: ADDRESSING ETHICAL ISSUES**

Keywords: Ethics, consultation, trial design, older people

#### **The involvement of consumers enabled researchers to address issues about ethics.**

The International Stroke Trial (IST 3) is one of the studies on the NIHR SRN portfolio and has recruited 884 patients to date (October 2010). This study is evaluating thrombolysis for acute ischaemic stroke and seeks to extend the time window for this treatment and evaluate its use in older people.

Working with consumers enabled the research team to address some of the ethical problems associated with research into this treatment. Following three consultation meetings the study was refined and consumers supported a research question and the trial design. Consumer involvement helped to refine trial consent procedures.

Significant changes were made to information leaflets and these were approved by a national multicentre research ethics committee.

Koops,L and Lindley,R. (2002): thrombolysis for acute ischaemic stroke: consumer involvement in design of new randomised controlled trial. *BMJ*; 325:415-423.

### **Case Study 23: IMPROVING TRIAL DESIGN**

Keywords: Focus groups, consent, outcome measure,

#### **Holding focus groups made extensive difference to trial design.**

The Stroke Oxygen Study (SOS) is one of the studies on the NIHR SRN portfolio and has recruited 2,083 patients to date (October 2010). When designing the study the research team worked with patients and carers to obtain their views on the importance of the study, consent issues, relevance and acceptability of the outcome measures and the preferred method of follow-up.

Three focus group meetings were held and the decision taken that either assent from a family member on behalf of the stroke patient or a doctor was acceptable. The

majority of respondents preferred personal contact with the researcher or a representative to a questionnaire for follow-up.

Ali, K. Roffe, C. Crome, P. (2006); What patients want; Consumer involvement in the design of a randomized controlled trial of routine oxygen supplementation after acute stroke. *Stroke*; 37:865-871.

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## Index and Cross Reference of examples in this collection

The following is a first draft attempt to find a way of cross-referencing the stories, examples and evidence is a way that makes them easy to access and simple to gather.

All the Topic Networks have a broad range of patient and public involvement activity and this ONLY refers to the stories in this collection.

	Diabetes	Mental Health	Cancer	Medicines for Children	Dementias	Stroke	Case Studies
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<b>Influencing Research</b>							
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Trial Design	✓	✓	✓	✓	✓	✓	3, 5, 9, 13, 14, 19, 21, 22, 23
<b>Informing Research Support</b>							
Research Delivery	✓			✓			1, 12
Informed Consent					✓		15
Trial Recruitment	✓	✓	✓	✓	✓		1, 4, 9, 10, 13, 16, 17, 18
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<b>Addressing other issues</b>							
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Partnership working	✓			✓	✓		1, 7, 13, 14, 18
Raising Awareness	✓	✓					2, 5
Lay Panels	✓	✓		✓			3, 6, 15
Service delivery			✓				12

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