INVOLVE

NHS
National Institute for Health Research

newsletter

Spring 2016

Welcome to the Spring 2016 edition of the INVOLVE newsletter, which opens with an introduction from our new director.

Introduction from Zoë Gray, Director

My first two months as the new INVOLVE Director have flown by. I am pleased to have this opportunity to introduce myself to those of you that I have not yet been able to meet, to share some initial observations and information about what we're up to at the Coordinating Centre.

My experience of patient and public involvement (PPI), prior to joining INVOLVE, was through my role as Chief Executive Officer of a regional charity empowering individuals to improve skills, work opportunities and health and wellbeing.

In that role, in partnership, I led the establishment of a local Healthwatch organisation and established a strategic partnership with a £1m investment to co-produce services. As a result families were able to address their own health, employment & relationship issues, which prevented children from going into care.

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Also in this issue:

These experiences, amongst others, have provided the evidence to reinforce my core beliefs about the transformative power of meaningful involvement; for people, for services and for systems.

So, for me, it is a privilege to have joined INVOLVE and the NIHR at this point in the journey. Strong PPI foundations are in place and today we have a significant - albeit distributed - PPI community across NIHR (in no small part thanks to the influence of INVOLVE's members and employees over the last 20 years). A community which – from my discussions so far - is clearly united by a huge amount of passion and a sense of shared responsibility for continuing to learn, improve and innovate.

To realise the vision of Going the Extra Mile recommendations, it is clear that we will need to harness that passion and shared responsibility within and beyond NIHR; connecting our distributed efforts and resources and collaborating to leverage the step-change that we want to create.

Connectivity and collaboration are key features of INVOLVEs new national to local way of working, underpinned by our established values. Through our partnerships with Research Design Service (RDS), INVOLVE is now working collaboratively to support the development and co-ordination of effective regional PPI networks which make best use of effort and resources increasing regional to local connectivity to extend and deepen PPI.

At a national level, INVOLVE is focusing attention on "Community Priority Areas" (Learning and Development, Equality and Diversity, Community & Partnerships), where INVOLVE will provide co-ordination and leadership and work with stakeholders to identify and prioritise key objectives for the next three years. The partnership working will continue to ensure we deliver substantive progress against these objectives.

Our Advisory Group will soon be in the position to recruit additional public members to guide our work, so if this might be something you would be interested in, let us know and we will keep you informed.

You can find out more about our current work and our new team members on our website: www.involve.nihr.ac.uk.

Finally, I am keen to continue learning from you; whether it's about your experiences of PPI or INVOLVE, what you're working on, how you can get involved or whacky ideas for progressing PPI! Please feel free to contact my colleagues and I at **involve@nihr.ac.uk.**

INVOLVE Coordinating Centre News

Welcome
We are delighted to welcome our two new Senior Public Involvement Managers

Gary Hickey
Gary has joined us from Kingston University where he was Patient and Public Involvement Lead, and established the Centre for Public Engagement. He will be leading on Community, Partnership & Networks

Paula Wray
Paula has joined us from the East Midlands NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC), where she was the Public involvement Programme Lead. Paula will be leading on Equality & Diversity

Gary and Paula will be working alongside Martin Lodemore, who will be leading on Learning, Development & Support. You can find out more about all of our staff on the **INVOLVE website.**

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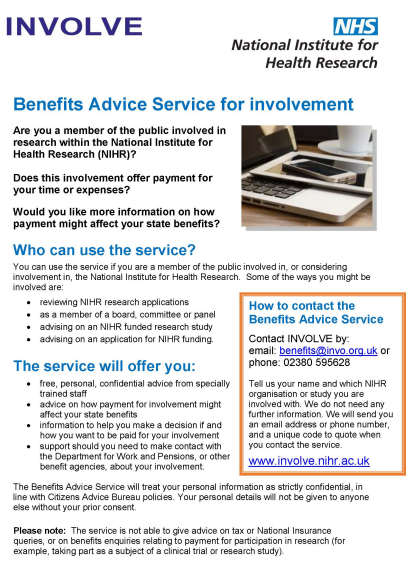
The Benefits Advice Service for involvement continues



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Benefits Advice Service for involvement

Are you a member of the public involved in research within the National Institute for Health Research (NIHR)?

Does this involvement offer payment for your time or expenses?

Would you like more information on how payment might affect your state benefits?

Who can use the service?

You can use the service if you are a member of the public involved in, or considering involvement in, the National Institute for Health Research. Some of the ways you might be involved are:

- reviewing NIHR research applications
- as a member of a board, committee or panel
- advising on an NIHR funded research study
- advising on an application for NIHR funding.

The service will offer you:

- free, personal, confidential advice from specially trained staff
- advice on how payment for involvement might affect your state benefits
- information to help you make a decision if and how you want to be paid for your involvement
- support should you need to make contact with the Department for Work and Pensions, or other benefit agencies, about your involvement.

How to contact the Benefits Advice Service

Contact INVOLVE by:
email: benefits@invo.org.uk or
phone: 02380 595628

Tell us your name and which NIHR organisation or study you are involved with. We do not need any further information. We will send you an email address or phone number, and a unique code to quote when you contact the service.

www.involve.nihr.ac.uk

The Benefits Advice Service will treat your personal information as strictly confidential, in line with Citizens Advice Bureau policies. Your personal details will not be given to anyone else without your prior consent.

Please note: The service is not able to give advice on tax or National Insurance queries, or on benefits enquiries relating to payment for participation in research (for example, taking part as a subject of a clinical trial or research study).

Following an evaluation of the pilot service in 2015, the Benefits Advice Service will continue to be provided by the Bedford Citizens Advice Bureau for the foreseeable future.

The INVOLVE Coordinating Centre continues to fund and provide access to the service on behalf of those involved with the National Institute for Health Research (NIHR), while other health and social care organisations can now fund their own access to the service.

The Benefits Advice Service offers personal advice and support on payment of fees and expenses for public involvement that might affect people in receipt of state benefits. The service covers public involvement activities in health or social care research, service design or service delivery.

Those able to access the service include:

- **members of the public involved with NIHR organisations, NIHR-funded research projects or funding applications to NIHR. Find out how to access the service**
- **staff within NIHR organisations who support members of the public to get involved. Find out how to access the service**

What did the evaluation of the one-year pilot tell us?

A survey of users who contacted the Benefits Advice Service during the first year (pilot) phase suggested that:

- 93.5% were satisfied with the response time
- 100% said the information received in response was very easy or fairly easy to understand
- 94% were very satisfied with the confidentiality of the service
- 100% said it influenced their decision on paid involvement
- 94% rated the service very highly
- 100% would use the service again for independent advice
- 100% would recommend the service to others.

Selected comments from users about the service:

"very good service – helpful and prompt"
"I never felt rushed and was accommodated superbly"
"the adviser was and is incredibly helpful and persistent in trying to get good answers from the DWP"
"I was speaking to a person who was helpful and gave facts!"
"no flaws in the service – five stars".

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Understanding the research patient experience: results of a participant experience 'OK to ask' post card questionnaire undertaken by UK Clinical Research Facilities

Authors: Caroline Saunders (NIHR/Wellcome Trust Clinical Research Facility, Cambridge) and Kate Sonpal (NIHR Clinical Research Facility & Biomedical Research Centre, Southampton) on behalf of the UKCRF Network PPI work stream

Background

This paper reviews the results of two patient experience questionnaires from the perspective of patients, healthy volunteers and/or their carers who have taken part in clinical research within a Clinical Research Facility (CRF). CRF's are purpose built, dedicated units for the conduct of clinical research in patients and healthy volunteers, such as testing out new drug treatments in clinical trials and or exploring disease mechanisms to identify new targets for treatment. There are around 40 units across the UK and Ireland, 19 are funded by the National Institute for Health Research (NIHR) in England. Patients and healthy volunteers participate in clinical research covering a wide variety of clinical diseases and in doing so, are helping to improve the health and wealth of the nation through research. A survey conducted on behalf of the NIHR in 2014 showed that 89% of people would be willing to take part in clinical research if they were diagnosed with a medical condition or disease, 3% said they would not consider it at all and 95% said it was important to them that the NHS carries out clinical research. In 2014 over 600,000 people took part in research which aims to improve diagnosis, treatment and care of patients in the NHS.

National PPI priorities

Involving the public in research is a key strategy for the NIHR. Promoting a 'research active' nation and increasing citizen engagement and participation in health, social care and public health research recognises that a 'good research experience' and 'recommending it to others' is key to increasing patient participation in research. The NIHR Patient and Public Involvement (PPI) strategy 'Going the extra mile' has set an ambitious target of all people using the NHS to be made aware of opportunities to contribute towards research by 2025.

The UK Clinical Research Facility Network (UKCRFN) PPI group is contributing to this agenda by undertaking research participant experience surveys.

The UKCRF Network PPI work stream

The UKCRFN was established in 2008 to share and develop best practice in delivering and supporting experimental medicine undertaken in CRFs across the UK and Ireland via formal work streams. It undertakes a program of work agreed by the Department of Health via the National Office for Clinical Research Infrastructure (NOCRI). A CRF PPI work stream was established in 2014 to undertake collaborative engagement and involvement work. Of particular interest to the CRF community is understanding and articulating the research participant experience.

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CRFs are well placed to capture this. In 2014/15 the 19 NIHR CRFs collectively supported ~ 3000 research studies, ~169000 patient visits and recruited ~52000 patients into clinical trials.

CRF Research Patient Experience survey 2014

The first patient experience survey was undertaken with the intention of sharing research patient experiences at CRF Open Days planned to coincide with International Clinical Trials Days in May 2014. The survey participants ranged from patients, healthy volunteers, parents or guardians of children, friends or carers.

A simple 'OK to ask' post card was designed, asking 3 questions:

1. Would you recommend taking part in research to family and friends?
2. Was everything explained to you on your visit?
3. Why did you take part in research?

This first post card survey received 185 research patient responses from five clinical research facilities.

Results showed:
96% of patients said that everything had been explained to them on their visit
95% would recommend taking part to research
57%* took part for personal benefit
61%* took part to help others
(* respondents selected more than one response)

Response rate and CRF engagement were lower than expected. This was due to the timing of the survey, difficulty finding appropriate PPI personnel within CRFs and other CRF work pressures (e.g. annual report writing). The results of the first survey were shared at the 2014 UKCRF Conference and at the NIHR Celebrating Nurses Day (May 2015). It was decided to repeat the 'OK to ask' patient experience questionnaire in 2015, with reworked questions, a wider time scale for completion and the option for electronic data capture.

CRF Patient Experience 'OK to Ask' Post Card Survey 2015

In 2015 PPI leads from CRFs from across the UK and Ireland were invited to help co-ordinate a second national research patient experience survey. This involved piloting and handing out ~50 'post card' questionnaires to patients and volunteers attending their CRF for research visits during a 2 week period in April 2015. The questions were selected by the UKCRFN workstream, and piloted with patient research panels from 3 CRF's.

Methods

Participants were approached at the end of their research visit to answer a series of questions anonymously using a printed post card or iPad.

The questions asked were:

1. Are you a healthy volunteer, patient, parent/carer or other?
2. Would you recommend taking part in research to your friends and family? If not, why not?
3. Was everything explained thoroughly to you on the day of your visit?
4. Why did you decide to take part in this study?

    For personal benefit
    Because of family illness
    For financial reasons
    To help others
    Other reason

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In total, 15 CRFs from across the UK took part, asking research participants (including patients and healthy volunteers) a series of five questions at the end of their research visit.

Headline results

The survey produced 825 returns: 577 patients; 220 healthy volunteers and 28 parents/carers:

- 97% of respondents said they would recommend taking part in research to others.
- 91% of respondents felt that things were explained clearly to them on the day of their visit.
- People take part in research for personal benefit, but also because they want to help others.
- Over half of healthy volunteers said they took part in research to help others, with just a quarter saying they took part for financial reasons.
- Parents/carers typically take part in research to help others.

Full results can be found on this link: **www.sites.google.com/a/nihr.ac.uk/ok-to-ask-survey**

Conclusions

In conclusion most people who were surveyed said taking part in research was a positive experience and the majority volunteered for personal reasons, whether it being for their own health, financial gain or because of a friend or family member having a particular condition.

People are finding benefits to taking part in research, and groups whether patients, healthy volunteers or carers have had a positive experience. The positive feedback from participants clearly shows CRF's, with their highly experienced staff and bespoke facilities, as providing an excellent environment to take part in research.

CRFs play an important role in contributing to wider understanding of why patients and the public take part in research and what their experience was like. A third survey is planned for 2016 with another question being added related to the CRF environment. In addition, for first time a child specific version will be available which will be reviewed by several children's PPI groups to ensure that it is relevant and useable.

Breaking news – initial results from the 2016 survey:

The results from the 2016 post card survey have been collected and are being analysed. With 19 CRFs participating, there were a total of 1,333 responses, collected from 1,191 adults and 142 children. Of these, 59.6% were patients, 37.9% healthy volunteers and 2.5% parents/guardians.

Initial results from the Adult Survey suggest that:

- 98.2% would recommend taking part in research to family and friends
- 99.7% said everything was explained thoroughly on day of visit
- 45.5% took part for personal benefit, 42.3% of altruistic reasons, 6% because of a family member having an illness, 3.9% for financial gain and 25.7% other
- 36.2% heard about study through a consultant, 13.2% by research nurse, 11.7% by advert, 7.5% GP, 4.9% healthy volunteer database and 19.8% other.

Initial results from the Children's Survey reported that:

- 99% said everything was explained on the day
- 100% said they would tell family and friends that taking part in research was a good thing.

We are always interested to hear about your experiences of active public involvement in research, whether you are a member of the public, a researcher or from a research organisation.

If you would like to contribute an article, news item or event notice please contact Gill Wren.

Tel: **023 8059 5628**
Email: gill.wren@nihr.ac.uk

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Helping researchers to produce better patient information sheets

by Will Cragg, Ben Cromarty, Bec Hanley, Claire Murphy, Richard Stephens – members of the MRC CTU at UCL working group for the PIS.

Before patients can take part in any trial, they need to give informed consent. Researchers or clinicians usually give them patient information sheets (PIS) about the proposed trial, which they are asked to read. Research has demonstrated that the content, format and layout of PIS all have an impact on how well patients receive and retain information about the trial.

The Medical Research Council Clinical Trials Unit at University College London (MRC CTU at UCL) has recently launched a template and guidance notes to help researchers write clear and easy-to-understand PIS for trials or other studies involving adults.

These resources have been developed in partnership by a small team of researchers and patient representatives at the MRC CTU. They are based on the evidence-based research done by Peter Knapp and colleagues.

There are some key features of the new template that are aimed at making the PIS easy to use and understand by patients. There is a clear summary cover page at the front of the PIS, which gives details of the contents of the PIS, and where to go to find that information. The key points about the trial are also summarised on the front cover, so that patients at a glance can get a sense of whether the trial is relevant and suitable for them.

The topics in the PIS flow in a logical fashion, taking the reader step-by-step through what it is they might want to know about the trial. The language used throughout is clear and in plain English. The PIS gives enough information to allow informed consent, without overwhelming the patient with too much detail. The PIS supports signposting for full detail elsewhere.

Knapp's research showed that layout was as important as content. All sections are clearly headed with numbered titles, with clear space and demarcation between sections so that the document is easy to navigate. If possible the PIS should be no longer than 8 sides in total.

The resources consist of:

A **template** (in the form of a Word document), which can be adapted for any adult trial or other type of adult study. It includes a front page with a list of contents, and a summary of why people are being invited to take part and the key things they need to know. This is then followed by these sections:

1 Why are we doing this study?
2 Why am I being asked to take part?
3 What do I need to know about the medicines, procedures or other interventions used in this study?
4 What will I need to do if I take part?
5 What are the possible side effects?
6 What are the possible benefits of taking part?
7 What are the possible disadvantages and risks of taking part?
8 More information about taking part
9 Contacts for further information

Each of these sections contain suggested wording, which can be adapted as appropriate to suit any adult trial or study.

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Accompanying **guidance** includes advice about writing in Plain English, formatting and layout. It also includes example text from two PIS for clinical trials called Add-Aspirin and SHINE. Both these studies have received ethical approval using this format.

All of the researchers at MRC CTU at UCL will use this template and guidance to write PIS from now on. This will mean that the information we produce is as clear and easy-to-understand as possible for potential trial participants, to enable them to consider whether or not they wish to consent to joining a trial.

We look forward to getting feedback from users of this PIS template, so that we can further improve the PIS in the future.

If you would like to receive a copy of the template and guidance please email:
mrcctu.ppi-resources@ucl.ac.uk

noticeboard

This is a regular column which can be used to advertise events, initiatives and publications about public involvement in Research and Development. If you would like to put an article on our noticeboard please contact the Coordinating Centre.

Job opportunity at INVOLVE

We are currently recruiting for an additional Senior Public Involvement Manager to join the coordinating centre team.
If you are experienced in and committed to public involvement, engagement and participation in health and care research and want to help shape the future of public involvement, engagement and participation across the UK and influence thinking across the world then this could be the job for you. **The closing date is 17th July**.
More details are available on our website: www.invo.org.uk/about-involve/involve-jobs/

Public consultation on "EU Guidelines on Summaries of Clinical Trial Results for Laypersons"

The Health Research Authority (HRA) are leading on the establishment of European Union guidelines for the production of lay summaries for clinical trial results. They convened a working group which included representatives from the NIHR and INVOLVE amongst others.

The draft guidelines are now out for consultation by the European Commission – **http://ec.europa.eu/health/human-use/clinical-trials/developments/index_en.htm**

The consultation was launched on 1st June and will run for three months until 31 August 2016 .

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