

NIHR patients and the public

September 2018

Do you want to help decide priorities for health research?

Imperial College London, in partnership with James Lind Alliance, have produced a short survey about ranking priorities or "questions" for research. The aim is to help make care safer for adults with complex health needs and prevent mistakes. People with complex health needs are those who have more than one illness or condition, need care from more than one service, or need care in more than one place.

The survey is available to complete [here](#) until 15th October.

Keeping co-production on the agenda - Dr Gary Hickey (INVOLVE)

Coproduction has a rich history and has been applied and developed in a range of disciplines. The term has been used for several decades and is usually associated with the design and improvement of services. It offers the potential to evolve and improve public involvement in research - a means of further ensuring that the public are active collaborators in research. Much of the drive comes from a perceived opportunity for coproduction to more closely align research and innovation with the values, needs and expectations of society.

Given the various ways in which coproduction has been interpreted and applied, it is hardly surprising that it is a contested concept with much confusion about what it is and how one "does" it. For example, for some coproduction is simply "good" public involvement in research, for some it is a vogue term that has been applied loosely to existing approaches to public involvement in research, and for still others it is a particular methodology. Despite this lack of clarity, research is being coproduced with the public and just as public involvement in research generally is now an international phenomena so is the coproduction of research.

The National Institute for Health Research (funded by the Department of Health and Social Care to improve the health and wealth of the nation through research) has committed to exploring how coproduced research might work in practice in health and social care research in England. To this end, INVOLVE has led on the development of guidance which is intended to provide greater clarity about what it means to coproduce research. There is no one set way of coproducing research. Rather, it is principle - driven and can take a variety of formats including partnerships between academia and organizations representing the public as well as members of the public being employed by organizations which undertake research, for example universities. The key principle involved in coproducing research is the sharing of power in key decisions. No longer do researchers and/or practitioners only own the decisions and the research. Relationships need to be valued and developed and maintained. Efforts need to be made to address power differentials.

"Co - producing a research project is an approach in which researchers, practitioners and the public work together, sharing power and responsibility from the start to the end of the project, including the generation of knowledge."

On the one hand, coproduction can be viewed as another approach to public involvement which sits alongside other approaches such as consultation, collaboration and user - controlled research. In practice of course there are often blurred boundaries between these approaches - and research can be a dance moving back and forth between approaches. For example, consultative approaches can merge into collaboration, and vice versa. Any framework then that seeks to distinguish between approaches is best seen as an analytical tool through which we can view and understand our world. However, coproduction is also an approach to research that goes beyond public involvement - it has principles that apply across the team and underpin the way the research is undertaken.

Guidance on principles and key features are useful in helping us move towards clarity but they do not show us “how” to coproduce or the various challenges that coproducing research presents. How, for example, do we share power when it is often a principal investigator who is accountable for decisions? How do we build the relationships in a research team that ensure that power differentials are addressed? Some suggest that coproduction represents a paradigm shift in research changing how we determine what to research, how it is undertaken, and how knowledge is generated. It challenges power structures and the way in which research is currently funded and governed; power is shared across those involved in the research; and plans are more likely to be emergent. It challenges what we mean by impacts - in coproduced research as much emphasis is placed on impacts that emerge from the process of undertaking the research, for example expanded social networks, as there is on the impacts of the outcomes of the research. It challenges what we mean by knowledge and research - the collection and analysis of empirical data is just one form of the generation of knowledge.

This edition of Health Expectations is timely, providing some examples of patient/consumer involvement and engagement in research.

The Editorial team also wish to solicit papers for a special issue of Health Expectations on Patient and Public Involvement and Engagement (PPIE) in health service provision and research. These paper submissions may include high - quality systematic review and original research papers reporting aspects of PPIE and coproduction with a particular focus on developing and emerging economies. If your research meets the above criteria, please consider submitting your work to Health Expectations. For further information, please see <https://onlinelibrary.wiley.com/doi/full/10.1111/hex.12821>.

Dr. Gary Hickey INVOLVE

The Impact of Integrating and Embedding a Patient and Public Research Advisory Group within a Multicentre NIHR RfPB Awarded Anaesthetic Trial – The TOPIC Study

Catriona Frankling, Fang Gao, Andrew Worrall (PPI) and Teresa Melody

Academic Department of Anaesthesia, Critical Care, Pain and Resuscitation, Heartlands Hospital, University Hospitals Birmingham NHS Foundation Trust, Bordesley Green East, Birmingham, B9 5SS

Abstract

Patient and public involvement (PPI) ensures that clinical research is for the benefit of patients and leads to improvements in healthcare. The TOPIC trial is a randomised controlled trial comparing the effectiveness of thoracic epidural blockade and paravertebral blockade in reducing chronic post-thoracotomy pain. The uncertainty in the original trial design promoted the implementation of a local PPI organisation, the Clinical Research Ambassador Group (CRAG). The TOPIC trial has utilised PPI from inception of the study through to dissemination of results and demonstrates the positive impact that PPI has on all aspects of the research process.

Introduction

Patient and public involvement (PPI) ensures that clinical research is for the benefit of patients and carers and leads to improvements in treatments and services¹. The National Institute for Health Research (NIHR) programmes now specify that researchers must engage PPI for their proposal to be accepted by the funding

programme boards². The TOPIC trial is a randomised controlled trial comparing the effectiveness of thoracic epidural blockade (TEB) and paravertebral blockade (PVB) in reducing chronic post-thoracotomy pain (CPTP)³.

The feasibility trial has been completed and demonstrated that a full randomised controlled trial was achievable. The full study is scheduled to begin later this year. The TOPIC feasibility trial was funded by an NIHR research for patient benefit (RfPB) grant and three PPI patient ambassadors were involved in the application process. Two PPI representatives went on to become involved in the trial management group. The definitive trial has been funded by the NIHR Health Technology Assessment (HTA) programme and PPI continues to be an integral part of the study. There have been changes made to the TOPIC trial based on feedback from PPI, and both programme funding review boards commended the input of PPI. The TOPIC study demonstrates the impact of PPI on many areas of the research process.

The Clinical Research Question and PPI

Post-surgical chronic pain is common, disabling and costly. As clinician researchers, we aim to reduce this health burden. The TOPIC research idea was initiated in a small specialty research grant application. The peer reviewers advised a review of the pain measurement tool used as the primary end point in the study. Out of three potential pain measurement tools, it was unclear which tool patients would prefer to use to express their pain. This led to the involvement of patient ambassadors to help make the decision, highlighting the crucial role of PPI even in the earliest stages of the research process.

Changes made to TOPIC's Study Design Following PPI Feedback

Two patient ambassadors initially became involved in the TOPIC study design. One patient had CPTP and had experienced both interventions in the study so was able to provide valuable insight into the implications of the interventions on patients. The other PPI representative had also suffered from CPTP and had previously been involved in research, providing experience gained from involvement in other studies. The patient ambassadors offered advice on the wording of the patient information sheet and questionnaires, ensuring that the language was suitable for lay people. They were also able to offer feedback on the running of the study, and whether they felt it would be manageable for patients, especially given their first-hand experience of the surgery and the interventions.

Successful RfPB Grant application

The TOPIC feasibility study proposal received £250,000 from RfPB. All PPI expenses were embedded within the grant application. Initially, there were two PPI co-applicants on the grant application. However, due to work commitments, one was unable to continue as a co-applicant, and another PPI representative took over. The co-applicants contributed to and reviewed the application to RfPB, and played active roles in the design, development and oversight of the study. The PPI co-applicants became members of the trial management group (TMG), which met regularly throughout the course of the study. The two PPI members provided feedback on study recruitment and conduct through the TMG meetings. The TOPIC investigators were committed to fully engage PPI and so recruited the third PPI representative to join the Trial Oversight Committee (TOC). The TOC met on a regular basis, providing supervision and advice to the TMG and overseeing patient safety of randomised participants.

Dissemination Using PPI

One PPI member of the TMG attended the INVOLVE conference in Birmingham in 2014 and discussed his role as a research ambassador within a clinical trial. He made a video recording of his experience, which (with his consent) has been presented at regional and national conferences and forums, such as the AAGBI annual update course on thoracic anaesthesia. The results of the feasibility study have been presented at PPI meetings and the investigators plan to utilise PPI to disseminate the results of the full study when completed.

HTA grant application and PPI

Following the successful completion of the TOPIC feasibility study to time and target, the TOPIC investigators applied for funding from the NIHR HTA programme. The PPI members who were involved in the feasibility study were able to continue in their contribution to TOPIC by becoming co-applicants for the HTA grant. The application was successful, and TOPIC was awarded funds in excess of £2 million. The review board highlighted PPI as a strength of the study design:

“Excellent patient and public involvement.”

“Excellent PPI - particularly like that one of the applicants/team has undergone both TEB and PAV so is well placed to guide the development of the application and the research conduct. Also that there is involvement at all stages of the process from pre application to research, and that PPI people are to be active in the dissemination.”

The full TOPIC trial is due to start later this year, and will continue to have PPI input throughout the study.

Challenges of PPI

The TOPIC investigators found it challenging to seek out an appropriate PPI representative for the study. They specifically wanted a patient ambassador with lived experience of CPTP, but initially found it challenging to find someone as existing pathways to engage PPI in research at that time were poor. The study team worked with surgical collaborators to recommend patients who had experience of CPTP. The first two PPI representatives were contacted at an early stage of the study process and were positive of the study aims and agreed to work with the research team. The challenges of involving and engaging patients for the TOPIC trial led to the formation of a local PPI group. In 2013, the Clinical Research Ambassador Group (CRAG) was created, which provides a structured pathway for researchers to integrate with PPI at a local level⁴. The aim of CRAG is to provide a group of patients, carers and members of the public to support the development of good quality and meaningful research projects and grant applications. Study milestones and progress have been presented to the group on a quarterly basis and members are eager to hear updates on the TOPIC trial.

The impact on PPI Representatives

Patients and the public who become involved in the research process have the opportunity to gain new knowledge and skills through their participation in PPI. One of the PPI members of the TOPIC TMG felt that he had personally benefited from his involvement:

“I now have a greater knowledge.....I do understand more now and I've found the [CRAG]

group to be very helpful. I've been able to explain to other people more because of my experiences within the CRAG group” PPI TMG member for TOPIC and CRAG member.

As consequence of his involvement in the TOPIC trial, one PPI TMG member is now on the steering group of PRIORITYII - a priority setting partnership with the James Lind Alliance to explore retention of patients in clinical trials.

Conclusion

The TOPIC investigators' experience of integrating PPI as members of a research team has been positive. Including a co-applicant with experience and knowledge of PPI integration has led to continuing dialogue with PPI members and has provided a personal oversight of PPI involvement, education and financial reimbursement. This has led to an overarching positive experience from PPI members and has led to sustained momentum of engagement through the trial. In the future, PPI engagement will continue to be an integral part of the TOPIC trial, and will lead the way for further studies to involve PPI throughout all stages of the research process.

1. Jones M M, Kamenetzky A . The National Institute for Health Research at 10 years. An Impact Synthesis. Summary Report. 2016.

Available at https://www.rand.org/pubs/research_reports/RR1574.html (accessed 15th January 2018)

2. NIHR. Funding and Support. Step 3 – Make a strong application. Available at

<https://www.nihr.ac.uk/funding-and-support/funding-for-research-studies/how-to-apply-for-funding/make-a-strong-application.htm>

(accessed 14th february 2018)

3. Yeung J, Melody T, Kerr A, Naidu B, Middleton L, Tryposkiadis K, Daniels J, Gao F on behalf of the TOPIC study investigators.

Randomised controlled pilot study to investigate the effectiveness of thoracic

epidural and paravertebral blockade in reducing chronic post-thoracotomy pain: TOPIC feasibility study

protocol. BMJ Open 2016; 6: e012735.

4. Skilton E, Aslam M, Yeung J, Gao F, Melody T. Embedding patient and public involvement within

research How to set up a research patient ambassador group within an NHS trust. JICS 2016; 17: 234-7

Help shape medtech research on diagnosing flu



Do you want to help in the development of the next generation of flu diagnostic products? During our project between 1st Jan 2018 and 30th Jun 2020 there will be a number of ways you can get involved. We will publicise these opportunities through this page of our website. We expect to hold various consultation activities and focus groups to inform the design and use of our innovative diagnostic product. If you have any comments on our project or would like more information on how to get involved please email us at info@flu-and-you.org.

Initial flu and you consultation

Currently we are conducting a simple survey to help structure our project, it only takes about 10 minutes to complete and will help us make important decisions informing the future of flu diagnosis, you can take part by clicking [here](#).

Patients' experience of taking part in the INFORM study

Researchers, surgeons and patients from around the UK have joined together to design and deliver the INFORM (Infection: Orthopaedic Management) research programme. Since 2014, they have been investigating why some patients develop infections after their hip or knee replacement surgery, and which type of surgical revision treatment is best. They have produced a video about patient involvement in the INFORM research project.

[Watch the full video here https://www.youtube.com/watch?v=TrZfHfVaMZE&feature=youtu.be](https://www.youtube.com/watch?v=TrZfHfVaMZE&feature=youtu.be)

NIHR Annual Stats: Record numbers take part in clinical research



More people than ever before took part in NHS clinical research studies sponsored by the life sciences industry over the last year - gaining earlier access to potentially cutting edge new treatments while helping to answer important health questions - according to new figures from the National Institute for Health Research (NIHR).

NIHR publishes its annual research statistics each year,

covering commercial studies sponsored by the life sciences industry - such as pharmaceutical companies - as well as non-commercial studies funded by organisations such as medical charities, research councils, the government or NIHR.

This year's figures, which cover the twelve month period between April 2017 and March 2018, suggest that health research is thriving across the country and the NHS continues to be seen as a good place to deliver high quality clinical trials.

The number of people participating in NIHR supported life sciences industry studies rose by 45 percent in the 2017/18 financial year - with NIHR helping to recruit 50,112 participants into commercial research studies within the NHS, primary care and other health settings across England.

Dr Jonathan Sheffield OBE, Chief Executive Officer of the NIHR Clinical Research Network (CRN) said: "By taking part in life sciences industry studies, patients are participating in new and innovative forms of treatment which will provide evidence for future improved care for all patients. The knowledge gained could provide the evidence to license new treatments in the NHS securing healthy lives for future generations.

"Partnerships between the NHS and the life sciences industry bring a range of benefits to the healthcare sector - giving trusts access to new treatments and funding for health research, while also boosting the wider economy each year through the development of cutting edge medical innovations."

Nicola Whitehill, 45, has taken part in three pharmaceutically-led clinical studies since being diagnosed with a rare, chronic disease - Raynaud's and Scleroderma.

Nicola, who was initially told she had 15 months to live in 1997 due to the aggressive nature of the disease said: “Before I started taking part in clinical trials, having been told the disease I had was likely to kill me and had no cure - my situation was like a dark tunnel without any light at the end.

“Taking part in trials provided a glimmer of hope, giving me access to new treatments which potentially could improve my condition. I’d recommend taking part in a clinical trial to any patient if they have the opportunity.”

Overall participant numbers near three quarters of a million

In total, more than 725,000 participants across the country signed up for clinical research studies supported by the NIHR in 2017/18 - including studies sponsored by pharmaceutical companies and those funded by NIHR, charities or other non-commercial organisations which are delivered in the NHS. This is the highest number since records began in England and a significant increase of nearly 10 percent from the previous year. Over the last five years, more than 3.2 million participants have taken part in studies supported by NIHR.

Record number of new studies

The number of new health research studies being set up during the year was also at its highest level yet, with the NIHR CRN pledging its support to 2,070 new studies over the course of 2017/18.

Jonathan Sheffield, OBE said: “Health research is the key to finding new and innovative cures, treatments and care for patients. Evidence also shows research active organisations consistently deliver better outcomes to all patients they treat, not just those involved in health research trials.

“We aim to ensure research is embedded in all aspects of care delivered in England. We also wish to provide an opportunity for anyone to be involved in a health research study. With nearly three quarters of a million participants in the last year we are moving closer to achieving this.”

Irene Soulsby, 60, decided to take part in a health trial after she was diagnosed with breast cancer in 2003. Since then she has taken part in many other studies as a healthy participant so she could give something back to the NHS.

Irene said: “Clinical research is vital to the NHS to help make improvements to patient care. I am excited to be involved in research that makes a contribution to the advancement of medical and scientific knowledge, even in a small way. Research helps everyone understand more about growing old and what that means, finding more treatments and cures for diseases. Eventually researchers hope to make disease a thing of the past. It’s only with real people’s contributions that research can move forward.”

NIHR Research Activity League Table published

Each year, the NIHR Clinical Research Network publishes the NIHR Research Activity League Table. It provides a picture of research activity across all NHS trusts and CCG regions in England. The table data includes how much clinical research is happening, where, in what types of trusts, and involving how many patients.

The 2017/18 league table is now available at www.nihr.ac.uk/nihrleaguetable, accessible to anyone wanting to understand how much research activity is happening in their local trust or CCG region.

Hear about the great PPI work being done across the ECMC (Experimental Cancer Medicine Centres) network

All ECMCs recognise the importance of involving people affected by cancer in their work and the positive impact it can have on research taking place at their locations. ECMCs are required to report on their activity and progress each year. As part of this ECMCs detail their patient and public involvement activities over the year. The ECMC Programme Office has collated the responses from the adult ECMCs and produced a report which showcases the amount of work being done in this area across the Network. Our main aim in doing this is to support and promote the sharing of knowledge, learning and good practice across the ECMC network and beyond.

Common PPI activities taking place across the Network include patient representatives on governance boards and trial specific steering committees, getting patient input into research documents such as protocols and patient sheets. Newer activities that are beginning to be undertaken by ECMCs include measuring the impact of PPI in research, ensuring that patient representatives come from a diverse background and trying to get PPI into commercial studies. Running alongside all of these activities is the need for engagement events, for example symposiums and open days which both raise the profile of research in a location and are a way to recruit members to patient groups or panels.

[Download the report of PPI activities in the ECMC network, 2017/18 here <http://www.ecmcnetwork.org.uk/sites/default/files/ECMC%20Network%20PPI%20Activities%202017-18.pdf>](http://www.ecmcnetwork.org.uk/sites/default/files/ECMC%20Network%20PPI%20Activities%202017-18.pdf)

Patient group shows power of working together

“Informative and inspirational”. For Cambridge BRC’s Georgina Norris, those two words summed up this year’s Beat SCAD conference, which took place in Birmingham earlier this month.

SCAD – or Spontaneous Coronary Artery Dissection – is a rare cardiac condition, which cannot yet be predicted or prevented. SCAD can cause heart attack, heart failure, cardiac arrest and can be fatal.

Although it has been reported across a wide age range, the majority of cases are in young- to middle-aged women.

Georgina – who is Patient & Public Involvement and Engagement (PPI/E) Co-ordinator at the NIHR Cambridge Biomedical Research Centre – said: “I first met Rebecca Breslin, who is one of the charity Beat SCAD’s co-founders, when working on PPI/E projects for rare diseases.

“Rebecca’s story – along with the 68 SCAD survivors who were also at the conference – is incredible.

“Aged just 34, Rebecca had a heart attack. She knew what it was but no one believed her, because she was young, slim and looked healthy.

“Working with Leicester-based interventional cardiologist and lead for the UK SCAD Research Project Dr Adlam at Leicester University, she then made it her mission to find out other people around the country who have also had SCADs. “This gave Dr Adlam the numbers he needed to run clinical trials to find out more about the disease.”

Patient power

At the conference Rebecca and Beat SCAD co-founder Karen Rockell both spoke about the charity’s fundraising achievements – which last year alone raised £25,000 for research carried out by Dr Abi Al-Hussaini, former research fellow in Leicester and now London-based cardiologist.

Rebecca and Karen also broke the news that a further £50,000 raised by Beat SCAD will help fund future research run by Dr David Adlam and his team.

Georgina said: “Researchers under Dr Adlam are looking to see if SCAD is an inherited condition.

“On the day SCAD research fellow Dr Alice Wood – who is part of Dr Adlam’s team – also talked about her work looking at sub-groups of patients, such as men, pregnant women and those who’ve had recurrent SCADs, and how this will help add missing information to the research jigsaw puzzle.”

Life after SCAD

For Georgina the day was a demonstration of PPI/E in action: “The day showed that when doctors and researchers work with patients and their carers, the results can be amazing.

“We know more about SCAD than we did even five years ago, and the example of Beat SCAD shows what can be achieved through patients joining forces and working with researchers.

“Above all it showed that there is life after SCAD.”

More information here <http://beatscad.org.uk/>

People in Research

The People in Research website is a database of opportunities for members of the public to get involved in research. Researchers can post their opportunities and members of the public can apply for opportunities that are of interest. Please can you help us with the future development of the website by taking a few minutes to complete a short survey on your user experience.

<https://www.surveymonkey.co.uk/r/JFDX6C2>

Help guide future research about problematic knee replacements

The British Association for Surgery of the Knee (BASK) are running a PSP in partnership with the James Lind Alliance (JLA). The aim is to bring patients and carers together with a range of healthcare professionals. They wish to highlight uncertainties relating to the assessment, management and rehabilitation of patients with a problematic knee replacement, to identify future research questions and ultimately publish a list of 'top 10 research priorities'. This will guide funders for future research.

[Complete the survey here https://jlarevisionknee.com/](https://jlarevisionknee.com/)

A look into the future of children's research - <https://tinyurl.com/y8reyndl>
10,000 Research Participants - Dementia Research <https://tinyurl.com/y8gdahpz>
INVOLVE publish new IN Bulletin - <https://tinyurl.com/y98q4yz9>
Patient Research Ambassador - <https://tinyurl.com/y8odm9xj>
News from NIHR - <https://tinyurl.com/yc58wo68>

**To ensure you continue receiving this newsletter
please update your preferences**

<https://tinyurl.com/ydh2u8xd>

@OfficialNIHR • www.nihr.ac.uk • www.youtube.co./user/NIHRtv
www.linkedin.com/company/nihr_2

Copyright © 2018 INVOLVE NIHR, All rights reserved

Mailing address: INVOLVE Coordinating Centre, Alpha House, University of Southampton Science Park, Chilworth,
Southampton SO16 7NS United Kingdom