NIHR | INVOLVE

Patients and the public

May 2019

Coping with Distress about Health – how Patient and Public Involvement helped to influence our study

Severe health anxiety is persistent worry about health, which is thought to occur in about five per cent of the general population.

In a study funded by NIHR, investigations were carried out to see whether clinical and economic results were improved by offering remotely delivered Cognitive Behavioural Therapy.

The problem

Severe health anxiety is persistent worry about health, which is thought to occur in about 5% of the general population. It can lead to increased, unscheduled use of services such as Accident & Emergency departments walk in centres, and urgent same day GP appointments. These visits often bring little benefit to patients.

Treatment option

Remotely delivered Cognitive Behavioural Therapy (rCBT) (by internet video link or phone) was considered as a treatment option. Funded by NIHR CLAHRC East Midlands we investigated whether clinical and economic results were improved by offering rCBT to people with severe health anxiety who frequently accessed unscheduled care. We offered six to 12 CBT sessions to 156 participants who took part in the study.

What we found

rCBT was shown to bring patients significant improvements in health anxiety at 6 months, maintained at 12 months, compared to those who accessed the usual treatment. General anxiety, depression and overall health also improved at 12 months. There were cost savings of £1,000 per patient (over 12 months) in terms of reduced use of NHS services. This demonstrated that targeted remote delivery of CBT is an effective and cost-saving method of treating repeat users of unscheduled care who have previously been difficult to engage in psychological treatment.

Patient and Public Involvement influence and impact

We included two Patient and Public Involvement (PPI) volunteers, David Waldram and Fred Higton in our team for this study, and their involvement was invaluable. Examples of the many things they contributed were:

- Attending monthly research study team meetings, contact with team members between Meetings and participating in group decisions
- Creating a study name that did not alienate patients.
- Providing input on the content and structure of all study tools.
- Using their strong connections to obtain additional feedback from other organisations
- Presenting at networking events and conferences

• Checking and advising on documentation.
• Advising on how the videos were presented (e.g. sound levels, use of subtitles and suitability for small screen devices.)

PPI played an essential role in ensuring that the study was sensitive to the needs and views of its participants and had a positive influence on recruitment, treatment methods and dissemination. PPI input meant the study was presented in a user-friendly way, and the careful choice of words used to communicate with participants, reduced any stigma associated with severe health anxiety. This was vital in helping the study to meet its recruitment target.

PPI involvement demonstrated how the quality of research and its impact can be enhanced by involving service users from the start and throughout the process. David Waldram is an electronics engineer by background and his knowledge and experience of technology allowed us to select the most appropriate video conferencing technology to deliver the remote therapy. He also tested the text messaging system used as part of the treatment offered. Fred Higton is a retired research chemist and a cartoonist who has considerable experience translating technical language into simple but meaningful messages. The treatment booklet was designed with Fred 's help. He advised on the layout and provided cartoon images, helping to bring the booklet to life; making it interesting and easy to read.
http://www.clahrc-em.nihr.ac.uk/clahrcs-store/cognitive-behavioural-therapy-health-anxiety

We produced eight video testimonials from participants sharing their experiences of having health anxiety and receiving the therapy. These will be a helpful resource for potential participants, as they offer realistic and personal views on what to expect from rCBT for health anxiety, and provide a clear explanation of how remotely delivered therapy can work. They will also provide a resource for healthcare professionals to provide a better understanding of health anxiety from the patient's perspective.
https://www.youtube.com/channel/UCSGnnBPGFosOwGCMGUn6K2w/videos

One of our participants shared her experiences of receiving the therapy on BBC East Midlands television and radio programmes. Since the broadcasts were aired, several people have approached her to talk of their own personal experiences of health anxiety, and mentioned that they hoped video/telephone therapy could be made more widely available.

https://www.dropbox.com/s/xfq20tp5iwh2cvr/THERAPY%20NO%201830%2031%201-h264.mov?dl=0

PPI feeding into research outputs: New tool to predict epileptic seizures in pregnancy

The EMPiRE tool is a new risk calculator for pregnant women with epilepsy which accurately predicts the risk of seizures during pregnancy and can help inform their care options. It was developed and validated using datasets from the EMPiRE cohort study which looked at 560 pregnant women with epilepsy on medication from 50 hospitals in the UK by researchers from Queen Mary University of London. ***Ngawai Moss took part in the study and fed into the project though a PPI advisory group called 'Katie's Team'.***

She said: "The model will be an asset for women living with epilepsy, like me, to inform us and our healthcare professionals about our anti-epileptic drug management and care in pregnancy. It will help us make informed decisions on how we manage our epilepsy and that in itself is extremely reassuring and empowering."
"The *Women's Health Research Unit's* at QMUL is genuinely committed to incorporate our voice as patients into the research lifecycle. This tool is a powerful example of how we directly feed into

research and have an impact on its outputs."
See below or read the accompanying open access paper.
The risk calculator has been found to accurately predict the risk of seizures during pregnancy and up to six weeks after delivery, and could save the lives of mothers and babies.
The EMPiRE tool has been made freely available online to help clinicians identify women at high risk of seizure, and inform their care through close monitoring and anti-epileptic drug management.
Women with epilepsy are ten-times more likely to die in pregnancy than those without the condition, with seizures as the main cause of death. It has been consistently highlighted that the main factor behind these deaths is a lack of recognition of the women's high-risk status by health professionals.
Pregnant women with epilepsy are advised not to alter their treatment without specialist advice. However, up to four in ten women discontinue their anti-epileptic medication in pregnancy due to concerns about the effects of drugs on the unborn baby, thereby increasing their risks of seizures.

Difficult decisions on epilepsy medication

Ngawai Moss, 38, has epilepsy, and is the mother of two children. She said: "It is a source of worry not knowing when you might have a seizure. Pregnancy makes you actively question how best to manage your epilepsy." Our medication can help prevent seizures, but it can also potentially be harmful to the health of the baby.

"This dilemma can make the decisions around continuing to take medication during pregnancy difficult. You want to do the right thing for the baby, but it's also important to be practical. If you have a seizure there is a possibility of drowning or sustaining a serious injury, like falling down the stairs which can also harm or kill the baby."

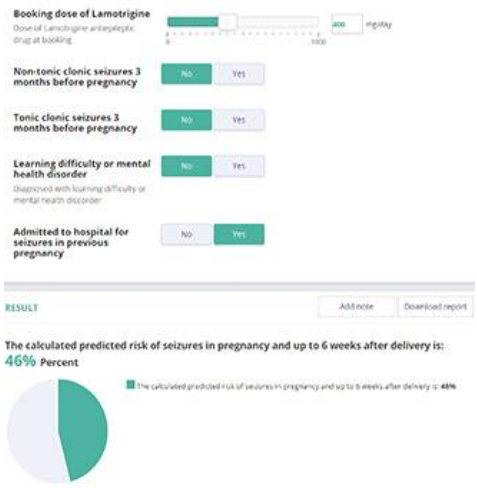
The new prediction model, which has been published in the journal *PLOS Medicine* and online by the research team, is able to generate accurate estimates of seizure risk at any time in pregnancy in women with epilepsy who are on anti-epileptic drugs, to help inform their care.

The model uses information which can be routinely collected during an antenatal appointment, such as age at first seizure, seizures in the three months before pregnancy and current dose of anti-epileptic drugs. It then processes the data to predict the likelihood of a seizure not only in pregnancy, but up to six weeks after delivery, a period with increased risks to the mother and baby.

First ever tool to predict seizures in pregnancy

Lead researcher Professor Shakila Thangaratinam from Queen Mary's Blizard Institute said: "The EMPiRE tool is the first ever to predict the risk of seizure in pregnant women with epilepsy who are on anti-epileptic drugs. Our model gave accurate predictions regardless of the type of care the woman received, and we're now making it freely available online via a web-based calculator so that any clinician in any part of the world can use it with their patients.

"By identifying the women who are at greatest risk of seizures, we can monitor them more closely during pregnancy, labour and childbirth, or consider increasing their anti-epileptic drug dose to reduce that risk."



Screenshot of the EMPiRE model

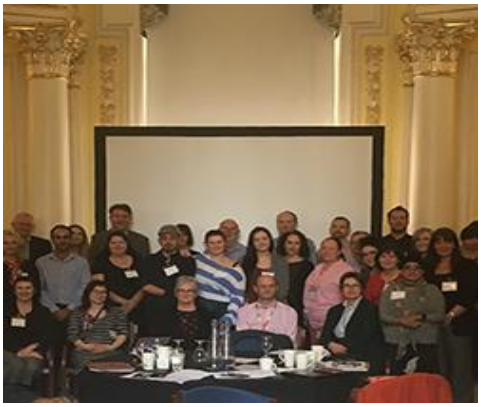
Dr John Allotey from Queen Mary added: "Such a tool can empower women to make informed decisions on their care, including shared decision making between the woman and their healthcare professional on the level of support needed in pregnancy and after childbirth. By being aware of their risk status, women's anxiety from the unpredictable nature of seizures could be reduced, and they may also be more likely to adhere to their medication if needed."
The team of researchers developed and validated the model using data from the EMPiRE cohort study which looked at 560 pregnant women with epilepsy on medication from 50 hospitals in the UK.
The freely available online calculator is aimed at general practitioners, epilepsy specialists, obstetricians, and midwives.
The work was carried out at Barts Research Centre for Women's Health, based at Queen Mary University of London, which is funded by Barts Charity.

'Empowering women to make informed decisions'
Victoria King, Director of Grants at Barts Charity, said: "Barts Charity invested in the Barts Research Centre for Women's Health to help research lead to tangible improvements in the health of women and their babies and this freely available tool has the potential to do just that for pregnant women with epilepsy.
"The tool can help pregnant women with epilepsy work with their healthcare team to make empowered and make informed decisions about what is right for them and their treatment during pregnancy and Barts Charity is very proud to support this."
The limitations of the model include that it is mainly applicable to high-income countries due to the source of data it is based upon, its clinical utility is restricted to thresholds above a 12 per cent risk of seizure, and the small validation cohort sample size may have affected the robustness of the external validation.

More information

- The online risk calculator is available from: https://www.evidencio.com/models/show/1799
- Research paper: 'Predicting seizures in pregnant women with epilepsy: Development and external validation of a prognostic model'. John Allotey et al. *PLOS Medicine*.

Patients and professionals develop strategy to improve research opportunities for teenage and young adult cancer patients.



Patients and professionals meet to explore ways to increase opportunities for TYA participation in NIHR Portfolio studies; to understand the structural and infrastructure factors that impact on TYA participation in clinical research and to develop combined stakeholder approaches to m meet the Cancer Taskforce Recommendation that 50 per cent of TYA patients are involved in research studies by 2025.

In 2015, the Independent Cancer Taskforce noted that, in comparison with children under 16 years, the outcomes for older teenagers and young adults are improving less rapidly, and that teenage and young adult (TYA) cancer patients are less likely to participate in research ("Achieving World-Class Cancer Outcomes – a Strategy for England 2015-2020"). It recommended:

"NHS England should ask NIHR and cancer research charities to consider ways in which access to clinical trials for teenagers and young adults with cancer could be significantly increased. NHS England should set an expectation that all Centres or designated units treating TYA patients should aim to recruit at least 50% of those patients to clinical trials by 2025."

In March 2017, the NIHR convened a Summit meeting to explore ways to increase opportunities for TYA participation in NIHR Portfolio studies; to understand the structural and infrastructure factors that impact on TYA participation in clinical research and to develop combined stakeholder approaches to meet the Cancer Taskforce Recommendation that 50 per cent of TYA patients are involved in research studies by 2025. The resulting 2017-2020 NIHR TYA Cancer Strategy set out strategic goals to meet the challenges of ensuring that TYAs have the opportunities to participate in world class research.

Max Williamson, an NIHR Clinical Research Network TYA Cancer Strategy patient representative, said:
"The sheer number of patient advocates involved in the development of the strategy means that this is truly an equal partnership between teenage and young adult cancer patients and professionals involved in treating us. This strategy will shape how and what research opportunities are offered to us and ultimately how we are treated as a patient group within the NHS."

Two years on, the Summit met again on 5 April to assess progress against the strategy objectives, consider any new developments and to refresh the strategy. Dr Amos Burke, NIHR Clinical Research Network National Specialty Lead for Children and Young People's Cancer, who opened proceedings and outlined the objectives for the day said:
"In the two years since the first NIHR TYA Summit there has been significant progress but much remains to be done. This Summit was focused on making sure that the objectives are still fit for purpose and ensuring that the right stakeholders are engaged to ensure successful delivery."

The meeting was larger in size than the 2017 Summit and was attended by the NIHR Clinical Research Network Cancer leadership team, Children and Young People's Cancer Subspecialty Leads from each Local Clinical Research Network, National Cancer Research Institute (NCRI), NHS England, clinicians involved in treating TYA cancer patients and key charities working for and with TYA cancer patients (Teenage Cancer Trust, CLICSargent and Teenage and Young Adults With Cancer). Crucially the Summit also included parents and TYA cancer patients all of whom were equally involved in reviewing and inputting into the strategy.

The morning session focused on reviewing the current strategy and assessing progress against the objectives from the viewpoint of the key stakeholders involved. A key achievement was the NIHR Clinical Research Network establishment of a TYA cancer research nurse in each of the 15 Local Clinical Research Networks in England with posts available from 1 April 2019. It also considered new developments such as Proton Beam Therapy and the pioneering work of the Fostering Age Inclusive Research (FAIR) Trials Working Group (part of Accelerate the key European organisation aiming to accelerate innovation in drug development for children and adolescents with cancer). FAIR advocates the development of more inclusive studies where the age of entry corresponds the biological age range of the disease rather than the traditional age of consent.

The afternoon session featured interactive workshops where attendees were split into groups and tasked with formulating actions around the key new areas to be included in the strategy refresh.

The day ended with discussion on plans for updating the strategy and the establishment of a Steering Committee to oversee the different work streams which will include representatives from the key stakeholder organisations involved, as well as charities and patient and parent representatives.

Debbie Binner, patient advocate, who has worked with the FAIR Trials Working Group said: "I was delighted to be involved with this conference and the development of this strategy. It was well thought out, targeted and ensured that we came out with some clear measurable, timed objectives. Removing the lower age range for clinical trials and the FAIR Trials work is extremely close to my heart as my own daughter suffered because of this cultural impediment. Change is never easy, but this kind of thoughtful strategic work is key to pushing down the barriers that currently prevent children and teenagers getting access to the newest treatments that are now coming down stream. This is an incredibly important piece of work and I'm extremely pleased to be part of it."

Toolkit to help engage BAME (Black and Minority Ethnic) groups.

Recently the CLAHRC (NIHR Collaborations for Leadership in Applied Health Research and Care) East Midlands developed a useful toolkit to help answer the question of how we better engage BAME groups.
The toolkit aims to capture such best practice and provide researchers with a framework on how to improve the participation of BAME groups in research.

The toolkit should help researchers develop more relevant research questions, consider engagement of BAME groups in a more structured way, and provide tips on better participation and dissemination of research findings. The toolkit covers:

- Section 1: Consideration of the communities which your research needs to involve.
- Section 2: Undertaking effective patient and public involvement (PPI) in research
- Section 3: Conducting effective recruitment in BAME communities
- Section 4: Ensuring cultural competency in the conduct of your research
- Section 5: Providing effective feedback to research participants
- Section 6: Recognising the importance of recruiting BAME communities in research: preparing a grant application
- Top Tips

You can download the toolkit here

It's not too late to apply for a small grant supporting diversity in patient, public involvement in health and social care research.

Got a good idea for building diversity in patient, public involvement in health and social care research? Funding is available to support innovations in patient, public involvement and engagement in research. Please note the PPIE Small Grants Scheme closes 31 May #BePartOfResearch.

The PPIE Small Grants Scheme (the Scheme) helps enable those working across the NIHR Clinical Research Network to access resources with the aim of supporting development of innovative practice in the delivery of patient and public involvement and engagement (PPIE) in health and social care research.

Sponsored by the NIHR CRN's PPIE Programme, the Scheme is primarily designed to enable people to work in a new space and is provided with the purpose of enabling time, skill and resource to work in new ways, try new things and ultimately be innovative.

Here are some examples of previous projects supported by the Scheme:

- engaging people living with dementia and their supporters to develop their confidence in public speaking and facilitation skills in order to host a workshop at Every Third Minute. This is a festival of theatre, dementia and hope at Leeds Playhouse which raises awareness about research and Join Dementia Research through short performances in local community settings with associated research cafes.
- using text messaging to communicate with patients and raise awareness of research opportunities in Primary Care by piloting a number of different text messaging campaigns.
- using hand held devices to enable stroke patients to give real time feedback on their experiences of taking part in research.
- supporting the development of Gypsy & Travelling (G&T) community leader(s) as patient research ambassadors, to build understanding about research and the benefits of participation in research with this community.

What do I need to do before I apply?

Please first read the Guidance for Applicants provided for this Scheme.

How do I apply?

If, having read the guidance, you would like to apply please complete and submit this application form.

Is there a closing date and time for applications?

The closing date is **Friday 31st May 2019 at 5pm.** After this date applications will not be considered.

If I have any questions before I apply who can I contact?

Please contact the Scheme Project Manager, Karen Inns, at: crnppie@nihr.ac.uk. Please use the email header: PPIE Small Grants Scheme.

Co-production: What are we doing?

An update from Gary Hickey, NIHR INVOLVE.

Our work on co-production continues to gain traction. We recently co-hosted, along with colleagues from the Centre for Public Engagement, Kingston University and St George's, University of London and University College London Centre for Co-production in Health Research a successful event on 'Co-producing Research: How do we share power?'
The event was put on by colleagues from INVOLVE, Centre for Public Engagement, Kingston University and St George's, University of London and University College London Centre for Co-production in Health Research.

We were supported by Academic Health Sciences Network for Kent, Surrey and Sussex and National Institute for Health Research Design Service London.
We are grateful to our speakers, attendees and followers on Twitter for making the day a successful one.
The sharing of power is the key principle in co-producing research and this is reflected in guidance co-produced by INVOLVE and colleagues from National Institute for Health Research and beyond.
The event was an opportunity to explore the power sharing aspect of co-production. It was also an opportunity for people to showcase their work and to network. Finally, with attendees including public members, researchers, healthcare practitioners and staff from National Institute for Health Research, it provided a platform for us to talk, learn from and challenge each other.
As was acknowledged during the event sharing power can be challenging. There were many observations and potential opportunities raised during the event, too many to list them all here but here are a small number of them:

- Simon Denegri, National Director for Patients, Carers and the Public, National Institute for Health Research kicked off the day and posed a series of questions including how do make sure that co-produced research becomes an accepted and valued approach to research? How do we push for more?
- Rebecca Baines, Researcher at University of Plymouth and John Donovan, public member, noted how co-producing research presented a challenge to how the research community currently views 'impacts'. It's not just about number of publications and conference presentations; the very process of co-producing can increase confidence of individuals involved in the research. Currently these are not valued.
- Rosie Davies, Michelle Farr (Collaboration for Leadership in Applied Health Research and Care West), and Nick Leggett, public member challenged researchers to be open to change. We need to build into research projects – and indeed value – the space to do things differently.
- Annette Boaz, Kingston University and St George's, University of London, co-editor of Evidence and Policy, gave an international perspective on co-production and noted that we now have a more nuanced understanding of co-production. This inevitably led to a debate about the merits or otherwise of having a 'tight' definition of co-production. In addition, via Twitter we were warned of the dangers of 'faux production!'
- Karolina Gombert, Kingston University and St George's, University of London, and Martin Malcolm, public member raised the issue of how to value and reward the input of public members.
- In the afternoon, there was a panel discussion where a significant plea was made to funders. If funders are to embrace co-production then they need to understand co-production and change their processes and procedures. Co-produced research takes time, in terms of relationship development, sharing power, working collaboratively and allowing solutions to emerge. It was acknowledged that this does not always sit easily alongside funders more rigid approach to research in terms of project plans, timelines and a hierarchical approach to research with a principle investigator being ultimately accountable.
- Finally, there were challenges to journals. In particular, peer reviewed journals were challenged to increase their understanding of 'non-conventional' co-produced research and the value of published articles co-authored with public members.

We may not have solved any of these challenges but as Rebecca Baines, Researcher at University of Plymouth and John Donovan, public member noted -'co-production begins with a conversation.'
This was our second event on 'co-production'. Our first one 'tested the market' and the 50 places available were snapped up in a day. This year we doubled the number and found that within four working days all the 120 tickets had gone and we had 50 people on the waiting list.

Already we have had people suggesting that this should be an annual event – and we will partner with the journal *Research Involvement and Engagement* in 2020 – and requests to 'take it on tour' (Manchester and Newcastle have already been suggested). All things (or nearly all things!) are possible and we would like to hear from potential partners from the different regions about working with them. Let's continue the conversation and build our co-production community.

Next up is a Research Medical Society and BMJ co-sponsored event 'Research co-production: What it is and how to do it'. This event will enlighten delegates about co-production of research and how to implement healthcare research collaboratively, using hands-on interactive workshop sessions. Co-production encourages patients and members of the public to work with clinicians and researchers to create, redesign and build medical research.

In contrast with traditional public and patient involvement, citizens are not only consulted, but they are part of the conception, design, steering, implementation, and management of the research. Involvement in co-production can be initiated by the public as they seek researchers and clinicians to partner with to conduct research.

Co-production is about making the best use of the assets, resources and contributions of citizens, patients, researchers and clinicians, as well as working with trust and transparency. Confidence and equality for working together can be reinforced by asserting that the best outcomes do not always come by blanket agreement without discussion but that mutual respect, flexibility, and resilience create an environment where everyone is heard and included.

Topics include:

- Learn what co-production in healthcare is and how it can be conducted, including the key stakeholders involved and their working processes
- Identify benefits and barriers to co-production in healthcare research
- Hands-on learning to effectively build co-production into your own work for research and healthcare

This will be followed by a presentation at the Social Care Institute for Excellence event on 'Sharing Power' as part of National Co-production Week.

National Co-production Week- Sharing Power: 1-5 July 2019

For the fourth year running, **Co-production Week** will celebrate the benefits of co-production, share good practice and highlight the contribution of people who use services and carers to developing better public services.

Co-production is about working in equal partnership with people using services, carers, families and citizens. Co-production offers the chance to transform social care and health provision to a model that that offers people real choice and control.

Sharing power

This year we want to talk about power- how this needs to be shared more equally with people who use services and carers.

We'll show, with practical examples, live guests and innovative seminars how more equal partnerships with people who use services and carers can be achieved. After all, it is only when everyone's contribution is valued equally and power is shared that meaningful co-production can happen.

Last year we wanted to break down the barriers to co-production. View full one hour webinar

This year we want people to tweet, email and blog about their experiences of power with examples of when this has been shared- what did this look like and what was the outcome? Tweet using #coproweek or email copro@scie.org.uk

What's happening in July 2019?

We are asking organisations and individuals to:

- hold events about co-production
- tell us about your event and we'll promote it
- tell us about examples of good practice in co-production. We will include the best ones in our co-production guide's 'practice examples' section
- tweet about co-production using the hashtag #coproweek
- contribute to the Co-production Week blog. Here's the 2018 version.

SCIE's Co-production Week activities

- The fourth annual Co-production Festival is on Thursday 4th July in London.
- Co-production taster sessions, webinars and more

Our work is also being referenced in publications on co-production, for example a recently released Carnegie Trust UK piece of work 'The many shades of co-produced evidence'.

Author: Pippa Coutts , **Year:** 2019 , **ISBN:** 9781912908066
Co-production of evidence is a process by which evidence is generated by the equal and reciprocal participation in research activities by academic and other partners. This briefing paper teases out the challenges and opportunities around co-producing evidence appropriate to participatory social policy and practice, and increasing people's control within communities and services. We view it as a contribution to discussions The Trust is involved in with co-production networks, academics and the social sector, and we would be delighted to hear your view on the co-production of evidence.

Finally, please look out for an upcoming publication 'Co-production in Action'. This will be the first in a series of three publications providing examples of co-produced research in practice.

The NIHR Central Commissioning Facility (CCF) has recently published their involvement and engagement plan for 2019/20.

You can access the report here.
Strategic priorities in the plan are:-

- VOICE – to ensure patients, carers and the public have a voice in how the NIHR works.
- FEEDBACK – to ensure patients, carers and the public get feedback on how they have made a difference
- STANDARDS – to define what good public involvement and engagement looks like.
- IMPACT/GETTING RESULTS -to understand and show the impact of public involvement and engagement.
- INVENTION – to test new ideas in public involvement and engagement and share the learning.

Our main focus is on delivering and improving our core activities which can be split into three areas:
• working with and supporting public contributors, for example in reviewing applications and contributing to decision making processes
• working with and supporting our NIHR Central Commissioning Facility (CCF) staff and research teams, for example in embedding effective practice in commissioning and monitoring processes
• working with colleagues across the NIHR, contributing to organisational wide activities, for example leading the development and implementation of the UK Standards for Public Involvement
We allocate the rest of our capacity and resources to develop our processes, and respond to ad hoc requests from colleagues and public contributors.

Thank you to those who commented on the draft. Please do not hesitate to get in touch with us (the CCF PPI team) if you would like to know more and/or help us to deliver our plan.

Patient and Public Involvement and Engagement (PPIE) sections of infrastructure and faculty annual progress reports

The PPIE sections of annual progress reports for NIHR infrastructure and faculty have now been published by the CCF. You can access the reports through this link.

Every year, over 100 National Institute for Health Research (NIHR) funded Centres, Facilities, Units, Schools and others provide an annual progress report to the NIHR. These reports are a source of valuable information that allows the NIHR to review performance, enable decision making on future funding requirements, answer Parliamentary Questions, prepare briefings for Ministers, and respond to other requests for information.

There is a patient and public involvement and engagement (PPIE) section in annual reports that asks for a brief summary of progress to date in implementing PPIE strategies.

Over the last few years, we have extracted and compiled the PPIE sections of annual reports and made them publicly available. Our main aim in doing this is to support and promote the sharing of knowledge, learning and good practice across the NIHR and beyond.

CCF aims to support and promote the sharing of knowledge, learning and good practice across the NIHR and beyond. We welcome feedback from anyone who reads the reports. For example, it would be helpful to us to know who reads the reports, whether readers find them informative and useful, or not and what we can do to improve them.
Additionally, over the coming months we will be working in collaboration with colleagues across the NIHR to seek further feedback from those who access these reports through an online survey or face-face/telephone discussions.
If you would like to give CCF feedback and/or are interested in taking part in the survey, please email us via ccfppi@nihr.ac.uk.

BE PART OF RESEARCH

Record number of people take part in clinical research

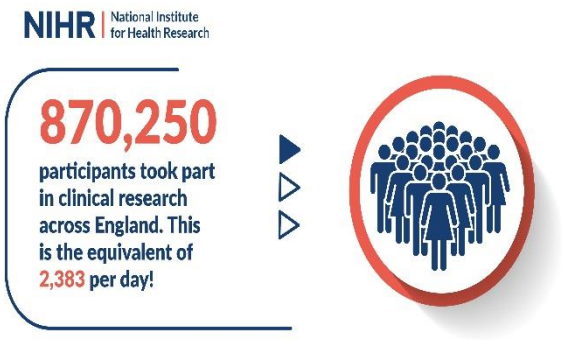
The number of people benefiting from clinical research in England reached record highs this year - with over eight hundred and seventy thousand (870,250) participants involved in studies supported by the NIHR's Clinical Research Network alone over the last twelve months.

- **Over 870,000 people participated in health and social care research across England - a huge increase from last year**
- **Record number of studies open for patients in England - delivered at every NHS trust across the country**
- **Researchers aim to make it even easier for people to take part in research, with launch of new website**

The number of people benefiting from clinical research in England reached record highs this year - with over eight hundred and seventy thousand (870,250) participants involved in studies supported by the National Institute for Health Research (NIHR) over the last twelve months.

The number marks a significant step towards the NHS Long Term Plan's goal of one million people taking part in clinical research by 2023/24 - part of the Government's strategy to improve care, treatment and NHS services in England.

Key areas of research



The most participants were recruited into children's research studies (81,892), studies delivered in primary care settings (78,533), reproductive health and childbirth research (74,128) , cancer research (67,652), and mental health research (65,645) leading the way in offering opportunities for patients to participate.

A couple from Lancashire were one of many to benefit from reproductive health and childbirth research over the last year. Jessica Corbally, 27, and husband Chris, 30, had struggled to conceive a second child for several years. They recently welcomed their new baby son into the family, having taken part in a fertility study testing a new procedure.

Discussing their experience, Jessica said: "We didn't know very much at all about clinical research until the consultant told us about this study. But everything was explained very clearly to us and we felt completely comfortable taking part. We had nothing to lose, yet we've gained everything we ever wanted. To anybody else, he might be just another baby, but to us, he is extra special. Not only have we benefited by having Joshua, we also feel like we have contributed a little something to medical research."

More studies than ever in England

The latest figures from NIHR show that patients now have more opportunity than ever to take part in clinical research and potentially benefit from new and groundbreaking treatments - with a record number of new studies (2,194) added to the NIHR's portfolio over the year, bringing the total number of ongoing studies across England to 6,106 - again the highest number yet. For the first time since 2015/16, every NHS trust across the country also supported clinical research by recruiting their patients into NIHR studies.

Evidence shows that being given the opportunity to take part in research benefits both patients and carers - and that their experience of being involved is overwhelmingly positive. The latest NIHR survey of those

taking part in research, completed by over 8,500 participants across England over the last year, found that 90 per cent of people had a good experience of participating in research.

Sheila Walker from Leeds is currently taking part in her second clinical trial investigating a form of injectable radiotherapy to treat breast cancer.

Sheila said: "Taking part in research has been amazing and I feel honoured to be giving something back. My care has been tremendous and the love and personal care I have received from the team has made it a more pleasant journey. I feel like I am part of a family and I appreciate the little things the team do and ask about when I visit for treatment."

Sheila would tell anyone thinking of taking part in a trial to go for it. "Why not? It's great to contribute to research, and it is something I am very proud of."

NIHR: Improving the health of the nation

Dr Jonathan Sheffield OBE, Chief Executive of the NIHR Clinical Research Network said: "We are delighted that this year alone, hundreds of thousands of people across the country have given their time to improve healthcare for others. Without their commitment, vital health research that changes lives simply could not happen.

"The benefits that clinical research bring to society are profound. People who take part in studies can gain access to cutting edge, innovative new treatments. While NHS trusts and health and social care patients also benefit significantly, with evidence and innovations identified through research pivotal to the development of new types of care and treatment - ultimately leading to the prevention of ill health, earlier diagnosis, faster recovery and better outcomes."

Life sciences research - improving the health and wealth of the nation

The number of new commercial studies set up across the year reached record levels - with 740 new studies sponsored by the life sciences industry registered on the NIHR Clinical Research Network (CRN) portfolio in 2018/19, bringing the total number of studies being delivered in partnership with commercial organisations to 1,523.

The number of participants taking part in commercial contract studies also remains high for the second year in succession. The NIHR CRN helped recruit 46,064 participants to commercial studies - the second largest number on record.

Professor Chris Whitty, NIHR lead and Chief Scientific Advisor at the Department of Health and Social Care said: "Research is a key part of our mission to improve care and treatment for patients - it is key in addressing the key health and social challenges we face now and those facing future generations. The latest NIHR figures show that patients have more opportunity than ever before to take part in clinical research and potentially benefit from new drugs or treatments."

Dr Jonathan Sheffield OBE, Chief Executive of NIHR Clinical Research Network (CRN) said:
"Despite the changing healthcare environment, clinical research in England is thriving - with record numbers taking part in studies supported by the NIHR over the last year. As an organisation, we continue to remain primed to provide high quality support and expertise that enables the life sciences industry to access key infrastructure and deliver research within the NHS and social care.

"Clinical research is vital for the UK economy and the NHS. More research being delivered within the UK by the life sciences industry, including global pharmaceutical companies, ultimately means more inward investment to the UK - aiding the economy by bringing in both jobs and services to the country while boosting NHS finances. We are pleased to see that the NHS continues to be seen as one of the very best places in the world in order to conduct high quality clinical research."

Be Part of Research

Increasing the number of people taking part in clinical research is a key part of the NHS Long Term Plan and the NIHR has taken steps to support this by launching a new website called Be Part of Research - which helps people to easily find and take part in studies across the UK.

Baroness Blackwood, Parliamentary Under Secretary of State at the Department of Health and Social Care said: "From the eradication of smallpox and the discovery of penicillin, the UK has a strong track record of public health successes which have saved countless lives.

"All of our successes to date would have been impossible without world-leading research and the selfless volunteers who take part in clinical trials.

"Through our Long Term Plan, we are determined to make it even easier for people to get involved in research and the NIHR's Be Part of Research website is an important step to making this happen."

Dr Sam Roberts, director of innovation and life sciences at NHS England and NHS Improvement and chief executive of the Accelerated Access Collaborative, said: "Clinical research brings significant benefits for patients and the organisations taking part, and I am delighted to see that as the NHS Long Term Plan prioritises better clinical research, a record number of patients participated in research last year with every trust in the NHS providing access to trials.

"NHS England continues to work in partnership with NIHR to make it easier to undertake research in the NHS so that even more people can participate and gain access to innovative new treatments."

Related links:

- Key statistics 2018/19 page
- Watch NIHR CRN Chief Executive Jonathan Sheffield's commentary on YouTube here

Case studies: Research participants

- Watch Sheila's story here (breast cancer trial)
- Watch Jessica and Chris's story here (fertility study)

About the NIHR Annual Statistics

The NIHR's annual research statistics provide the most comprehensive data around the state of health research across the country. NIHR plays a key role in supporting and funding clinical research in England - including recruiting patients into vital studies which can potentially lead to the development better care and treatments in areas such as cancer, dementia, mental health or fertility - ultimately making a difference to people's lives.

Note:

All data represents clinical research studies supported by the NIHR Clinical Research Network (CRN). Data are sourced from the NIHR CRN Portfolio of studies. More information is available here. The data does not include numbers of participants recruited into studies across other parts of the NIHR, particularly NIHR Biomedical Research Centres and Clinical Research Facilities, which are collated annually and will be available in June.

“From my vantage point I was watching someone working in a small greenhouse”.

This was not an unusual activity for early May, the full gardening season now being upon us. What was out of context was that this small oasis of plant life was on the tarmac at the rear of a four-storey residential block in Holborn. There was no garden, just car parking and large bins surrounded the 'glasshouse'. It just shows that nurturing has few limitations and that was the spirit in my room.

Our venue was a meeting area on the 13th floor London offices of the Medical Research Council at Kemble Street. I was with my UK Standards Development Partnership Group for another day to be spent discussing the Standards for Public Involvement (PI). It was to this very floor that I had come nearly three years ago for the first meeting of these partners. In the time since, with the help of many others, our public involvement product has grown considerably, but it is not finished yet. We could compare it to a vine that grows continually and becomes ever more fruitful, even if it needs pruning and a slight re-set at times. Well that's my belief and what I contribute genuinely matters in this room. I, along with Una Rennard, the other public member, have been with this work since the start. There is no tokenism here in terms of contributor status. We are with partners from all over the UK who meet, discuss content and make decisions with a view to advancing our production. A four nations’ show skilfully coordinated by Sally Crowe, our facilitator and support.

Our joint overall aim is to prepare a set of PI Standards that will assist with further improving the quality of public involvement in health research. Public involvement in research is already happening and it is on that solid foundation that we are building. Some existing work is very good and we are not seeking to stifle or inhibit that. But you probably already know all this! You will be aware that the four nations have rather uniquely in these times decided to work jointly. That the first version of the Standards had nearly 700 responses to a consultation and that the duly adjusted version has been trialled for a one year period with 10 Test Beds around the UK. Also, one of those Test Beds is assessing the suitability of the Standards for social care research.

Indeed, over 50 individuals and organisations from different research settings applied to be a Test Bed. A further 47 individuals and groups have used the Standards on a 'freestyle' basis, more assistance in testing our 'product. So many people being interested, engaged and prepared to help. We take that as an indicator of the enthusiasm of others to further improve. After all, if you are getting the public involved, then let's maximise the input and benefits. It is a great motivator that so many are working alongside us in this way.

So. that is the show that we have on the road and in this room we are again here to discuss progress and options. Most of the partners are in the room (Julie Simpson having set off at very early o'clock by train from Edinburgh, my train from Neath being just early o'clock) but some join by phone. Today we are to discuss the end of the Test Bed phase. The London debrief day is to be held nearby for all participants in a few weeks’ time. We need to capture the facts - how has our 'vine' fared when in use at working venues? What has worked well and what may benefit from change or adjustment? Also, there is the survey of the freestylers and the analysis of their views. When all this feedback is known, it has to be fully considered and then worked up into a version of the PI Standards that we can finally launch for use across the UK. So quite a lot to do and we must consider that for all the employed National Institute for Health Research, INVOLVE, Health and Care Research Wales, Public Health Agency (Northern Ireland) and Chief Scientist Office (Scotland) partners here this is not their entire 'day job'. We meet and we then do a lot more business remotely- away from the greenhouse.

Another subject matter of today will focus on how the finished product will be supported after launch because it will continue to need attention. This is a discussion that I have prompted as I see the need to iron that out. For her part, Una offers to lead on debriefing the public member attendees during the debrief day. This work is 'status free.' We are espousing what we advocate-the only set requirement is that when you are in a position to do so, then you contribute. This will go on to be another high-paced thorough day with little

more scope for window gazing. At the end of it, we will all go our own ways, but in the same direction as far as this work is concerned.

So bear with us, we have taken time to thoroughly test this product and we will further improve it. We are still four countries working together and if you are one of the 'Jo publics' who gets involved, rest easy – you are still meaningfully and well represented at the big shiny table.

UK Standards Development Partnership would like to thank all those who have actively contributed to the 12-month piloting period of the UK Standards for Public Involvement.
On the 16 May 2019, the 10 Test Bed sites joined the Partnership for a final workshop in which they shared their experiences. You can follow the day on Twitter using the #UKPIStandards hashtag. Our ten Test Beds were:

- Asthma UK Centre for Applied Research (@AUKCAR)
- Clinical Research & Innovation Office, Sheffield Teaching Hospital NHS
- Foundation Trust (@Shef_Research)
- Implementing the New Standards for Public Involvement in Research Environments (INSPIRE), Keele University (@keelePPIE, #KeeleINSPIRE)
- Kidney Patient Involvement Network (KPIN) (@p_ormandy, #KPIN)
- Northern Ireland Cerebral Palsy Register (NICPR), Queen's University Belfast(@QUBSONM, #engagehsc)
- Palliative and End of Life Care Patient and Public Involvement (PPI) research group, School of Medicine, Dentistry and Nursing, University of Glasgow (@BridgetJohnst)
- Royal College of Obstetricians and Gynaecologists' (RCOG) Women's Network – Public Involvement in O&G Research Prioritisation (@RCObsGyn)
- Royal College of Speech and Language Therapists (RCSLT) research priorities project (@RCSLTResearch)
- The Public Programmes team, Manchester University NHS Trust (@researchdialog)
- The Wales School for Social Care Research and CADR (the Centre for Ageing and Dementia Research) (@WalesSSCR, @CadrProgramme)

We are also extremely grateful to the 30 individuals and organisations who registered and shared their experience of being a freestyle pilot site.
Our 30 Freestylers were:

- A public contributor
- Asthma UK
- Bowel Cancer UK
- Cardiff University School of Medicine
- Centre for Dementia Research, Leeds Beckett University Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation, King's College London
- Collaborations for Leadership in Applied Health Research and Care (CLAHRC) West Midlands
- Edinburgh Centre for Research on the Experience of Dementia, University of Edinburgh
- Edinburgh Clinical Research Facility Patient and Public Involvement Group
- Edinburgh Critical Care Research Group
- GPs in EDs Study, Swansea University
- Health and Care Research Wales Support and Delivery Centre
- Health Research Authority
- NHIR Evaluation Trials and Studies Coordinating Centre (NETSCC)
- NIHR Central Commissioning Facility
- NIHR Devices for Dignity MTC
- NIHR Doctoral Research Fellowship (DRF-2016-09-119) 'Good practice guidance for the prediction of future outcomes in health technology assessment'
- NIHR INVOLVE
- NIHR National Director for Patients, Carers and the Public
- NIHR Public Involvement Collaborative East of England
- NIHR Surgical MedTech Co-operative
- NIHR Surgical Reconstruction and Microbiology Research Centre
- NRS Primary Care Network Public and Patient Involvement Group
- Parkinson's UK

- People in Health West of England (PHWE)
- Stories of Dementia Research Group , Cardiff University
- SUPER and PRIME Projects, PRIME Centre Wales
- University of Surrey
- Wales Cancer Research Centre
- Wessex Public Involvement Network (PIN)

The data from all our pilot sites is currently being analysed and the Standards will be refined over the summer. We will be sharing more information in the coming months but overall, we are encouraged that the Standards have been welcomed and are creating the ambition to improve public involvement and in many cases are already improving everyday practice.

460 patients took part in NIHR-funded research to help identify the best treatment for open fractures of the lower limb. Read our Making A Difference story to learn about the benefits of taking part.

The challenge

A broken bone, or fracture, of the lower limb is a common injury which occurs when a force exerted against the bone is stronger than the bone can bear. If the fracture is 'open', where the bone has broken through the skin, the wound is exposed to contamination - leading to an increased risk of infection. In the UK general population, the risk of open long-bone fractures occurring is approximately 11.5 per 100,000 people per year. However, this type of injury is much more common for military personnel, who often suffer more severe injuries too. Open fractures require urgent surgery to clean the wound, remove dead tissue and stabilise the broken bone. However, despite the surgery, there is still a risk of wound healing complications such as infection.

In severe cases, the risk of an open fracture becoming infected can still be as high as 27%.

As well as affecting the recovery of the patient, infections can also increase healthcare costs due to longer hospital stays or extra treatments.

One of the factors which may improve wound healing after an open fracture is the choice of dressing applied to the wound at the end of surgery. Standard dressings have a non-stick surface which is applied to the wound covered with a waterproof layer.

Negative Pressure Wound Therapy (NPWT) is an alternative dressing for open fractures. The device creates a vacuum using a suction pump which removes blood and fluid that may collect in a wound. However, NPWT dressings and the vacuum machines are considerably more expensive than traditional wound dressings, and whilst popular with surgeons and patients, there was little information about its effectiveness prior to the WOLLF (Wound Management of Open Lower Limb Fractures) study.

The research

As part of the NIHR-funded WOLLF study, 460 patients across 24 major trauma hospitals took part in research comparing NPWT with standard dressings for open fractures of the lower limb.

The £2.18m trial was funded by the NIHR Health Technology Assessment Programme and supported by the NIHR Oxford Biomedical Research Centre, the NIHR Collaboration for Leadership in Applied Health Research and Care Oxford, and the NIHR Clinical Research Network who helped to consent patients to take part in the trial.

The findings of the research showed that there was no evidence that NPWT reduced patients' disability after 12 months, and therefore the research doesn't support this particular treatment for severe open fractures.

As a direct result of these findings, NICE clinical guidelines for the assessment and management of complex fractures will be updated. This update will focus on the role of NPWT in open fractures.

Given that NPWT dressings and the vacuum machines are considerably more expensive than traditional wound dressings (with NPWT costing on average £84 compared with approximately £4 for standard dressings), the research and subsequent change in guidelines will be expected to lead to considerable cost-savings for the NHS.

Patient story

Dominic Burton, a demonstration car driver from Banbury, was enrolled onto the study in 2013 after sustaining an injury to his right leg following a forklift truck accident at work. The ambulance crew made the decision to admit him to the John Radcliffe Hospital in Oxford, a major trauma centre serving the Thames Valley region.

Explaining his decision to take part, Dominic said: "Everything was explained in terms of what the trial was aiming to do and what it would focus on. "I knew I probably wouldn't be coming home in the next couple of days and was feeling a bit low at that point, and I thought about how the trial might help someone else who found themselves in the same position as me, so I said it was absolutely fine."

Dominic was given a standard dressing and was in hospital for just over three weeks before he was discharged. He experienced benefits from the trial that he did not initially expect.

Patients taking part in the trial were required to complete questionnaires during the year after sustaining their injuries, to allow the research team to assess their level of disability, rate of infection and quality of life. This aspect of the research supported Dominic's 18-month recovery in additional ways.

"By asking about my personal wellbeing in addition to my physical injury, the questionnaire made me think a bit differently." "I don't think I would have even considered some of the questions had I not been asked them as part of the trial."

BE PART OF RESEARCH

NIHR celebrated International Clinical Trials Day on 20 May through its Be Part of Research campaign, encouraging patients, carers and the public to get involved in research. The campaign coincides with the launch of the new Be Part of Research website (formerly UK Clinical Trials Gateway), which allows anyone to search for opportunities to participate in research. You can get involved by pledging to take part in research and supporting the campaign on social media - visit our website to find out more.

The website will show you what you can do and displays a Pledge button for you to commit your support. There are links where you can share a message of support on your social media account, add a Twibbon to your social media profile and share a picture with our social media board.

You can order printed materials to help spread the message.

Talking about research really helps. You could:

- ask you GP of healthcare professional about opportunities to participate in research
- suggest a friend takes part in research
- run a local event to raise awareness

Dementia Action Week: everyone has a role to play in dementia research.

Professor Martin Rossor reflects on how far we've come and the next steps for dementia research in his blog for Dementia Action Week 2019. You can help research take the next step forward by registering with Join Dementia Research. Read his blog:-

21 May 2019 - We are fast approaching five years since the publication of the Dementia 2020 Challenge, which set the ambition to make England the best country in the world for dementia care, support, research and awareness.

Reading the Dementia 2020 challenge: Phase 1 progress review, it is remarkable to see the progress made to date. Importantly, we can now look beyond 2020, understanding international priorities for tackling dementia by 2025 (WDC Defeating dementia: the road to 2025).

Over the last few years, there has been significant investment in dementia research in the UK. We've come a long way in building our research infrastructure and improved collaboration between initiatives. While there have been disappointing results from some recent studies, there are many other studies that build on the knowledge gleaned from unsuccessful trials.

Why we need dementia research

Here in the UK, the Dementia Attitudes Monitor, published by Alzheimer's Research UK in January, served as a reminder of why research is important to improving the lives of people affected by dementia. Members of the public identified cures and prevention as their priorities for research, and those with experience of dementia also highlighted a need for research into improving care. The monitor showed people would be prepared to undergo diagnostic tests for dementia at an early stage, if we can develop less invasive techniques such as eye scans and blood tests.

The good news for researchers, who are critically dependent on volunteers to take part in their studies, is that 50% of those who responded to the survey said they would be willing to participate in research studies. Some of the key challenges that remain are how we help those people find studies to participate in and how we raise awareness of what research can involve - a key barrier identified in the report for many of those who currently don't want to take part.

Improving coordination between researchers

As a result of the Dementia 2020 Challenge, a number of initiatives supporting public participation and involvement in research have successfully been developed. In January I convened a workshop to review the overlaps and gaps between several UK dementia research registers. Our aim was to ensure that members of the public can access information about the many ways in which they can contribute to dementia research. Join Dementia Research was identified as the best service through which we can signpost opportunities, as a national publicly accessible service that provides genuinely informed consent.

Beyond the scope of clinical research, I recently attended the first meeting of "Dementia Ecosystem UK". This is a new collaboration which will bring together the major UK dementia research initiatives working across the research pathway, from those investigating in the lab to those working with the public to see which treatments provide real benefit. The aim is to create a joined-up community so we can accelerate research and ensure that there is a strong pipeline of potential new treatments.

All healthcare professionals can help accelerate research for patient benefit

Over 40,000 volunteers have already registered with Join Dementia Research but we need more people affected by dementia to sign up. To do this we need to spread the word to those affected by dementia.

It has been heartening to see the importance of research being recognised in the post-diagnosis pathway for people with dementia over the last year. Research is now included in both the NICE Guidelines (Dementia: assessment, management and support for people living with dementia and their carers), and in NHS England's Dementia: Good Care Planning Guidance. Additionally, new SNOMED codes are available which will enable clinicians to log any conversations they may have with patients about dementia research.

A simple tool to give you the confidence to talk about research

Join Dementia Research is the easiest way for health and care professionals to meet the recommendations set out in these guidance documents. Trusts have been working very hard to embed Join Dementia Research in their routine practice but we acknowledge the need to support health and care professionals to talk about research with patients and their families.

For this reason, the NIHR has developed a simple online learning tool. Taking just ten minutes to complete, it is designed to help healthcare professionals understand why dementia research is important for their patients, and how talking about Join Dementia Research can help them deliver best care according to clinical guidance.

You will watch a short informative film, answer a few questions (just to check you were paying attention), and then be asked to provide a little bit of information about yourself. Finally, you will be able to access further resources, and receive a digital certificate for completing the process.

Everyone has a part to play

As we near the end of the Dementia 2020 Challenge, I reflect on how far we've come and how much more we need to do. What remains clear to me is that each of us, whether as researchers, members of public or health and care staff, has a role to play in progressing research into dementia.

Trusts and healthcare professionals can access the Join Dementia Research learn tool at any time. The module takes just ten minutes to complete.

- Anyone aged 18 and older can register with Join Dementia Research and choose to take part in studies they match to on a case-by-case basis.

- Researchers can see if their study can use Join Dementia Research to find study participants.

Dementia Awareness Week runs 20-26 May 2019

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