NCRI Demystifying PPI in Cancer Research

Webinar Q&A

The following pages contain answers to over 50 questions that were asked at the NCRI webinar 'Demystifying PPI in Cancer Research' held on Thursday 12th November 2020.

We have grouped the questions where appropriate and have aimed to answer each point raised. The panel members and two additional members of the NCRI Consumer Forum, drafted and reviewed all the responses. Their bios are at the end of this document.

We were delighted to have so many people attend the webinar and thrilled that it has generated so much interest in PPI, the NCRI Consumer Forum and the other opportunities for involvement provided by the NCRI Partner organisations.

If you still have unanswered questions after reading the paper then please do not hesitate to reach out to us by email at consumers@ncri.org.uk

With my best regards,

Emma Kinloch
NCRI Consumer Lead, and panel Chair

Contents

1. Patient & Public Involvement

Getting involved, first steps, the role, time commitment, skills needed (and more!)

Q. If a past cancer patient is interested in becoming involved with PPI for their specific cancer, what's their best first step?

Liane Hazell, NCRI Forum Programme Manager said:
There are a wide range of different involvement opportunities available for those interested in becoming involved with PPI. We would recommend taking a look at the 'PPI opportunities across the NCRI Partnership' booklet as a first step for those wanting to get involved in cancer research specifically. This includes more detailed information about the range of involvement opportunities available at NCRI and our Partner organisations, and how you can sign up to hear more and get involved. Some partners are focussed on specific cancer types and some opportunities are more general.

At NCRI the majority of our consumers (patients, carers and others affected by cancer) are involved in our work through the NCRI Groups. The majority of our Groups are site-specific e.g. Breast Group, Bladder & Renal Group, Lung Group etc., and other Groups are 'cross-cutting' (i.e. do not focus on a specific cancer type), for example the Living With and Beyond Cancer (LWBC) Group or our radiotherapy and pathology initiatives. I would recommend taking a look at our website, to decide which Group(s) you may want to get involved in, based on your interests and experiences.

To hear more about the opportunities available at NCRI, and to express your interest in getting involved with a particular Group(s), please fill out our 'Expression of Interest' form.

Q. Do I need to have a scientific background?

Liane Hazell, NCRI Forum Programme Manager said:
A scientific background is ***not*** essential for Patient and Public Involvement (PPI).
All NCRI activities have direct input from patients and carers who are experts in the experience of cancer and therefore can make contributions as a result of their lived experiences. You can read more about this here. For all NCRI roles consumers (patients, carers and others affected by cancer) receive comprehensive induction training. This includes training on scientific language/jargon and equips you with the skills required to take part in our activities.

NCRI also ensures that all consumers who join our Groups are assigned a 'Scientific Mentor', the role of the mentor is to support consumers with any queries relating to their role on the Group. This could include queries regarding meeting content, and scientific language/terminology. Consumers are also assigned a 'consumer buddy' who provide additional peer support. The NCRI Consumer Forum members are connected by a shared email group and regular meetings, where good practice and ideas are discussed and formed.

Many of the NCRI Partners also provide training for their PPI roles, and more information can be found here. If in doubt, please don't hesitate to get in touch.

Q. What is the range of different time commitments for patient involvement? If my situation changes and I have less time to give, will I be letting people down?

Liane Hazell, NCRI Forum Programme Manager said:
This can really vary, so please make sure you always check the role description and/or advert carefully before applying for a PPI role. Depending on what organisation you are looking to get involved with, you may find one-off opportunities for involvement (e.g. designing a survey, facilitating a focus group or taking part in a NCRI Proposals workshop), as well as longer-term commitments (e.g. NCRI Group roles, Prioritisation and Funding Committee roles etc.) The best way to find out about NCRI opportunities is to sign up to our network or email us at consumers@ncri.org.uk.

Emma Kinloch, NCRI Consumer Lead said:
It is important that when you apply for a PPI role, that you are able to meet the time commitments outlined in the role description and/or advert. That being said, throughout healthcare research there is an understanding that circumstances may change and that we may need to adapt accordingly. Be sure to let the organisation you are working with know if this is the case, and they will be happy to help.

Q. I support a network of patients and carers in Yorkshire. How can I signpost them to getting involved in research?

Liane Hazell, NCRI Forum Programme Manager said:
We would recommend signposting the 'Demystifying PPI in Cancer Research' webinar which can be viewed for free 'On Demand' by visiting our website, as well as sharing this supplementary Q&A document and 'PPI opportunities across the NCRI Partnership' booklet. Your patients could also be directed to local hospitals in your area, which may offer additional opportunities to get involved. Yorkshire Cancer Research also has involvement opportunities https://yorkshirecancerresearch.org.uk/

Q. As a patient, with a specific cancer, how do you equip yourself to contribute effectively to research into other/all cancers?

Emma Kinloch, NCRI Consumer Lead said:
Whilst many of the effects of cancer are 'cancer specific' there are also many that span across cancer types and there are opportunities to get involved in these more 'general' areas such as the NCRI 'Living With and Beyond Cancer' (LWBC) group.

In general, the skills needed to contribute effectively are common across cancer types e.g. clear communication, lived experience. All of us involved in PPI develop, learn and adapt as we become more experienced and this is true of all cancer types.

Q. Do Research Champions have a role to play within cancer research?

Liane Hazell, NCRI Forum Programme Manager said:

Yes - NIHR (National Institute of Health Research) Research Champions 'volunteer their time to help spread the word about health and care research to patients and the public, and especially those groups who are currently less likely to take part in research.'

There are a number of ways to get involved, and you can learn more by visiting their website.

Q. Would the panel members comment on the role of the PPI lead (or the role of the PPI co-applicant), i.e. someone in a leadership in PPI role. NIHR have a job description for this role.

Richard Stephens, NCRI Consumer Forum member said:
The answer depends on what the leadership role includes – and also on how the organisation or group wishes to fill it. At the NCRI the Consumer (PPI) Lead has been a patient since 2015 and combined with the Chair of the Consumer Forum (previously Consumer Liaison Group), which has always been a patient. Unlike at the NIHR and elsewhere, the postholder is a volunteer not an employee but the NCRI does have a role description and formal open selection process.
For PPI on a study team (including co-applicant) the MRC CTU has some excellent materials available, co-designed with PPI representatives who have been co-applicants, members of TMGs etc - www.ctu.mrc.ac.uk

Q. Any thoughts on the 'Public' role as opposed to the more obvious 'Patient' in PPI?

Tim Banks, Tenovus Cancer Care said:
I think the public play a key role in PPI, but it should be recognised that this role is different to that of the 'Patient' who offers a unique perspective. The public getting involved though is vital. We are increasingly seeing applications in population-based research as well as research that focusses on prevention and early diagnosis. By its very nature, it is the public who are perfectly suited to get involved and share views on these projects. As I say though, the 'Patient' through their lived experience of their illness offers additional expertise and insight. We also need to consider how others 'affected' cancer might also be involved such as carers and those bereaved. They are also incredibly important and perhaps neither the term 'public' or 'patient' recognises their position fully? Finally, we must also recognise that the terms are fluid with many people occupying each term simultaneously. You are both a 'Patient' and member of the public. You might be a 'Patient' and 'Carer' simultaneously or sadly a carer who becomes bereaved so whilst each term has something to offer, very often the individual is perfectly placed to give multiple perspectives.

Q. Should there be more emphasis on the time dedicated to PPI work? Charities that are lucky enough to have paid staff invest incredible time and efforts to collaborate on PPI work - but this time is not always compensated. Could this time/cost be factored in for funding applications of clinical trials?

Tim Banks, Tenovus Cancer Care said:
I think the time dedicated to PPI work should certainly be better recognised. I know that many give huge amounts of time to their input. However, when we consider increasing diversity and inclusivity, a key part of this might be ensuring that involvement is manageable both in terms of time and compensation. Many applications we [Tenovus Cancer Care] receive do recognise that good PPI needs to be properly financed and they are scored for this, but I appreciate this is not

across the board. As we are seeing a tighter squeeze on charities and research in general, I fear that budgets will be even more constrained. I would urge all funders not to allow the money to be saved by cutting PPI input. One of the challenges in PPI is the lack of numbers of those involved. This inevitably means those who are involved find their time increasingly taken up. Whilst their commitment is laudable and should be recognised, we must also strive to increase the numbers involved to help, hence events such as this.

Q. I think the role/importance of PPI is now well-established in the UK. My opinion is that we need to include PPI earlier in the process - directing funding to areas of interests to patients. How can we embed PPI into funding streams and panels, more effectively?

Tim Banks, Tenovus Cancer Care said:
I could not agree more. At Tenovus Cancer Care, we have had PPI involvement in many of our grant streams; indeed, they exclusively made up one of our panels. The NCRI took this even further with the Living with and Beyond Cancer prioritisation exercise where patients helped to set the research agenda. Having PPI at every stage of the process, on both the researcher and funding panel, often makes for more impactful, relevant and successful research. A good start to encourage earlier involvement is by increasing recognition of the benefits and by running events such as this to encourage people to think how they can make it happen successfully in their own individual situations. Providing forums to share best practice is also a good idea. Making sure those involved are properly trained, supported and recognised can increase their motivation as well as their effectiveness which will hopefully, in turn, ensure they are retained as well as encouraging others to join.

Richard Stephens, NCRI Consumer Forum member said:
In January there is a research study starting within NIHR that will be looking at improving the quality of PPI input to their funding mechanisms. It is scheduled to report in autumn.

Q. How do you achieve a good balance between the level of PPI's input/advice and researcher's experience/expertise?

Emma Kinloch, NCRI Consumer Lead said:
The NCRI Groups model allows for the PPI input to be on an equal footing with that of the researcher. At Group meetings, all members have an equal voice and it is the responsibility of the Chair to ensure that discussions include all Group members. The balance of input will sometimes depend on the topic for discussion and so may vary on a case-by-case basis. The important point is to ensure that there is an opportunity for all perspectives to be heard and included.

Q. Sometimes, important PPI suggestions or recommendations are made, but not necessarily upheld, especially re access to drugs post clinical trial. How can we ensure this important factor is always upheld?

Roger Wilson, NCRI Consumer Forum member said:
Access to drugs post-trial is not usually something that researchers can influence as researchers – they may have other roles though. The research results must be peer-reviewed and published

before moves towards being used in standard-of-care can be considered. A new drug may need an application to the regulators for marketing authorisation and it may need to be appraised by NICE for cost-effectiveness. No recommendations made by patients at an early stage will be considered by the regulatory bodies, they have their own patient involvement approaches. A funder (e.g. a pharma company) may listen to patient input at an early stage but its strategy through and post development will usually be dictated commercially. We need to be pragmatic and have expectations appropriate for the stage of a drug's progress to acceptance, failing to do that damages our credibility. However, we should also identify the appropriate channels in which to make our voice heard at each stage. We should also of course challenge structures which need changing.

Q. What is meant by 'patients with agendas'?

Dave Chuter, NCRI Consumer Forum member said:
This was a comment raised by me, although it is very uncommon there has been a patient or two who wanted to get involved with research because their treatment or experience was consider wrong or poor and not as they expected so was only getting involved to voice their anger and frustration to the researchers and research organisation.
We as patient or public representatives need to be unbiased and without any baggage to be able to concentrate on the research put to us, to use our experience as a patient to give our views and be able to represent all patients for safety, quality of life, wellbeing, better outcomes and if in our view the research is suitable and will be able to recruit patients.

Q. Does the research include looking at the effects of treatment and how sometimes the cure can cause side effects, e.g. use of PPI (Proton Pump Inhibitor) can push some patients towards diabetes and other problems?

Dave Chuter, NCRI Consumer Forum member said:
Yes, the research does include the looking at the side effects of treatment which could include surgery, chemotherapy, radiotherapy, other drugs including Proton Pump Inhibitors.

As the Lay person / Consumer I do look at all of the treatment, drugs, etc. in all arms of the trial to ensure patient safety and quality of life is maintained and explained fully in lay terms for the patients.

Treatment is about removing (surgery) or killing the cancer cells by drugs or radiotherapy, all do have side effects and can harm normal cells, so it has to be a balance to treat and prolong life vs causing side effects that can do harm.

PPI use I can personal comment on as have been taking daily for the past 14 years after surgery for Oesophageal cancer, without it I do suffer from reflux and bile rising up all of the time which would cause more harm to my throat and lungs, all Oesophageal cancer patients will be taking a PPI after surgery for the rest of their lives and is a balance of the risk of long term use against being able to control the reflux and bile, a quality of life and wellbeing choice for me.

Q. The issue is finding more consumers to take part in research projects. I note on the be part of research website it states for the trial to be included in the listing it must be registered with ISRCTN or clinical trials.gov. This is the root of the problem in that by that time the research project has already been developed. We need consumer input earlier.

Dave Chuter, NCRI Consumer Forum member said:
Finding consumers to take part in research projects is often due to the time required to be involved as a volunteer especially if the patient has work or family commitments, or if the research is for a rare cancer group, or if the researchers do not have the contacts of patient groups, charities and organisations that can help.

There are no reasons for Consumers to not be included at the concept, design and development of the trial, many funders are looking for and requesting consumer input from the start and I have been involved with trials from the design stage and listed as co-applicant on the funding applications.

The larger Pharmaceutical companies are also very aware that Consumer input from the outset is important and required, especially to recruit patients on to the trial when funded and recruiting.

I feel the root of the problem of involving consumers at the concept and design stage is more an issue with the research organisations but it is changing, and the importance is now being recognised.

Q. Do you take ideas from patients and design studies on them?
Is any of the research that is chosen driven by a patient request into a specific area?

Alison Fielding, NCRI Consumer Forum member said:
The ideas of patients and public representatives do feed into research projects. A current example is the work that has followed the 'Living With and Beyond Cancer' project to prioritise research into the short, medium and long term side effects of cancer and its treatment. Quality of Life outcomes increasingly feature in research projects as a result of PPI input.

The Consumer Representatives on NCRI groups have an opportunity to raise possible areas and work with the researchers to identify if there is a possible project, how it fits with the priority research questions and, very importantly, whether it can get funded.

Q. Do have any thoughts on if the cancer community does PPI well compared to others? Could we learn from other disease areas or could we share our PPI experience with others?

Liane Hazell, NCRI Forum Programme Manager said:
We certainly do feel that the cancer community does PPI well, across both the NCRI Partnership and beyond. That being said, we are always open to learning and this includes learning from other disease sites, as well as sharing our own cancer PPI experiences with others.

The NCRI, alongside many of our Partner organisations are members of the Shared Learning Group on Involvement (SLG), and its subgroup the Charities Research Involvement Group (CRIG). This

collaborative group aims to encourage shared learning about Patient and Public Involvement between national voluntary sector organisations in the UK. The membership therefore goes beyond the cancer community, and we meet throughout the year to share best practice, discuss common areas of interest and collaborate on specific pieces of work.

A recent report created by members of the CRIG focuses on 'how involvement in research adds value for charities' and can be accessed here.

Richard Stephens, NCRI Consumer Forum member said:
Most NCRI Consumers are involved in health research activities beyond the NCRI itself, including several internationally, and there is wide sharing of good practice, journal papers (especially from the journal of Research Involvement and Engagement) and so on. Good PPI is a continuing conversation, not just us with researchers, but us with each other too.

Q. I was last treated 7 years ago and have been involved for many years. When does the panel think my validity as a patient might expire?

Emma Kinloch, NCRI Consumer Lead said:
No one that has experienced a diagnosis and treatment for cancer has their validity as a patient 'expire'. Cancer treatments are changing and advancing and as such, there are new concepts and approaches for us all to keep up to date on and be aware of, in order to contribute effectively in the research arena. This doesn't mean that if you weren't treated with a particular treatment that you are not able to effectively contribute to discussions around it. One of the key points for NCRI consumers is that they are connected to other patients and are able to represent their views/experiences even when different from that of the individual.

Q. Is there a danger that a PPI representative could become 'serial/career' representatives over a long term? should PPI representatives be cycled every few years to ensure new views are heard?

Emma Kinloch, NCRI Consumer Lead said:
There are some people who have dedicated their working life to PPI and been involved for a number of years. The NCRI Consumer Forum is a mix of these 'longer standing' consumers and newer consumers, who have more recently become involved in PPI. The mix of experiences and tenure is a key strength of the Forum. Understanding the history and background to issues can be key in understanding the current climate/discussions. Similarly, having newer members allows for us to hear new views, and welcome those with experiences of the most up-to-date treatments.

Q. Do you have any suggestions for involving people living with dementia in PPI?

Liane Hazell, NCRI Forum Programme Manager said:
Although NCRI does not have specific expertise in involving people living with dementia in PPI, we would recommend getting in touch with the following charities who may be able to offer guidance: Alzheimer's Research UK and Alzheimer's Society.

Alzheimer's Research UK have developed 'Lived Experience of Dementia packs' which may provide some useful insight.

Alzheimer's Society have produced the following blog about the impact of their Research Network Volunteers, and how Patient and Public Involvement (PP) helps dementia research to progress.

Here is a resource is from the Nursing Times - a learning unit on 'Involving people with dementia in research'.

Here is an additional article on 'Alzheimer Europe's position on involving people with dementia in research through Patient and Public Involvement (PPI)' which may also be of use.

2. Terminology

What should we call patient representatives and advocates?

Q. I notice that Emma and the Panel are quite happy to use the term PPI which could be confused with Payment Protection Insurance. NCRI uses the term Consumers but there are so many terms- does the Panel think that the different terms for those with lived experience could hinder people getting involved in research?

Liane Hazell, NCRI Forum Programme Manager said:

Take a look at our blog 'what should we call patient representatives and advocates' which explains why we use the word 'consumer', as well as addressing the debate around alternative terminology.

This also includes a link to 'In praise of the "consumer"' written by NCRI Consumer Forum member Roger Wilson CBE, in which he debates the semantics of patient involvement, centring around the different terms used.

3. Involving patients in my research

Guidance for researchers

Q. We talk a lot about PPI at the start of a trial during the development. Are there any thoughts on how best to relay trial results to patients/family of patients?

Alison Fielding, NCRI Consumer Forum member said:
It is important that trial participants and the wider patient community are able to access plain language summaries of the outcomes of trials. This includes personal feedback from the medical team working with the patient whilst on the trial and written information. Briefing patient groups so that they can share information in plain language is also a useful strategy. The use of infographics is useful in helping people understand the data. The International Kidney Cancer Coalition has worked to produce its own infographics to help researchers, clinicians and patient groups explain trial outcomes. Some samples are included here.
https://ikcc.org/infohubpost/graphic-trial-results/

Q. How can researchers get more PPI involvement in their trials other than just the traditional review of documents and Trial Management groups?

Liane Hazell, NCRI Forum Programme Manager said:
One of the activities the NCRI Consumer Forum hosts regularly is the 'Dragons' Den', which provides an opportunity for researchers to present their research ideas to people directly affected by cancer (our Consumer Forum members).

During the session, participants discuss proposals at *any* stage of the research process, from patient information and consent, studies seeking support for funding or ethics applications, trials with recruitment problems, to completed studies which require dissemination for example.

The events are a great example of how NCRI encourages collaborative and productive involvement from patients and carers. Researchers apply in advance to attend the session, so that Consumers with experience in a particular topic or issue can be assigned to a relevant research proposal.

For more information click here, and the application form can be found here

Q. We would like to increase out PPI in radiotherapy research - what is the best way to approach people to potentially join or to see if patient would want to be involved?

Liane Hazell, NCRI Forum Programme Manager said:
There are some radiotherapy focussed PPI groups at some local hospitals who undertake research.

The NCRI Consumer Forum has many members with experience and an active interest in radiotherapy research. This may include consumer members of site-specific groups, NCRI CTRad (Clinical and Translational Radiotherapy Research Working Group) or members of the wider Consumer Forum. If you would like to learn more or discuss opportunities then please get in touch with us by emailing consumers@ncri.org.uk.

Q. I am a researcher and setting up our first patient advisory group, would anyone already doing this be prepared to share standard operating procedures or terms of reference with me?

There are some resources that can be leveraged for general guidance on PPI across disease areas and the UK:

1. The NIHR Training and Resources for PPI in research https://learningforinvolvement.org.uk/
2. The UK standards for public involvement https://sites.google.com/nihr.ac.uk/pi-standards/home
3. Wiley-Blackwell BMJ pocket guide, "*Patient and Public Involvement Toolkit*" by Julia Cartwright and Sally Crowe. Available on Amazon.
4. Health Education England, Terms of Reference: https//www.hee.nhs.uk/our-work/patient-advisory-forum

For more specific guidance around PPI in cancer research, please reach out to us at consumers@ncri.org.uk

4. Involving patients in the 'virtual world'

Q. Social media has been mentioned. Is there any guidance for researchers in terms of social media use to promote PPI? or social media use in general?

Liane Hazell, NCRI Forum Programme Manager said:
Here is some useful guidance from the National Co-ordinating Centre for Public Engagement titled 'What Works – Engaging the Public through Social Media'

Here is some additional guidance from NIHR (Involve) titled 'Guidance on the use of social media to actively involve people in research'

Dave Chuter, NCRI Consumer Forum member said:
You can find additional guidance via the following links from University College London (UCL); the University of York and Lancaster University.

Q. How do you engage with the groups given face to face isn't so easy at the moment? Teams discussions? Emails?
Q. Here in Manchester we had started to talk about research at patient group meetings now they no longer take place due to covid how can we still get the message and info through?

Alison Fielding, NCRI Consumer Forum member said:
It is excellent that you were talking to patient groups directly. Many patient group meetings are still possible using technology such as Zoom and MS Teams. In fact, some patient led groups are now having more people attending their virtual meetings than came in person. Others are using popular platforms such as Facebook Live to host events. The appropriate one depends on your group and the sensitivity/confidentiality required for the discussion.
Many institutions have 'Involvement' teams to help facilitate discussions with patients and the public and they are a good starting point for your project.

Where people are using video technology for the first time, offer a written guide and an opportunity to try it out before any larger events. Other patients may be able to help with this mentoring.

As online meetings tend to be shorter and suffer from poor connections, it is important to consider how best to get the information exchanged and to have follow up information to send out.

If your patient group does not have a high internet literacy, then consider printing an email newsletter and sending by post or having information in clinic.

You can use Twitter to share information as many patients follow their teams and hospitals online.

5. Involvement with Pharma/Industry

Q. I work in Pharma and want to support co-authored narrative articles with patients, carers and clinicians. Which organisations can help broker trust and manage such projects. They are generally linked to portfolio studies but obviously of broader appeal?

Roger Wilson, NCRI Consumer Forum member said:
We know of no organisation which includes that kind of engagement within its brief at present. The starting point may be the Chief/Principal Investigator of the study, asking them to providing contacts among their colleagues and patients associated with the study. Another option may be to develop relationships with appropriate charities.

Richard Stephens, NCRI Consumer Forum member said:
There is some movement in this area though with open access publisher BioMed Central seeking to encourage patient (co-)authorship later in 2021, in both their journal *Research involvement and Engagement* and also in the flagship journal *Trials*.

The Envision Pharma Group is working on patient (co-)authorship in industry as a field to develop and published early thoughts in two articles in the ISMPP Newsletter in May 2020, including a proposed tool:

'Patient Authorship: Three Key Questions (& Answers!) for Medical Communication Professionals' Part A and Part B

Emma Kinloch, NCRI Consumer Lead said:
We (as in the NCRI Consumer Forum members) are seeing more interest from Pharma companies to engage with patients and carers and co-author/co-produce documents. There are a few projects underway that members of the NCRI Consumer Forum are part of. Please do get in touch if there is something specific that we can assist with – even if it's just an initial 'fact finding' chat!

Q. Patient and carer perspective has to be part of the industry culture too. Do commercial companies do enough? What are they doing to take away the burden of participants?

Roger Wilson, NCRI Consumer Forum member said:
Patients and carers are increasingly being involved by pharma companies in their new drug development. It is certainly not 100% coverage and the smaller bio-tech companies are (as I see it at present) the least likely to have reached out in this way. Do companies do enough? We would say no, and many in industry would agree with us. But the landscape is changing and structures within companies are evolving to take responsibility for patient/carer involvement away from front-line researchers into a dedicated unit/team which works alongside them. Where this is working there is certainly patient involvement, earlier and more completely in the process.

All clinical researchers are aware of patient burden. Remember that they are doctors and the "do no harm" lesson is deeply engrained. However, in research there are unknowns, especially side effects in new drugs, and on occasion (rarely) there are "serious adverse events" (SAEs) which

require a trial to be stopped until regulators have reviewed what happened and make a ruling. No researcher wants this to happen and whether working as an academic or in industry they will do their best to ensure that it doesn't.

6. Diversity & Inclusion

How do we define 'diversity'? what steps can be taken to improve diversity & inclusion?

Q. I run both an ethics committee and a biobank. Engaging with patients to become involved in the running of the biobank and reflecting the ethnic diversity in the management committee is a challenge. We currently have a 30% PPI membership- is there any advice from the panel on how to increase this?

Q. "How can we improve recruitment of patients from a wider variety of backgrounds e.g. ethnicity, first language, reading level, disabilities, age etc?"

Q. What are those "good initial steps" being taken to improve diversity in PPI?

Tim Banks, Tenovus Cancer Care said:

To increase diversity and inclusion in research, in the first instance, is to recognise that we mean just that, providing appropriate and useful opportunities for *everyone*. As Dave pointed out, in certain instances this means the population that is most representative for the research but there are also many examples where PPI representation would be best served by being as diverse and inclusive as possible. This extends beyond ethnicity to include, age, language, gender, disability, education level plus many more demographics. My first instinct to make an impact in diversifying the pool of those involved is to think differently about how we consider what PPI is and what it needs to be.

We need to think about how we provide opportunities and what those opportunities might be. Ensure they are varied in terms of what activities are available, what skills are required, how much time might be needed and when etc. Can we make sure those who participate are not left out of pocket? Think about how we advertise. Does it always have to be online or in specialised locations? I think it can be all too easy to use the same methods and rely on the same systems to recruit. Perhaps being more pro-active and creative in thinking about other groups and forums for recruitment will pay dividends. Research champions can really help here. By this I mean working with people from the community who others can relate to.

Do meetings always have to be in the working week, face to face, with agendas and minutes? Does there always need to be meetings at all? Does everything have to be written down? Can views and input be given orally? We have seen with the pandemic a huge growth in the use of online platforms. Can we harness this opportunity to also increase accessibility?

We also need to challenge our own unconscious bias and assumptions. Why not provide the opportunities and let the potential PPI representative help you identify where they can provide assistance?

Events such as this webinar are a great start and there is a growing recognition for a need for greater diversity in research and PPI. Guidance such as the following is also a step in the right direction, but we know there is more to do.

To help improve diversity in trial recruitment, NIHR have just published a Roadmap which can be accessed here.

7. 'Impact' of Patient & Public Involvement

Q. How would you show whether/ how impactful PPI is in research? - and at what stage e.g. from study design and outcome measure to implementation of results?

Roger Wilson, NCRI Consumer Forum member said:
It is becoming increasingly clear that looking for 'impact' is to look for the wrong kind of measure – even if it is the one which senior managers grasp at. Patient involvement is subtle, a question asked, a comment made over coffee, an observation passed in discussion – all can have an influence on a study and no-one is taking notes about that. When asked a specific question, or challenging a particular draft, it is certainly clearer when a patient influences the direction or the detail of a study, but even so no-one is taking notes, there is no objective record. Add to that the absence of criteria which allow post-study review and you can see that 'impact' is impossible to report, even after 20 years or so. The issue is about changing the culture of research, in individuals, in a specific team, department, company, university, country. How you measure that is only going to be through subjective and qualitative measures, through anecdote, recall of what has not been recorded etc.
Recent paper in Research Involvement and Engagement is the latest element of the wider discussion:

Russell, J., Fudge, N. & Greenhalgh, T. The impact of public involvement in health research: what are we measuring? Why are we measuring it? Should we stop measuring it?. *Res Involv Engagem* **6,** 63 (2020). https://doi.org/10.1186/s40900-020-00239-w

Q. How do you best convince researchers of PPI value at the very earliest lab stages when the impact on actual patients is very distant?

Roger Wilson, NCRI Consumer Forum member said:
The biggest input that patients bring at the early stages can be summed up as 'the questions patients want to ask'. Many will of course have been thought of already, but some may not. The downstream ownership of research questions can be helped by having patients on board early because the questions which patients ask will have already been debated and addressed. This will help the project, especially if it is leading toward a clinical study which is where actual patients have to be convinced to enter it.

Richard Stephens, NCRI Consumer Forum member said:
Patient or public involvement in basic science is difficult. There are some papers published in Research Involvement and Engagement and the NCRI Research Groups and the Consumer Forum's Dragons' Den hold some good examples. CRUK's website on their Cancer Grand Challenge projects will have some examples showcased later in 2021, and there will also be opportunities for people to get involved: https://cancergrandchallenges.org/

One other aspect of patient/public involvement in lab research is the issue of tissue; biobanking, the donation of patient samples, the consent needed, what data is attached to it, etc. It is an area of increasing patient and public involvement.

Q. Does the panel feel that Patient Involvement must make a difference and that something has to change (i.e. have "impact") or can it also be quality-assurance (adding value)? Are there any examples that come to mind?
Q. How do you evaluate the impact/influence/outcomes for PPI?
Q. How can we better quantify the impact of PPI work? Especially with regards to industry work?
Q. PPI has to be impactful and shown to influence and have an effect – not just a token exercise

Roger Wilson, NCRI Consumer Forum member said:
The earlier discussion on impact applies here too, and the reference is also applicable.
We are at a stage in the development of our understanding of patient involvement where we are recognising that the 'impact' is subtle and hard to measure because it is cultural change, it is about small shifts in behaviour at different levels in the research hierarchy. This is qualitative data which is not generally kept, nor is it easy to develop. There are no criteria yet identified which we can use to measure/assess this change and the absence of a pre-PPI baseline will not help – especially as that baseline will have been different in different organisations. Fairly crude numerical indicators are available because there tend to be specific staff – numbers of patients consulted, numbers of multiple involvements by individual patients etc – but these are about activity not outcome. The NIHR PPI Standards provide a useful underpinning on activity and intent but further qualitative research is needed for the real outcomes.

Richard Stephens, NCRI Consumer Forum member said:
Personally, I prefer "adding value" to having impact. Most PPI is about conversations and it is hard in any conversation to show whether or not you have influenced outcomes or decisions, and if so, how much. The important thing for PPI is to be having the conversations, including the challenging ones.

Q. All PPI that must involve change or evidence of agreement from patients - are trials monitored for how much effect/influence PPI as had?

Roger Wilson, NCRI Consumer Forum member said:
This would be impossible as each study would need to have a comparator parallel study without PPI. We have to be cleverer than that.

Richard Stephens, NCRI Consumer Forum member said:
MRC CTU has published a couple of papers about the effect of involvement on trials, including this one:

South, A, et al,
Models and impact of patient and public involvement in studies carried out by the Medical Research Council Clinical Trials Unit at University College London: findings from ten case studies

Trials volume 17, Article number: 376 (2016)
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-016-1488-9

STAMPEDE is a cancer study worth looking at for very active patient - and participant – involvement, especially in the way it presents information: http://www.stampedetrial.org/participants/about-stampede/

Patient Advocates have suggested that the new NIHR Centre for Engagement and Dissemination should publish some of NIHR's evaluations of their PPI, and we know that patient-to-patient consenting for tissue donation has proved successful at several hospitals in the UK.

Q. Can you please share the reference Tim mentioned about value of PPI for charities?

Liane Hazell, NCRI Forum Programme Manager said:
Here is the link to the 'Value of PPI for Charities' doc referenced by Tim: https://bit.ly/3nda2O2

8. The 'future' of Patient & Public Involvement?

Q. In which ways do you see Big Data and mobile technologies changing research and the role of PPI in research?

Roger Wilson, NCRI Consumer Forum member said:
This is one area where we can see huge and important change on the way. The growing need for direct patient reporting (PROs) in research (rather than clinician observation and interpretation of what patients' experience/say) also suggests that patients should be able to respond as and when they wish. This indicates use of smartphones and other mobile devices. Used effectively such systems will generate massive amounts of data which will need AI and other interpretive techniques to analyse. There is also the opportunity with such technology to identify 'red-flag' situations and automatically advise clinicians when such situations arise, allowing early interventions. So, there are also good clinical reasons for following the technology path. An avenue which a research group in the Netherlands is following is looking at AI natural language processing to analyse patient support group webchat/Facebook pages, so the net for patient input could spread wider than formal responses to structured questions in research projects.

Q. Executive Summaries of Patient Information Sheets should be compulsory. Can the NCRI help persuade the HRA to make it mandatory via ethics committees?

Roger Wilson, NCRI Consumer Forum member said:
We have often discussed the need to give patients the information they require to make a decision in a manner which is sensitive to their situation at the time that decision must be made. This is in contrast to the information which risk analysts, insurers and lawyers want them to have, especially as they insist on using words with a legal significance to reduce their liability. It is an ongoing challenge as the risk analysts, insurers and lawyers are better resourced and have a louder voice. We will get there. Our view is that a one-page summary should be the front page of consent information. Behind will be the fuller description of the project, behind that will be the legal notices. We have yet to convince the ethics specialists but it is probably a step at a time. Remember that the HRA provides guidance, not strict rules, so wider consent from the system is also needed.

Q. I don't know how involvement can be made mandatory for individuals, even if it's mandated for organisations/institutions. I wonder if there shouldn't be far more studies exclusively aimed at the unmet needs of all the underserved groups in society, so that they can stop being marginalised.

Richard Stephens, NCRI Consumer Forum member said:
The NIHR has a newly appointed Director of Equalities, Diversity and Inclusion, whose brief includes addressing the challenge raised in the second part of the question. It is also an implicit part of any stratified or precision medicine study, and meeting unmet need is an explicit ambition in CRUK's Research Strategy.

Q. Could ethics boards make it more obligatory to include PPI work?

Roger Wilson, NCRI Consumer Forum member said:
I think it is likely that they will tighten matters up. I think, for example, that studies using PROs will not get approval unless patients were involved.

Q. Could we work with ABPI or EFPIA to make PPI work mandatory? And avoid making such work a tick box exercise?

Roger Wilson, NCRI Consumer Forum member said:
We are working with ABPI and EFPIA in Europe is also part of the wider movement. The big issue is that most industry studies are driven from US research centres. However, most of industry is moving in the right direction, if slowly. The problem area is with small biotech companies.

Emma Kinloch, NCRI Consumer Lead said:
The ABPI has a Patient Organisation Forum ('POF') which the NCRI Consumer Lead is a member of.

Q. If grant awarding bodies did not require PPI as part of the application would researchers/clinicians still engage with PPI

Roger Wilson, NCRI Consumer Forum member said:
We are seeing a cultural shift, particularly in the UK, so we would be optimistic that PPI is here to stay.

Emma Kinloch, NCRI Consumer Lead said:
I believe that in the UK, for cancer research, the answer is 'yes' for the majority of researchers/clinicians. I would hesitate to say a definitive 'yes', that covers absolutely everyone, but there is a genuine appreciation of the value of PPI and the difference that it makes to the quality of research and patient outcomes. Those that are not yet fully 'on board', I am sure will be very soon.

9. Finally, a bit about us…

Emma Kinloch

Emma is the Chair on NCRI Consumer Forum and brings with her a wealth of experience in galvanising patient involvement in research. Having founded a London based Head and Neck cancer support group, Emma went on to set up Salivary Gland Cancer UK, a charity focused on furthering research, increasing awareness and providing support for those affected by rare salivary gland cancers. She is a member of the Head and Neck EURACAN domain, sits on the NCRI Head and Neck Clinical Studies Group, the PHR Programme Funding Committee and The BMJ Patient Advisory Panel.

Dr Tim Banks

Tim undertook his PhD in Social Sciences before joining Tenovus Cancer Care firstly as Research Officer then as interim Research Manager. In 2017 he was appointed to his current role as Head of Research. As part of this work, he oversees the Tenovus Cancer Care research portfolio, heading up the team responsible for funding and undertaking a variety of research projects aimed at improving the lives of those affected by cancer. With a passion for public patient involvement, Tim is thrilled that as part of his remit, he is responsible for developing a number of PPI projects, processes and initiatives. This included the Research Advisory Group; a group of individuals affected by cancer who review and ultimately determine which projects receive research funding in our community focussed grant scheme.

Dave Chuter

Dave's pathway into cancer research was after his treatment for Oesophageal cancer in 2006 and was his way of giving back to the hospital and helping new patients with support from patients. So many new patients were being invited to join studies and trials and all had questions Dave could not answer so he joined his local Cancer Partnership Research Group (CPRG) to find out about these trials and help patients make an informed decision. In 2006 Dave started up the Guildford OG cancer support group and still coordinates and runs it 14 years later. In 2009 Dave was elected Patient Governor at the Royal Surrey NHS FT hospital and stepped down in July 2016 to concentrate more on his NCRI Upper GI Clinical Research Group (2014 – 2017) and CRUK Clinical Expert Research Panel (2015 – 2019) roles. Dave was asked to stand again as Hospital Rest of England Governor in Oct 2018 and now Chairs the Patient Experience Committee for the Trust. Dave joined the OPA (Oesophageal Patients Association) in 2015 as Trustee and Chaired the Charity from 2017 – 2020. Dave also volunteers as a PPI member for other organisations including the NCRI Consumer Forum and Independent Cancer Patient Voice (ICPV).

Alison Fielding

Alison Fielding is a patient with dilated cardiomyopathy and Stage 4 kidney cancer. She has worked with Cancer Research UK including being a member of their National Cancer Insights Panel for 2 terms and is a member of their internal strategy board on treatment access. She received a commendation in their Sharp Mind award in 2018 for her contribution to their work. She is also active in the Kidney Cancer Support Network (KCSN) and as part of this has represented patients at a NICE Technology Appraisal for a new drug approval, the European Medicines Agency and at Parliament. She is interested in promoting research focussed on patient priorities and sits as a consumer member of the National Cancer Research Institute Consumer Forum. She is a member of the Bladder and Renal Group which oversees a research portfolio across the UK. She is a co-author on a published paper in a European academic journal on the value of PPI in setting research goals and is a member of several clinical trial management groups. She has a special interest in cardio-oncology and provision for those with multi-morbidities. She is active on Twitter as @alisonrfielding

Richard Stephens

Richard Stephens has survived two cancers, a heart emergency, and continued co-morbidities and late effects. He has participated in four interventional studies and nine others. A patient advocate for two decades, Richard has been involved in the design and delivery of over 30 clinical trials and studies and has sat on many UK and European strategic bodies. He works globally with patient groups and advocates, with academics and industry, with researchers and clinicians, and with policymakers and service deliverers.Richard is the founding co-editor of the *Journal of Research Involvement and Engagement,* chairs BBMRI-ERIC's Stakeholder Forum, and chaired the NCRI Consumer Forum 2012-2019. He has had professional careers in journalism, education and local government.

Roger Wilson CBE

Roger Wilson was diagnosed with a sarcoma in 1999 and has had six recurrences since. His latest surgery in 2013 was bilateral thoracic metastectomy.
He has been an active patient advocate since 2002 working in the UK's cancer research community. He chaired the NCRI patient group from 2004 to 2007 and has chaired a number of national groups in prevention, survivorship, and palliative care. In 2003 he founded and ran Sarcoma UK until it moved to London in 2011 and he co-founded Sarcoma Patients Euronet in 2009. He is now Hon President. He currently chairs the EORTC's Patient Panel. He has a particular interest in quality of life appraisal and in PROs (patient reported outcomes), working with NCRI, the University of Birmingham Centre for PRO Research (CPROR) and with EORTC's Quality of Life Group. He was appointed CBE in the 2011 New Year Honours. By background he was a journalist and TV producer.

Did you find this FAQ useful? Let us know! Still have questions? Get in touch!
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