DIALOG

French Collaborativ Group for Geriatric Oncology Research

The involvement of patients in research: why? how and when?

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DIALOG
UPEC, Inserm, APHP

8ème Journée Scientifique DIALOG

Definition (1): what means Patient and Public Involvment in Research?

Patient and Public Involvement in Medical Research :

as “research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them. The “public” refers to **patients, potential patients, carers and people who use health and social care services** as well as people from **organisations that represent** people who use services.

healthtalk.org

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https://oxfordbrc.nihr.ac.uk/wp-content/uploads/2017/03/A-Researchers-Guide-to-PPI.pdf

National Institute for Health Research (INVOLVE project). [http://www.invo.org.uk/about-involve/]

Definition (2) Distinguish clearly between "involvement," "participation," and "engagement":

- **Involvement:** Actively shaping research (patients/public as partners).
- **Participation:** Taking part as study subjects.
- **Engagement:** Information sharing about research findings with the public.

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National Institute for Health Research (INVOLVE project). [http://www.invo.org.uk/about-involve/]
Locock L, Boylan AM, Snow R & Stanisewska S. (2016). The power of symbolic capital in patient and public involvement in health research. Health Expectations.
Crocker JC, Boylan AM, Bostock J & Locock L. (2016). Is it worth it? Patient and public views on the impact of their involvement in health research and its assessment: a UK-based qualitative interview study. Health Expectations. DOI: 10.1111/hex.12479.

For which purposes ? (1)

Purposes and Values of Patient and Public Involvement

Patients and members of the public bring an "expert" insight into individual research projects because of their experiences of living with a particular condition or using health services. Involving PPI contributors in research allows "the colour and nuance and diversity" of different types of knowledge to be valued and to improve research. Involving those with "lived experience" enables researchers to access a fuller understanding of the condition being studied and may help generate research which is more meaningful research. PPI also serves to challenge research that may be driven by the interests of pharmaceutical companies or individual researchers.

Involvement is about increasing public accountability, and democratising health and medical research, which is often funded using public money.

It's to make research more efficient, more accurate and more reliable, and sometimes make the results more meaningful...It kind of guides the way for researchers into what they should be researching. Because obviously they're doing research for patients, but if they don't know what patients want, that's probably not the best way forward. **Stephen, PPI representative**

I think that's what a PPI person brings – is being the person who walks into the room who is terrified for their own or their child's health and, or concerned if not terrified if you're not in a critical condition, and who constantly comes up against the medical jargon, a system of how things work... Having experienced a terminal cancer diagnosis for my husband, nothing can prepare you for the shock that you go into when you have a terminal diagnosis. And no matter how much training and no matter how many years you sat as a medical person, handing out that diagnosis and watching people in front of you, you don't know what it's like until you've been that person at home, trying to eat a dinner and throwing up at the thought of the person opposite you dying – **Catherine, PPI representative**

3

For which purposes ? (2)

- To improve relevance of the research
- To increase recruitment, retention,
- To. Increase dissemination of findings.
- To Increase public trust and acceptance of research outcomes
- To Enhance ethical standards and transparency.

Health Services Research

RESEARCH ARTICLE Open Access

Patient engagement in research: a systematic review

Juan Pablo Domecq[1,2,5], Gabriela Prutsky[1,2,5], Tarig Elraiyah[1,5], Zhen Wang[1,5,6], Mohammed Nabhan[1,5], Nathan Shippee[1,5,6], Juan Pablo Brito[1,4,5], Kasey Boehmer[1,5], Rim Hasan[1,5,8], Belal Firwana[1,5,8], Patricia Erwin[1,7], David Eton[1,5,6], Jeff Sloan[1,5,6], Victor Montori[1,2,4,5,6], Noor Asi[1,5], Abd Moain Abu Dabrh[1,5] and Mohammad Hassan Murad[1,3,5,6*]

At which step of the research process? (1)

Preparation:

- Topics identification
- Protocol design /information sheet

Execution

- Enrollment
- Retention
- -Data coll.
- -Data analysis

Dissemination
Implementation
Impact

At which step of the research process? (2)

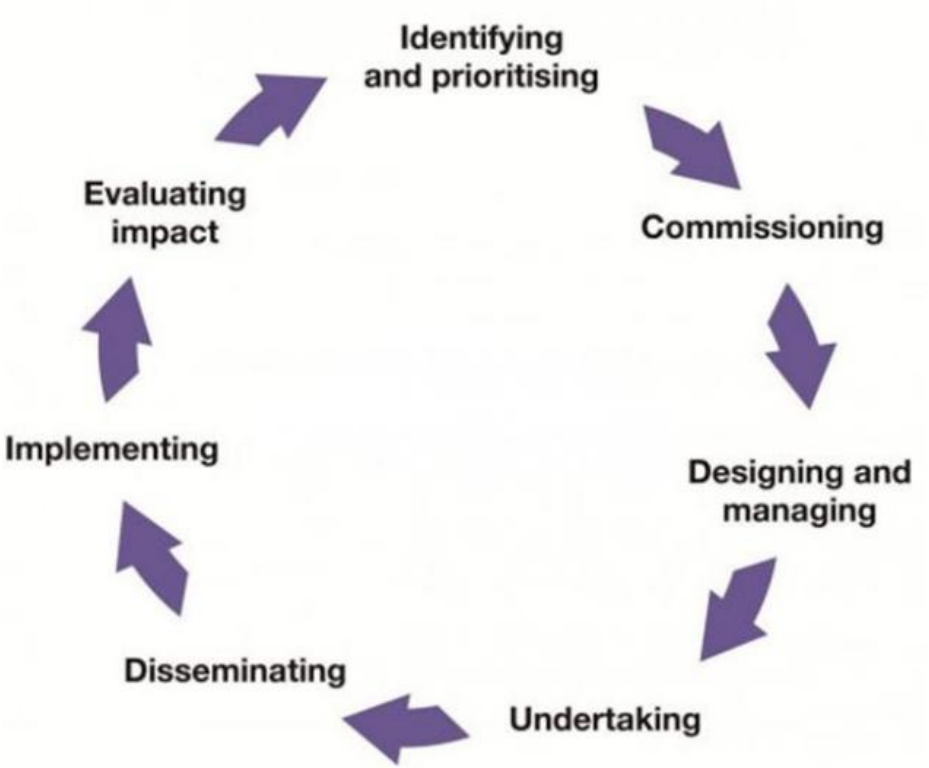

Figure taken from INVOLVE (2012) Briefing notes for researchers.

1- Research Preparatory Phase

https://doi.org/10.1186/s40900-020-00214-5

Research Involvement and Engagement

RESEARCH ARTICLE Open Access

The impact of patient involvement in research: a case study of the planning, conduct and dissemination of a clinical, controlled trial

Pernille Christiansen Skovlund[1,2,3*], Berit Kjærside Nielsen[3,4], Henriette Vind Thaysen[3,5], Henrik Schmidt[2], Arnstein Finset[6], Kristian Ahm Hansen[2] and Kirsten Lomborg[3,7,8]

1- Research Preparatory Phase

Table 1 The case of PPI in the research project

The advisory board

Before recruitment of PRPs, the six researchers (a cancer consultant, two clinical professors (one specialized in patient involvement), a professor in patient involvement, a health psychologist, a clinical nurse specialist, and a nurse Ph.D. student (principal investigator (PI)) agreed that the researchers had scientific responsibility, but the PRPs had the responsibility to bring forward the lived experience. Accordingly, the aim of the advisory board was to ensure quality, enable completion of the trial, and keep the intervention meaningful to patients and health care professionals. For the recruitment of PRPs, an open invitation was announced on the Facebook group site of the Danish melanoma network. The network has about 180 paying members and 890 members in their Facebook group. We assumed that patients who joined such an organization were likely to have the required skills and resources to contribute to an advisory board. We asked for patients who had experiences of living with metastatic melanoma and the treatment hereof within the last 5 years, and who believed they could express viewpoints and experiences to the researchers. Furthermore, patients should be able to communicate via email and to attend 6–12 meetings over a project period of 3 years. Four patients applied for the three positions. They were approached by email and telephone in order to align expectations. The three included patients represented a diverse range of experiences of living with metastatic cancer (from 2 months to 6 years) but a narrow age range (62, 65, and 65) and gender (only males). Due to the death of two patients within the first 1.5 years, two new patients were recruited through the same Facebook group. Two females (aged 52 and 49 with 1.5 years and 4 months of living with metastatic melanoma, respectively) joined the group after individual telephone contact, followed up by project information. One of the new members had a progression of her disease shortly after the telephone contact and never joined the following meetings.

The overall framework of activities

All meetings took place at the university hospital from February 2016 to November 2019 and had predefined agendas. In order to accommodate the participation of patients who were in the labour market, the meetings were mainly organized after normal working hours and lasted for 3 h. At least one meal was served at each meeting and a refund of PRPs' travel expenses was offered.

Activities in the design and management phase

In this phase, information about the PRPs' motivations for and expectations of joining the advisory board were gathered, and a clear division of tasks and responsibilities was discussed. The main activities were selecting of PRO measures and composing the patient information sheet. All meetings were planned and managed by the PI with a mixed level of engagement, alternating between consulting and collaboration in decision-making.

Activities in the analysis during the undertaking phase

RESEARCH

Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis

Joanna C Crocker,[1,2] Ignacio Ricci-Cabello,[3,4,5] Adwoa Parker,[6] Jennifer A Hirst,[7] Alan Chant,[2] Sophie Petit-Zeman,[2] David Evans,[8] Sian Rees[9]

2- Execution phase

Table 3 | Contextual/clinical trial characteristics of studies included in review

Study	Participants	Geographical setting	Clinical trial intervention(s)/treatment(s)
Arean et al, 2003[34 35]	People aged ≥65 with symptoms of depression, anxiety, and at-risk drinking	San Francisco, USA	Three types of psychosocial intervention for depression; social service model of care delivered in community geriatric medicine clinic
Chlebowski et al, 2010[36 38]	Healthy white men aged ≥55 years and healthy black men aged ≥50 years	USA (multisite)	Selenium and vitamin E *v* placebo for prevention of prostate cancer
Cockayne et al, 2017[39 40]	People aged >65 who had attended routine podiatry appointment within previous 6 months	UK (multisite)	Podiatry intervention *v* usual care for prevention of falls in older people
Dear et al, 2012[41 42]	Cancer patients consulting with their physician	Australia (multisite)	Various (multiple trials included)
Donovan et al, 2002[43 44]	Men aged 50-69 years with localised prostate cancer	UK (multisite)	Surgery, radiotherapy, or monitoring for treatment of localised prostate cancer
Du et al, 2008[45]	Patients aged 21-80 years with lung cancer	Detroit, USA	Various therapeutic and non-therapeutic interventions (multiple trials included)
Ford et al, 2004[46]	African-American men aged 55-74 years	USA (multisite)	Screening for prostate, lung, and colorectal cancers
Fouad et al, 2014[47 48]	Minority ethnic, low income women with low grade cervical cytological abnormalities	Jefferson County, AL, USA	Immediate colposcopy, triage, or conservative management of cytological diagnosis of atypical squamous cells of undetermined significance
Guarino et al, 2006[49 50]	Gulf War veterans with fatigue, musculoskeletal pain, and/or cognitive complaints	USA (multisite)	Cognitive behavioural therapy, aerobic exercise, or both *v* usual care for treatment of Gulf War veterans' illnesses
Horowitz et al, 2009[51 52]	Adults with pre-diabetes	East Harlem, NY, USA	Community based, peer led weight loss programme to prevent diabetes
Hutchison et al, 2007[53 54]	Patients with colorectal, breast, or lung cancer and clinically eligible for entry into randomised treatment trial	Glasgow, UK	Cancer treatment *v* control/standard treatment or best supportive care

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2- Execution phase

Table 4 | Characteristics of patient and public involvement (PPI) interventions included in review

Study	Primary aim of intervention	PPI component(s)	Other (non-PPI) components*	Authors' proposed mechanism
Arean et al, 2003[34 35]	To improve recruitment and retention of older minority adults to trial	All recruitment and study procedures were discussed at bimonthly consumer advisory board meetings. A community member was trained by research staff to recruit and screen participants	A range of other "consumer centred" strategies including face-to-face recruitment, personalised mailings, and in-home interviews.	Overcoming stigma and mistrust barriers associated with research in minority communities
Chlebowski et al, 2010[36-38]	To improve rates of consent to randomisation in trial	Women already participating in a large health research project were asked to recruit their husbands	None	Women participating in clinical studies are altruistic, and their husbands share this quality and are willing to participate in a similar clinical trial
Cockayne et al, 2017[39 40]	To improve trial recruitment rates	Two different PPI interventions: "bespoke user-tested" PIS: formal user testing of PIS by 30 members of public; "template developed PIS": historical non-bespoke user testing; PPI group reviewed PIS and gave feedback.	"Bespoke user tested" PIS: design input by researchers and commercial company. "Template developed PIS": design input by experienced researchers	Improving the quality and appearance of patient information sheets
Dear et al, 2012[41 42]	To improve proportion of patients with whom participation in any clinical trial was discussed	Consumer input into design and content of consumer friendly online cancer trials registry	Online cancer trials registry developed by web company with input from staff at Australian New Zealand Clinical Trials Registry	Improving consumer knowledge and understanding of clinical trials; enabling patients to search for local trials they might like to join; providing decision support for patients considering joining a trial
Donovan et al, 2002[43 44]	To improve rates of consent to randomisation in trial	In-depth interviews with potential participants who had been invited to take part	Qualitative analysis of interviews by researchers. Other qualitative research methods, including interviews with recruiters and analysis of audio recorded recruitment appointments. Findings were used to change patient information and train recruiters	Uncovering problems with information and communication during recruitment to the trial

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2- Execution phase

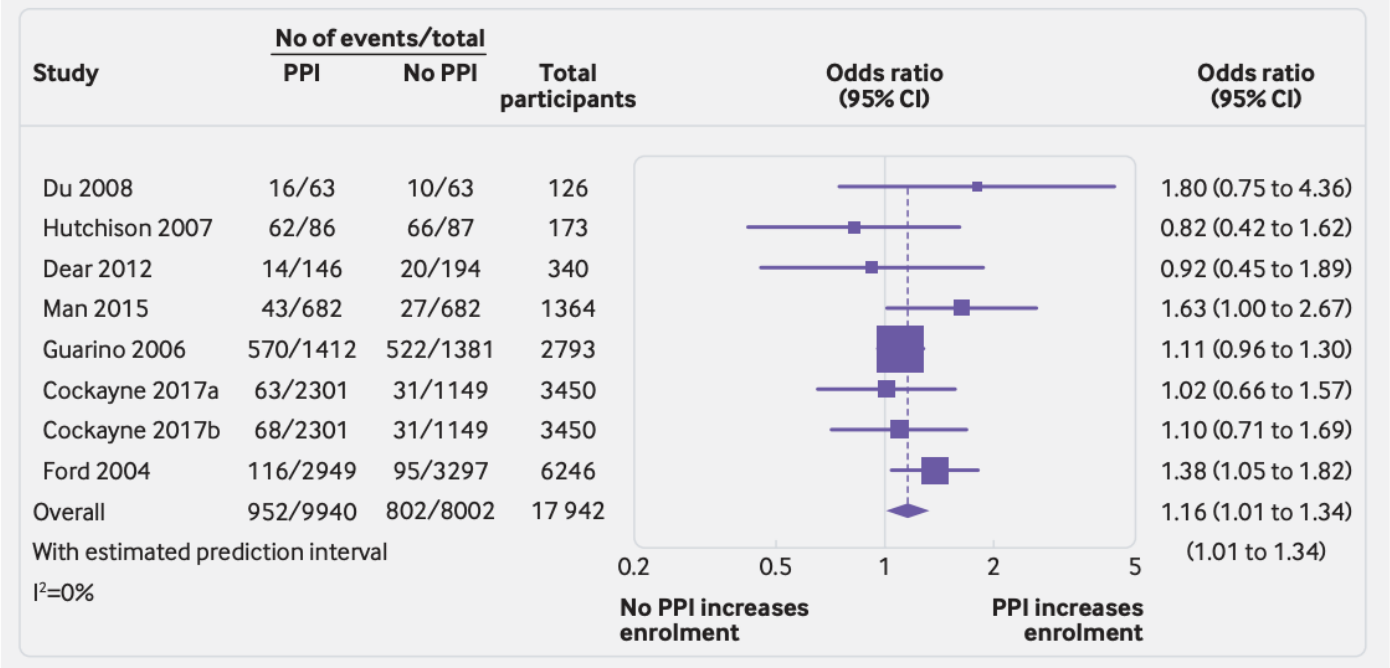

Fig 2 | Odds ratios for patient enrolment in clinical trial with versus without patient and public involvement (PPI) intervention (randomised studies only)

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(fig 3). Exploratory subgroup analyses showed that the overall positive association between PPI interventions and enrolment substantially increased when at least one involved person had lived experience of the health condition under study (odds ratio 3.14, 1.89 to 5.22) and all but disappeared when the involved people had no such lived experience (1.07, 0.74 to 1.53). Meta-regression confirmed that this effect was statistically significant (P=0.02). Subgroup differences between

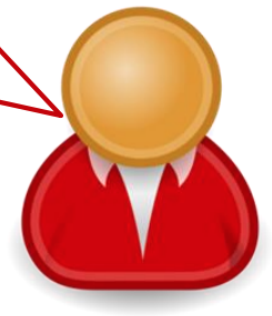
3- Dissemination phase

Disseminating

PPI contributors are more successful at the disseminating stage if they have been involved in the earlier stages of research. Through being involved from the outset, they gain ownership and knowledge of the context of the project and are able to disseminate the results through their networks.

- They can help write and summarise research findings in ways that is accessible to a public audience
- They may have access to groups or forums that researchers are not aware of
- They can co-author academic papers and disseminate findings to academic audiences – the papers we have published from this research include PPI contributor co-authors

And I sat next to Iain Chalmers in a bus going to a wine region for a reception or something and I said, "You know, I'd really like to do a review." "Yes of course you can," he said. "I'm not a scientist or a doctor." He said, "Doesn't matter. We can provide all those people as co-authors but you have the desire to do it and nobody else has, you can be the lead author." And I looked at him as though he was mad of course [laughs] and then he said, "And when you've done it you'll be an expert in vitiligo." Which I laughed out loud actually [laughs]. But in one sense he wasn't wrong because I'm not a scientist, I'm not a doctor but I know a lot about vitiligo, it's what I do [laughs] and I think the other thing that I do, which came also from my experience as an academic librarian in the science, bio sciences, is what they used to call selective dissemination of information – **Maxine, PPI contributor**



3- Dissemination phase

Communication of study/trials results to the patients?

Key elements to report a study/trial with PPI components

Table 2 GRIPP2 short form

Section and topic	Item	Rep page No
1: Aim	Report the aim of PPI in the study	
2: Methods	Provide a clear description of the methods used for PPI in the study	
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	

PPI=patient and public involvement

PDF
Help

OPEN ACCESS

GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research

S Staniszewska,[1] J Brett,[2] I Simera,[3] K Seers,[1] C Mockford,[4] S Goodlad,[5] D G Altman,[6] D Moher,[7] R Barber,[8] S Denegri,[9] A Entwistle,[4] P Littlejohns,[10] C Morris,[11] R Suleman,[4] V Thomas,[12] C Tysall[4]

BMJ: first published as 1

Take-home messages

- PPI may improved differents facets of your research
- Can take place at differents steps: preparation, execution and dissemination.
- Need time, ressources, training, flexibility
- Potential harms: tokenism, power imbalance
- Potential difficulty/specificities in GO : find volonteers, access to digital tools, transportation/mobility, care

DIALOG

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Merci de votre attention !
Thanks for your attention

Questions/réponses

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Background

- 5 challenges identified by **researchers**
  - Time
  - Recruitment
  - Ethics
  - Power
  - Inequality.
- 3 challenges identified by **patient research partners**
  - Communication
  - when you get information that is hard to handle
  - recruitment.

Skovlund *et al.*
Research Involvement and Engagement (2024) 10:3
https://doi.org/10.1186/s40900-023-00533-3

Research Involvement and Engagement

RESEARCH Open Access

Recommendations for successful involvement of patient partners in complex intervention research: a collaborative learning process

Pernille Christiansen Skovlund[1,2,4*†], Jeanette Finderup[2,3,4†], Sanne Aabo[2], Flemming Jensen[2], Henning Søndergaard[2] and Lotte Ørneborg Rodkjær[2,5,6]

→ **3 recommendations were developed:**

- create specific programmes that aim to involve all kind of patients (even vulnerable patients) as patient research partners
- produce ethical guidelines
- develop a national strategy for patient research partner involvement

6. Challenges and Barriers to Effective PPI

•Resource limitations (time, funding, training).
•Cultural resistance among researchers or institutions.
•Power imbalance between patients/public and researchers.
•Ensuring genuine representation and avoiding tokenism.

7. Solutions and Best Practices

•Provide clear role definitions and training for patients and researchers.
•Allocate adequate resources and funding specifically for PPI.
•Establish policies or guidelines to support and institutionalize involvement.
•Monitor, evaluate, and report PPI impact clearly and transparently.