



Training for Parent and Public Involvement (PPI) in Large Simple Perinatal Trials

Results from a rapid review of literature to inform the development of a training program for PPI in international neonatal/perinatal trials

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Introduction

Following funding from Sydney University to explore the feasibility of a Global Register of Consumer Partners in Large Simple Perinatal Trials, this document was commissioned to inform work on the development of a training program to increase the capacity of consumers and their communities to partner with researchers in international neonatal-perinatal clinical trials.

This document summarises the findings of a rapid scoping review, an international scan of key resources from research funders and other organisations supporting patient-centred trials, and a review of grey literature. The review was conducted in August 2022 and identified current initiatives and best practices to prepare patients, potential patients, carers, and people who use health care services to partner with researchers conducting clinical trials.

This document outlines:

- Possible examples of existing training resources for curation from which potentially relevant partnerships can arise
- The unmet gaps that require the development of new training resources.

Adopted terms

This document adopts the term “*parent and public involvement (PPI)*,”* to describe research carried out ‘with’ or ‘by’ consumers and communities rather than ‘to’, ‘about’ or ‘for’ them (1). The term ‘**PPI partner**’ is used to denote individuals that partner with researchers and research-active organisations.

* *There is a lack of international consensus on terminology used for PPI. Terms in use include ‘public involvement’, ‘patient engagement’, ‘patient and public involvement’, ‘consumer and community involvement’, ‘consumer engagement’, and ‘service user involvement’.*

The rationale for training PPI Partners

“Nothing about us without us” (James Charlton)

PPI is now supported internationally by clear political mandates. Government agencies and research-active organisations are increasingly recognising the importance of PPI in health research, not only because the public has the right to contribute to decisions about what taxpayer-funded research is carried out, but also because, when meaningful partnerships are formed between researchers, patient groups, patients, and their communities, the quality and relevance of research is improved [1]. Several systematic reviews describe the positive impact of PPI on research, including refining research questions [2], optimising patient-facing documents [3-5], making trial outcomes more meaningful [6-8], improving the quality of data collected [9], refining research tools [10], reducing the burden of participation

on patients [11-13], providing access to local communities [14, 15], which in turn, may account for emerging evidence of its impact on trial recruitment [4, 16-18].

National funders such as the Patient Centred Outcomes Research Institute (PCORI) in the United States [19], the Strategy for Patient Oriented Research in Canada [20], and the National Institute of Health Research in the UK [21], have also identified the role that meaningful PPI can play in supporting equity, tackling health inequality, [22] and increasing trust in the research enterprise [2, 13, 23]. Therefore, for both normative and benefits-driven reasons, many governments and public organisations have introduced policies that have embedded PPI as a research requirement. In fact, PPI is increasingly a funding requirement [20, 24], an ethics requirement [25] and in Australia, PPI in clinical trials has been incorporated as a health system accreditation standard [26]. As a growing international movement, PPI in neonatal and perinatal trials will require greater numbers of well-equipped PPI partners to meet the growing demand.

The benefits of training PPI Partners

“One of the key things to support public contributors, or people with different experiences is providing training. Giving them that support and building confidence can help them get their voices heard.” (K Mistry- South Asian Health Network)

Training supports the personal development of PPI Partners, for example, by providing them with the confidence and skills needed to carry out their role [27-30] and by making the process less intimidating [31, 32]. Training is also valued by PPI Partners. It helps them to ‘learn the language’ of involvement, which prevents marginalisation during meetings where the use of unfamiliar research jargon may exclude the possibility of contribution [31]. Furthermore, an increase in knowledge can enable PPI Partners to be more discerning in their decisions to enter into research partnerships [31]. Finally, training that includes content on the principles of evidence-based medicine (EBM) can equip CCI Partners with knowledge that helps them make more informed decisions about their own health care [33]. The provision of training opportunities also gives PPI Partners recognition and reward for their involvement [1, 34].

The acquisition of knowledge can occur in many ways including formal group sessions, self-directed learning through provision of learning materials/guidance documents, academic courses, on the job training including through networking with other PPI Partners or groups.

Summary of training content described in the literature

Overview of Research

- What is research, the research process and research design. [29, 31, 32, 34-47]
- Evidence based medicine and the value of research. [33, 36, 39, 41, 46, 48, 49]
- Research terminology. [31, 39, 50]
- Research methods. [32, 40-42, 51-54]
- The research cycle. [38, 41, 47, 55, 56]
- Drug development process. [57, 58]
- Interpreting, research findings. [51]
- Critically appraising/evaluating research findings. [41, 42, 49, 51, 59]
- Responsible research practice including confidentiality. [29, 54]
- Research ethics and GCP consent. [31, 34, 41, 53, 54, 56, 60]

Overview of PPI

- What is PPI? [38, 61]
- Why PPI is important (understanding the research drivers). [36, 41, 48, 62]
- What is the expectation of the role. [52]
- How PPI partners can be involved? [32, 41, 62]
- Where in the research cycle can PPI happen? [38]
- Barriers and facilitators for PPI. [43, 61, 62]
- Building/maintaining relationships [58, 63, 64]
- How individual experiences may influence research. [38, 60]
- Research Ethics. [52, 61]
- Understand why research/PPI should be diverse and inclusive. [41, 43, 44, 51]

Soft Skills

- Drawing on and sharing personal experience effectively and constructively. [37, 43, 44, 48]
- Communication skills, listening skills and deliberative decision-making. [41, 58, 64]
- Teamworking/dynamics, meeting participation and confidence to speak. [28, 34, 37, 41, 52, 62]

Training for lay-researchers

- Qualitative research design. [53, 55, 56, 58]
- Conducting interviews. [41, 43, 55, 65]
- Devising questionnaires/surveys. [41, 55, 60]
- Analysing findings of qualitative research. [28, 40, 66]

General recommendation for training

The following is a list of recommendations from selected papers:

- Base any training on a needs assessment involving a discussion between PPI partners and researchers [29, 36, 67] and tailor the training to the situation, needs and roles of PPI partners [41, 52, 68, 69].

This could be achieved by modularising units for an online course and signposting to other free resources.

- Use community pedagogy where possible – the sharing of experiences/storytelling that includes content that illustrates how people’s life experiences relate to a course topic [29, 31, 32, 43] and how experiences may influence research [32].
- Adapt existing resources to align with project requirements. **Appendix 1** provides examples of existing PPI training.

Consider using a content sharing agreement to secure permission to adapt existing PPI training resources for the Global Register.

This could be achieved by developing country-level videos featuring patients describing how the sharing of their life experiences was used to influence research. In addition, consider the use of existing resources such as healthtalk.org

Training for PPI Partners for the Global Register

The literature review and international scan identified several resources that might be accessible for curation to support the development of bespoke training for people willing to be involved as PPI Partners in neonatal and perinatal trials. (Appendix 1) Training content covers the research process, methods, and frameworks, as well as training on how consumers can effectively partner with researchers at a trial level. However, most of the training is organisation-specific and needs to be adapted to remove any non-generic content.

Regarding gaps in training provision, the international scan did not identify specific training relating to perinatal research. Development of a module covering this topic is recommended.

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Appendix 1: Example training courses

Organisation	Content	Access
Australian Clinical Trials Alliance Consumer Involvement and Engagement Toolkit (Consumer webpages)	Website with an induction pack for consumers and videos on “what is randomisation” and “what are clinical trials” Videos describing the value of PPI	Open
Cochrane Cochrane Evidence Essentials	An online introduction to health evidence and how to use it to make informed health choices	Open
European Patients' Academy on Therapeutic Innovation (EUPATI)	A comprehensive program delivered through an online platform (Open classroom) Medicines development and HTA	Open Online
Patient Centred Outcomes Research Institute (PCORI) Research Fundamentals	Modular courses covering stakeholder-driven research – 5 online modules	Registration
PCORI Engagement Toolkit	A range of written resources	Open
PCORI engagement resources	Links to PCORI resources	Open
PCORI diversity and inclusion	Document with Guiding Principles	Open
The Neuromuscular Disease Network for Canada	A summary of national and international resources	Open
Ontario SPOR Support Unit Patient Engagement Resources and Training Capacity Building Compendium	Beginner, intermediate and advanced training. Online and F2F training - Providing skills and knowledge to engage meaningfully in patient-oriented research.	Ontario specific
Kidney Pro	Example of an online resource for patient-oriented research	Open
National Institute of Health Research (NIHR)	An interactive course of patient involvement	Open
NIHR diversity and inclusion	Webpages	Open
WHATN	Consumer Involvement online course	Free
Global Health Network	Training on research processes and methods	Free
Imperial College PPI training	Public Involvement in Research course for researchers or patients	Free (with small fee for certification)

Appendix 2: Sample content sharing agreement to enable adaption of external training courses

Patient and Public Involvement & Engagement (PPI) CONTENT SHARING TERMS

Patient and Public Involvement & Engagement (also known as Consumer and Community involvement & Engagement) in research is rapidly becoming an important global movement. Many organisations have developed guidance documents and website toolkits containing rich content that is transferable to other countries, but is likely to require adaptation (e.g., to align with locally agreed terminology or practice). This document provides terms to enable organisations developing and maintaining PPI materials to share best practice and content.

Its purpose is to:

- Accelerate the development of resources for active and meaningful PPI amongst organisations.
- Facilitate the creation of collective knowledge on how best to involve and engage consumers.
- Help ensure public funds are not wasted through duplication of effort developing similar materials across organisations.
- Ensure that those organisations sharing content with others, are acknowledged.

Organisations supporting this collaboration agree to share with each other, the PPI content that they post on the public domain with appropriate recognition.

Recommended acknowledgements:

1. Where full documents, tools, flowcharts etc. produced by one organisation are adapted for local use by another, a statement should be included on the local document that clearly acknowledges the source.

Suggested wording: *Adapted with kind permission from [document/website name and date] + [organisation].*

2. Where extracts of wording from published guides, documents or websites, the creation of an 'Acknowledgements' section within the documents/website

Suggested wording: *We would like to acknowledge the following organisations who have kindly shared resources to enable the development of this Guidance/Toolkit/Document.*

**Note images used on websites and documents may not be royalty free are excluded from these terms.*