

**R46- Peter Bower, Bridget Young, Jenny Donovan, Paula Williamson, Peter Knapp, Heahter Bagley, Hugh Davies, Carrol Gamble.**

**1<sup>st</sup> April – 30 November 2014**

The aims of the workshop were to:

- create a draft definition and core dimensions of a 'patient centred clinical trial'
- outline potential research questions concerning 'patient centred clinical trials'
- develop a strategy to involve the wider trials community, including a website

We ran 2 workshops in Manchester, with a range of stakeholders, including academics, patients, patient and public involvement organisations, and representatives from charities, ethics committees, funders and the research networks. Some people attended both workshops, but we also brought in new people to workshop 2 after the initial discussions in workshop 1

- We developed a draft definition and core dimensions of a 'patient centred clinical trial' (appendix 1)
- We developed a list of potential research questions (appendix 2)

We have developed a website which will go live on 9<sup>th</sup> February (<http://www.population-health.manchester.ac.uk/patientcentredtrials/>) will be used for dissemination

- We have established a Twitter account for the wider patient theme (@PatientTheme) which will also be used for dissemination and as a platform to engage more widely through twitter chats as outlined in the engagement strategy (available upon request).

Additionally, we have:

- Drafted a paper related to some of the issues discussed in the workshops
- Prepared presentations for:
  - North West Hub Trials Methodology Research conference (April 2015)
  - User Involvement in Voluntary Organisations Shared Learning Group (London: January 2015)
  - SCOPE Summit (Florida: February 2015)
  - Health Services Research Network (Nottingham: July 2015)
- Convened a PPI steering group to have input into the developing programme of work.

### **Next steps**

- Develop bids to MRC Hub Network or HSDR for:
  - scoping research around existing measures (led by Claire Planner as part of her NIHR School for Primary Care Research seedcorn funding)
  - key indicators of a patient-centred trial: a consensus study. NIHR School for Primary Care Research seed corn grant (funded for £7K research costs)
  - feasibility study around measurement, looking at the introduction and use of measurement in 1-2 trials to assess issues around implementation
  - larger bid to Health Foundation or NIHR HSDR to develop and validate patient experience measure or other technologies for assessment
- Continue development of the website, which will include the addition of videos and podcasts to describe specific aspects of the work.
- Explore links with INVOLVE (initial discussions have been held with Simon Denegri- Head of INVOLVE), charities (initial discussions have been held with Cancer Research UK, Parkinson's UK, Macmillan and Alzheimer's UK) and other stakeholders

## Appendix 1 Draft definition of 'Patient Centred Trial'

We explored current definitions of patient-centredness in a clinical context and considered how well that generalised to trials. A definition of person-centred care is structured around experience; dignity and compassion; activation; shared decision making; person-centred communication; and support for self-management

It was acknowledged that there were *potential* differences between clinical care and trials – for example, support for self-management may not be an explicit goal of taking part in a trial (although it could relate to adherence, and patients do not get to decide their allocation, although shared decision making is critical to decisions about taking part in trials).

We discussed the importance of clarity around those aspects of the trial where there was flexibility to deliver the trial to meet patient expectations and preferences, and those aspects where flexibility may be more limited (especially allocation, blinding, core outcomes). We also discussed the differences between 'expectations' and 'preferences' (prior to taking part in a trial), 'experiences' in trials, and 'outcomes' of those experiences [2], which might relate to *satisfaction with participation* ('I made a contribution', 'I would recommend this study to family and friends', 'I would take part again')

Patient-centredness in trials could be potentially delivered in many different areas in the lifetime of a trial: question setting (i.e. is it a priority for patients?); design (input into the design, tailoring and adjustment); delivery (communication, burden); outcomes (importance, relevance, sensitivity); dissemination (results, closure)

A starting point for definition might be 'a patient centred trial is designed and conducted in a way that takes into account, as far as possible, the needs, priorities and views of patients and trial participants, so that they feel a valued and respected part of the research process'

## Appendix 2 Research questions

- What are the core dimensions of a patient-centred trial?
- What do we mean by 'patients' in 'Patient-Centred Trials'? Patients in a trial? The group affected by the results of the trial? The wider public? PPI collaborators?
- How do we know current trials are not patient-centred? What is currently known about patient experience in trials?
- What are the key outcomes of 'Patient-Centred Trials'? What is the relative importance of recruitment, retention in the index trial, or later trials? Is patient experience more important than either?
- What are the costs of 'Patient-Centred Trials'? What are the implementation issues? e.g. training staff
- What are the advantages and disadvantages of standardised measures in achieving 'Patient-Centred Trials'?
- What is the correct balance between quantitative and qualitative approaches?
- Are there generic questions about trial experience that are relevant to all patients in all trials? (Dignity, compassion and respect. Would you recommend to friends and family? Would you take part again?)
- How important is the idea of 'closure' in trials (thanking patients, providing results). How often is that conducted, as compared to how often it is promised?
- What is the role of PPI in the design, delivery and evaluation of a 'Patient-Centred Trial'?

What is the role of technology in 'Patient-Centred Trials' e.g. live tracking of progress through a trial, decision aids?