Models and impact of patient and public involvement in MRC Clinical Trials Unit at UCL studies

Annabelle South[1], Bec Hanley[1], Mitzy Gafos[1], Ben Cromarty[2], Richard Stephens[3], Kate Sturgeon[1], William J. Cragg[1], Conor Tweed[1], Jacqueline Teera[1], Karen Scott[1], Claire Vale[1]

[1]MRC Clinical Trials Unit at UCL, UK [2]North Yorkshire AIDS Action, UK [3]National Cancer Research Institute Consumer Forum, UK

Abstract

Background

Patient and public involvement (PPI) in studies carried out by the UK Medical Research Council Clinical Trials Unit (MRC CTU) at University College London varies by research type and setting. We developed a series of case studies of PPI to document and share good practice.

Methods

We used purposive sampling to identify studies representing the scope of research at the MRC CTU and different approaches to PPI. We carried out semi-structured interviews with staff and patient representatives to determine the aims and motivations for involvement; activities undertaken, their impact on the studies and lessons learned. Interview notes were transcribed and analysed descriptively.

Results

Between March and November 2014, we conducted 17 interviews about 10 case studies, including randomised controlled trials, observational studies and one systematic review. Interviews were updated in Summer 2015 where there had been significant developments in the study. The case studies included open and completed HIV and cancer studies, with start dates between 2003 and 2011. A wide range of PPI models, including representation on trial committees or management groups, community engagement, one-off task-focused activities, patient research partners and participant involvement had been used. The model chosen depended on what the desired area of impact was. Overall, interviewees felt that PPI had a positive impact, for example, positive influences on the research question/study design; improved communication with potential participants/boosted recruitment; increased confidence to carry out or complete a study; better interpretation and communication of study results; and influencing future research.

Conclusions

A variety of models of PPI can impact upon studies. Researchers should consider different approaches to PPI, based on the desired impact and the people they want to involve. Use of multiple models may increase the potential impacts of PPI in clinical research.

Background

Patient and public involvement (PPI) describes a variety of activities that ensure research is carried out with patients and / or members of the public.

The MRC Clinical Trials Unit (MRC CTU) at UCL designs, conducts, analyses and reports high quality randomised controlled trials (RCTs), meta-analyses and other clinical studies in a variety of healthcare areas, primarily cancer, HIV and other infectious diseases. The Unit is committed to active PPI, having developed a policy and guidance to support PPI in its clinical research (details can be found at http://www.ctu.mrc.ac.uk/resources/patient_involvement).

We carried out case studies of PPI to:

- Better understand PPI in different areas of our clinical research
- Document the variety models of PPI being used
- Assess the impact of PPI
- Highlight innovative PPI for future research
- Share examples of good practice with others

Methods

- Purposive sampling to identify a cohort of studies representing the scope of research, approaches to PPI and geographical spread
- Lead researcher (or other key staff members) plus one or more nominated patient/lay/community representative(s) invited to participate in semi-structured interviews about PPI within the study
- Semi-structured interviews were conducted following a topic guide
- Written summaries of each interview were produced, checked for inaccuracies or inconsistencies with the interviewees, who also verified the final versions
- Content of the summaries was analysed to identify emerging themes, which were discussed and agreed by the MRC CTU PPI steering group

Results

Data collection

We conducted 19 interviews with 13 researchers and 7 patient representatives, collecting information on:

- 8 individual randomised controlled trials
- 1 observational study

Data collected from 2 researchers and 4 patient representatives for a previous project regarding PPI in a meta-analysis were also included in the analysis.

Models of involvement

The most common models of PPI was patient / community representatives being on:

- trial steering committees (5 studies, all HIV)
- trial management groups (4 studies, 3/4 cancer)

All HIV studies also used additional models of involvement (Table 2).

Impact

All interviewees felt that PPI had impacted on the study, although the type of influence varied (Figure 1).

Table 1: Case studies

Study (and status at time of interview)	Patient population
Cohort studies	
AALPHI (ongoing)	Young people in the UK who are HIV-infected or live with someone who is HIV-infected
Randomised controlled trials	
BREATHER (ongoing)	Young people with HIV living in Africa, South America, Asia, Europe and North America
DART (completed)	Adults living with HIV in Uganda and Zimbabwe
MDP301 (completed)	HIV-negative women living in South Africa, Tanzania, Uganda or Zambia
PIVOT (completed)	Adults living with HIV in the UK
PROUD (ongoing)	HIV-negative men who have sex with men in the UK who are at high risk of HIV
QUARTZ (ongoing)	Adults in the UK whose non-small cell lung cancer has spread to their brain
SORCE (ongoing)	Adults in the UK with kidney cancer
STAMPEDE (ongoing)	Men with prostate cancer in the UK and Switzerland
Individual participant data meta-analysis	
Cervical cancer meta-analysis (completed)	Women with cervical cancer, who took part in RCTs worldwide

Table 2: Models of PPI

Role	Managerial	Oversight			Responsive					
Models	Patient /public representative on **Trial Management Group**	Patient/ public representative on **Trial Steering Committee**	Patient/public representative on **Data Monitoring Committee**	Patient research partners	Involvement on specific tasks facilitated through existing patient groups	Ad hoc participant meetings	Ongoing participant groups	Community advisory groups specific to study	Community advisory groups providing advice across several studies	Community meetings to advise trial teams
Who is involved?	Patient or public representatives					Study participants		Community members		
Duration	Long-term				One-off	Ad hoc	Long-term			Ad hoc
Studies using this model	PROUD QUARTZ SORCE STAMPEDE	AALPHI BREATHER DART PIVOT PROUD	PIVOT PROUD	Cervical cancer meta-analysis	AALPHI BREATHER	BREATHER PROUD	DART MDP301	MDP301 PROUD	MDP301	MDP301

Figure 1: Areas of impact of PPI in the case studies

Acknowledgements

We thank the researchers and patient representatives whom we interviewed. We would also like to thank the participants in the workshop on 'Promoting Patient and Public Involvement in Clinical Trials at the Medical Research Council Clinical Trials Unit', who gave us the idea for this study. This work was funded by the Medical Research Council.

Participant Involvement

We also identified 4 HIV studies that had actively involved study participants, e.g.

- Ad hoc participant meetings to discuss a specific topic (eg. recruitment issues, future research priorities etc) – 2 studies
- Ongoing participant advisory groups – 2 studies

Participant involvement was not the only approach to PPI used in these studies, but complemented other approaches

Although participant involvement is recommended in the Good Participatory Practice Guidelines for biomedical HIV prevention trials and TB trials, we are unaware of examples being reported in the published PPI literature.

Conclusions

Models of involvement

- Half the studies combined more than one PPI model, eg. long-term involvement in formal committees and one-off activities
- Different models may be better for involving different patient groups, eg.
  - Studies in young people tended to involve in one-off activities (eg. commenting on questionnaires, designing posters etc)
- Participant involvement, in addition to more traditional approaches to PPI, may have advantages, eg.
  - Where the intervention being tested is novel

Impact of involvement

- All studies reported some impact from PPI; 8/10 reported impacts at multiple stages of the research process
- No negative impacts from PPI were reported

Recommendations

- Use of multiple models within a single study may help to maximise the potential impact of PPI
- Researchers should familiarise themselves with a range of PPI models, and select those that are the most appropriate for the specific study based on the people they want to involve, desired impact, and resources available
- Further evaluation of participant involvement is needed to better assess its potential impact