UKCRC Registered Clinical Trials Units

# Patient and Public Involvement and Engagement Task and Finish Group Report

## May 2018

UK Clinical Research Collaboration

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# UKCRC Registered CTU Network Patient and Public Involvement and Engagement Task and Finish Group Report May 2018

Bagley H., Beever D., Hughes-Morley A., Rick C., Cleland J.G., Thorne K., Mader L., Blackburn S., Vale C. & Muir D.

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# Abbreviations

PE – Public Engagement

CI – Chief Investigator

CTU – Clinical Trials Unit

CLAHRC – Collaboration for Leadership in Applied Health Research and Care

HEFCE – Higher Education Funding Council for England

Network – UKCRC Registered CTU Network

NIHR –National Institute for Health Research

PPI – Patient and Public Involvement

PPI&E – Patient and Public Involvement and Engagement

RDS – Research Design Service

UKCRC – UK Clinical Research Collaboration

# Terminology

Please note, in this report where we refer to 'the Network' we are referring to the UKCRC Registered CTU Network.

# Executive Summary

## Introduction

This executive summary reports the findings of a scoping exercise, conducted in 2017 by the UKCRC Registered Clinical Trials Unit (CTU) Network Patient and Public Involvement & Engagement (PPI&E) Task and Finish Group.

Patient and Public Involvement in research is research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. Public Engagement (PE) is sharing information and knowledge about research with the public.

## What were the aims of the scoping exercise?

Our aims were to:

- Survey UKCRC Registered CTUs on current models of delivering PPI&E
- Develop a list of PPI&E contacts at each of the registered CTUs
- Arrange and deliver the PPI&E scoping workshop with delegates from across the UKCRC Registered CTU Network
- Develop an action plan to improve collaborative working in PPI&E within the UKCRC Registered CTU Network, share best practice and avoid duplication of effort.

## How was the scoping exercise conducted?

We conducted an e-survey across registered CTUs and hosted a workshop with numerous activities to explore PPI&E practice across the Network.

## What did we find?

- **PPI&E are developing areas** in registered CTUs with patient and public involvement (PPI) currently more advanced than public engagement (PE) and drivers including: recognition of the potential benefits of PPI&E; institutional and funder requirements; existing collaborations; the support of senior management and interest of trialists in these areas.
- **Numerous challenges exist** in conducting PPI&E including: time; funding; training; recognition; finding patients to involve; misconceptions about and buy in to PPI; lack of training in PE and a lack of consistency and standardisation in PPI.
- **The infrastructure to support PPI&E varies** across the UKCRC Registered CTU Network with examples including PPI co-ordinators and PPI steering Groups
- **Numerous resources exist already to support PPI&E** but there is duplication of work in developing resources and inconsistent awareness of external resources, whilst there are also a number of **gaps in available resources** or they are not specific enough to clinical trials. Additionally there is **no way currently of sharing these resources** across the Network.
- Numerous PE campaigns that relate to clinical research, but there is **inconsistency** in how registered CTUs across the Network approach public engagement in clinical trials.
- Staff in registered CTUs are keen to **share resources,** to **communicate as a network** and to **work collaboratively** in PPI&E

# What are the implications?

Based on the findings of this scoping exercise we have made the following ten recommendations:

## Priority recommendations

1. Support the continuation of the PPI&E Task and Finish Group to deliver the agreed action plan, including workshops to advance the sharing and development of PPI&E models and resources.
2. Provide funding to support the crucial involvement of Public Contributors in the PPI&E Task and Finish group's activities.
3. Establish a communication strategy and methods for the PPI&E community and Public Contributors.
4. Develop a UKCRC Registered CTU Network strategic approach to public engagement, working with other PE clinical research campaigns and initiatives to raise awareness of clinical trials.

## Secondary Recommendations

5. Provide a central repository for sign-posting to relevant external PPI&E resources and sharing CTU developed resources and training, including within the developing International PPI Network.
6. Promote a positive core message and vision for PPI across the UKCRC Registered CTU Network, aligned with developments in the NIHR Public Involvement National Standards and potentially engage with funders of clinical trial research and registered CTUs (NIHR, MRC, charities) to consider providing PPI infrastructure and delivery costs for the design of studies.
7. Review existing PPI training and mentoring for CIs, trial staff and Public Contributors in relation to the training needs identified in previous research. Explore the potential of a core set of PPI&E training materials and a mentoring system for both Public Contributors and for CTU professionals.
8. Raise awareness of existing resources to support the process of disseminating clinical trials results to patients and showcase examples of approaches to the dissemination process through the UKCRC Registered CTU Network.
9. Explore potential ways that the UKCRC Registered CTU Network might work with patient organisations both to promote PPI opportunities and to engage their patient communities around clinical trials in general and in relation to disseminating study results.
10. Develop a system of sharing opportunities for Public Contributors to be involved in studies throughout the Network.

# Plain Language Summary

## Introduction

Clinical Trials Units (CTUs) are specialist units which have been set up to design, conduct, analyse and publish clinical trials and other well-designed studies. The UKCRC Registered Clinical Trials Unit (CTU) Network is a network of academic clinical trials units (CTUs). To become a registered CTU the unit is assessed by an international panel of experts in clinical trials research. Specific criteria are used in this process. The UKCRC Registered CTU Network provides its members with information and guidance and it represents registered CTUs in key strategy groups and consultations. Further information about the Network can be found here: http://www.ukcrc-ctu.org.uk/ . The Network were keen to set up a Task and Finish group to explore patient and public involvement and engagement in registered clinical trials units.

Patient and Public Involvement (PPI) in research is research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. PPI is considered an essential element of clinical trials, helping improve how clinical trials are designed and conducted and helping to improve information about the results of the trial when it has been completed. Organisations that fund research are increasingly requesting evidence of PPI both in the development of the research study and whilst if is being carried out.

Public Engagement (PE) is sharing information and knowledge about research with the public and is therefore an important part of the work of clinical trials units, including for example, activity to explain clinical trials to the public and providing information about the results of the research once it's completed.

## The Patient and Public Involvement and Engagement Task & Finish Group

The UKCRC Registered CTU Network set up a Patient and Public Involvement and Engagement (PPI&E) Task and Finish Group in 2017. The first task of this group was a 'Scoping Exercise' to:

- Find out how PPI&E was being carried out in registered CTUs in the UK
- Develop a list of people working in PPI&E in registered CTUs.

## How was the scoping exercise carried out?

We carried out a survey across registered CTUs and held a workshop with numerous activities to find out about how PPI&E is done across the Network. This is the report of this work.

## What did we find?

- **Patient and Public Involvement and Engagement (PPI&E) are developing areas** in registered CTUs with patient and public involvement (PPI) currently more advanced than

public engagement (PE). Key drivers for PPI&E include: recognition of the potential benefits of PPI&E; organisations and institutions that fund and conduct trials are increasingly requiring evidence of PPI&E; the support of senior management and interest of people working in clinical trials in PPI&E.

- **Numerous challenges exist** in carrying out PPI&E including: time; funding; training; recognition; finding patients to involve; misconceptions about and buy in to PPI; lack of training in PE and a lack of consistency and standardisation in PPI.
- **The organisation of PPI&E varies** across the Network of registered CTUs with examples including PPI co-ordinators and PPI steering Groups
- **Numerous resources exist already to support PPI &E** but there is duplication of work in developing resources and inconsistent awareness of resources that have been developed by external organisations. There are also a number of **gaps in available resources** or they are not specific enough to clinical trials. Additionally there is **no way currently of sharing these resources** across the Network.
- Numerous PE campaigns that relate to clinical research exist, but there is **inconsistency** in how UKCRC Network of registered CTUs approach public engagement in clinical trials.
- Staff in registered CTUs are keen to **share resources,** to **communicate as a network** and to **work collaboratively** in PPI&E

# What are the implications?

Based on the findings of this scoping exercise we have made the following ten recommendations:

## Priority recommendations

1. Provide funding and support so that the Patient and Public Involvement & Engagement Task and Finish Group can continue and carry out the agreed action plan. This would include workshops to further share and develop approaches to PPI&E and resources for the Registered CTU Network
2. Provide funding to support the crucial involvement of Public Contributors in the activities of the PPI&E Task and Finish group.
3. Establish a strategy and methods for communicating with the PPI&E community within the Registered CTU Network and Public Contributors
4. Improve ways that the Registered CTU Network engages with the public, including participating in other national campaigns and initiatives to raise public awareness of clinical trials.

## Secondary Recommendations

5. Provide a central repository of resources and training for PPI&E which have been developed either within or outside the Registered CTU Network for all to use including within the developing International PPI Network.
6. Promote a positive message and vision for Patient and Public Involvement across the Registered CTU Network, which is consistent with the new NIHR Public Involvement Standards. This might encourage funders of clinical trial research and registered CTUs to consider providing funding for Patient and Public Involvement infrastructure (staff and systems) and activities to support design of research studies. Patient and public involvement

during this early phase of research has, up to now, largely been unfunded in most registered CTUs.

7. Building upon the training needs identified in previous research, review existing training and mentoring for Patient and Public Involvement and Engagement for research leaders, staff and Public Contributors. Explore the possibility of having a main set of training materials and a mentoring system for both Public Contributors and registered CTU staff
8. Raise awareness of approaches and resources for communicating the findings of research with participants and the general public. This will include showcasing good examples of how to communicate research findings across the Registered CTU Network
9. Explore how the Registered CTU Network can work closer with patient organisations to promote opportunities for involving patients and the public in clinical trial research, engaging with patient communities, and communicating research findings with the public.
10. Develop a way for sharing new opportunities for involving Public Contributors in research across the Registered CTU Network

# 1. Introduction

Patient and public involvement (PPI) is an essential element of clinical trials and helps improve its design, delivery and dissemination (Staley, 2009). Research funders increasingly request evidence of PPI as a requirement for funding (e.g. the National Institute for Health Research- NIHR). PPI may also provide 'added value' when addressing the ethical acceptability of research (Staley & Elliott, 2017).

The NIHR recently published 'Breaking Boundaries', a review of PPI which sets out recommendations for the next 10 years (http://www.nihr.ac.uk/get-involved/Extra%20Mile2.pdf). The report highlights the need for a more strategic approach to PPI and recommends that PPI leads should have opportunities to network and share best practice. Though resources already exist to support PPI activities in research in general, few are focused specifically on clinical trials. Gamble et al (2015) conducted a retrospective study of PPI in clinical trials and identified the need for "greater engagement between Registered Clinical Trials Units (CTUs), INVOLVE and funders of research to benefit PPI activity".

**Patient and Public Involvement (PPI)**
*Research done with or by the public*

**Public Engagement (PE)**
*Sharing information and knowledge about research with the public*

There is also increasing emphasis on the need to engage* the public in clinical trials: raising awareness of both clinical trials in general and sharing trial findings to the wider patient population. For example, the NIHR 'OK to Ask' and 'I am Research" campaigns (https://www.nihr.ac.uk/news-and-events/support-our-campaigns/i-am-research) and the MRC Hubs for Trials Methodology Research 'Trials Change Lives' initiative (http://www.methodologyhubs.mrc.ac.uk/research/trials-change-lives/) will benefit from increased collaborative public engagement (PE) by registered CTUs.

## The UKCRC Registered CTU Network Patient and Public Involvement and Engagement (PPI&E) Task and Finish Group

To increase knowledge and improve efficiency in public involvement and engagement, informal information sharing between a small group of people with PPI roles within CTUs had taken place for some time. Building upon the success of this the group decided to formalise and widen the network. Following an invitation via the UKCRC CTU Network, 22 people joined the first teleconference hosted

by Liverpool Clinical Trials Research Centre in April 2015. A key outcome of the call was an enthusiastic response to working more collaboratively across the CTU Network. An application was therefore made to the UKCRC Registered CTU Network to establish a Patient and Public Involvement and Engagement (PPI&E) Task and Finish Group.

The overall aims of the Patient and Public Involvement and Engagement (PPI&E) Task and Finish Group Funding were to:

- To identify successful approaches for delivering PPI&E within registered trials unit
- To map existing PPI&E resources along the timeline of a clinical trial.
- To develop more effective collaborative working across registered CTUs in relation to PPI&E

To deliver these aims, the following activities took place:

1. Establishing the PPI&E Task and Finish Group
2. Involving patients and members of the public in the activities of the PPI&E Task and Finish Group
3. A survey of registered CTUs on model of PPI&E
4. A workshop bringing together representatives from UKCRC Registered CTUs to explore and share approaches to PPI&E and to discuss ways to improve collaborative working.

# 2. Methods

## 2.1 Establishing the PPI&E Task and Finish Group

Task and Finish Group members were formally recruited through the standard Network selection process via Directors of the UKCRC Registered CTU Network. The Terms of Reference and membership of this group can be found in Appendix 1.

Members of the Task and Finish Group were invited to contribute to one or more of the following three work-streams:

1. Patient and Public Involvement (PPI) Work Stream – To organise patient and public involvement into Task and Finish Group's activities.
2. Survey Work Stream – To develop and administer a survey of PPI&E models, resources and activities across the UKCRC Registered CTU Network.
3. PPI&E Workshop Work Stream – To organise and deliver a workshop to further explore models, resources and the potential for greater collaboration in PPI&E.

## 2.2 Patient and Public Involvement Work-stream

The involvement of people with experience of having Public Contributor roles in trials was crucial to the work of this Task and Finish Group. We established an application process to recruit members of the public with experience of PPI&E in CTUs to participate actively in the planned workshop and to comment on the action plan in this report. Applications were sought from the trials units where members of the main Task and Finish Group worked, recognising this would help to ensure appropriate support for our Public Contributors in the run up to the workshop. Following telephone interviews, four Public Contributors were identified and invited to the workshop. The main expenditure in this initial Task and Finish Group was to fund Public Contributor attendance at the workshop.

## 2.3 Survey Work-stream

An electronic survey (Appendix 2) was designed and developed to explore both involvement and engagement in registered CTUs, including:

- how these activities are coordinated within CTUs
- facilitators and barriers of PPI&E
- what resources exist to carry out these activities

With the support of the Network Secretariat, a link to complete the survey was sent to Directors of registered CTUs on the 11th October 2017. The survey was open for completion for three weeks, with two reminders sent via the Network Secretariat.

## 2.4 The Workshop Work-stream

The workshop work-stream group designed their event with the following key objectives:

- For delegates to network with others working in PPI&E
- To share and explore the results of a recent survey about PPI&E in trials units
- To map out what PPI&E resources exist for supporting trials units, and identify where there are gaps
- To discuss ways to work more collaboratively

The workshop was hosted at the University of Liverpool in London and funding for catering was provided by the North West Hub for Trials Methodology Research. The programme for the event can be found in Appendix 3.

# 3. Results

## 3.1 The Survey Results

The response rate for the survey was excellent. Of the 51 CTUs with UKCRC Registered CTU status at the time of the survey (October 2017), 90% (n=46) completed the survey.

### 3.1.1 The coordination of PPI&E activities within UKCRC Registered CTUs

*Responsibility for PPI&E* -15/46 CTUs reported having one person with overall responsibility for PPI&E, but the majority (n=14) of these people spent less than 50% of their time on PPI&E activities. In 7 of the 15 CTUs that person was a dedicated PPI lead, but the remainder were a range of staff including trial managers, research nurses, research fellows and directors or deputy directors who had taken on this responsibility.

*PPI&E steering committee* - 13/46 trials units described having a specific PPI&E steering committee designed for strategic approaches to PPI&E. Within these 13 CTUs the majority had < 10 members (n = 9) with staff members including trial and data managers, clinical staff and statisticians. In 6 of these committees they had between 2 and 10 Public Contributors as members, the remaining 7 CTUs having no Public Contributor members.

### 3.1.2 Resources to Support PPI&E

*Policies and guidance* - 11 CTUs had PPI guidance for trial staff, whilst only 2 CTUs had PE guidance. 12 CTUs had a policy on PPI whilst only 3 CTUs had a policy on PE. 6 CTUs use a standard operating procedure for PPI and 13 follow a payment policy for Public Contributors.

*External resources –* The majority of CTUs (n=40) reported using external resources to support PPI&E with most of these being INVOLVE (n = 34) and Research Design Service (n=21) resources. When CTUs have come across a problem relating to PPI, the majority (n=30) have turned to INVOLVE for help, whilst others have turned to the Research Design Service (n = 20), to others undertaking PPI in other CTUs (n=17) and to regional PPI Networks (n = 12).

*In house resources –* In addition to external resources, 12 CTUs have developed in house resources for PPI, 2 for PE and 6 for both PPI&E.

*Willingness to share resources –* Respondents were asked if their CTU currently shared or would be prepared to share resources in the future. 16 CTUs said that they didn't have resources to share. Of the remaining 30 CTUs, 5 said they already did this and 20 said that they would be happy to share resources in the future. No-one answered 'no' to this question, whilst 3 people expressed uncertainty and 2 selected 'other' explaining that their resources were study specific or that the resources were not developed enough for sharing yet.

### 3.1.3 Training in PPI&E

21 CTUs reported offering specific PPI&E training to staff and Public Contributors. Most CTUs also reported signposting staff to external support and resources – again notably INVOLVE and Research Design Services.

### 3.1.4 Reward and recognition for PPI&E

Only 12 CTUs reported reward and recognition for staff involved in PPI&E. Examples included:

- Rewards, awards or prize schemes (institutional and external)
- Recognised in promotions and also personal development and/or appraisal processes
- Attending conferences and authorship of papers

### 3.1.5 Reimbursing and payments for Public Contributors

The majority of CTUs (n=32) report that they reimburse or pay Public Contributors over and above covering expenses. This is mostly done via institutional schemes or processes (n=19) or via payment in cash or vouchers (n=18). 10 CTUs described offering training for Public Contributors as a form of acknowledgement.

### 3.1.6 Methods research in PPI&E

Just over a third of CTUs (n=16) had been or currently were involved in methods research about PPI&E.

### 3.1.7 Evaluation of PPI activities

18 CTUs reported regularly or routinely evaluating their PPI activities.

### 3.1.8 Factors helping registered CTUs with both PPI and PE

Responders to the survey were asked to provide free text responses to identify factors that they felt helped their CTU with both PPI and PE. Numerous factors were identified:

#### *Patient and Public Involvement*

The **support of senior management and CIs** was identified as an important driver for PPI by 15 respondents: "*A strong culture of the importance and necessity of PPI from the most senior researchers*"; and "*Supportive and engaged CI's who see the importance of PPI*". Likewise the support from other CTU staff helped in undertaking PPI: "*The enthusiasm from the whole unit to develop this area*".

Another key driver (n=17) was **funder requirements and support for PPI**: "*NIHR funding for most grants so PPI is seen as integral and normal for all grants"*

The benefits of having **access to Public Contributors and specific patient panels** was acknowledged, alongside the importance of investing in building networks: *"access to PPI panels to discuss grant/protocol developments."*

Seven respondents identified the importance of having **someone with responsibility for PPI** as being helpful, whilst 12 respondents also identified the importance of **working collaboratively**, for example with the Research Design Service and other organisations: "*assistance from PPI leads at collaborative institutions*", "*Good regional links with other organisations that enable comprehensive PPI*" and "*Co-location of Research Design Service and CTU*".

A growing **awareness of the potential value of PPI** and **positive experiences** of undertaking it were recognised as helping (n = 7): "*Increased appreciation within the academic community on the benefits to PPI*".

#### *Public Engagement*

A driver for PE was recognised as **institutional or funder requirements for PE** (mentioned by 17 respondents), for example *"Incentivised by the university and as part of REF*" and "*Greater awareness and expectation from funders for PE*". Wider institutional support through, for example, university public engagement facilities, was recognised as benefitting some of the CTUs, for example: "*University links and Public Engagement Committees to share resources and ideas*".

Another key factor seen as important (n=8) was that of the **experience and interest of staff** in relation to public engagement: "*Enthusiasm of investigators and staff*" and others talked about the benefit of having links with a PE group.

Several respondents (n=8) recognised the benefits of **existing collaborations**, for example with the Research Design Service and other organisations, for example: "*Improved dissemination through contacts with national/regional third sector organisations/charities*" and "*Links with the Trials Change Lives Initiative*".

A small number of respondents (n=5) acknowledged how **PPI itself had improved public engagement**, for example "*Utilising the knowledge and skills of PPI to better understand how to share information and research with the general public*".

Five respondents indicated that it was too early to comment about public engagement, suggesting that it was in the early stages of development, for example: "*As a CTU we haven't explored PE to any extent but would be interested in doing so*"

### 3.1.9 Barriers to PPI&E in registered CTUs

Several barriers were identified in relation to carrying out PPI&E in registered CTUs:

#### *Patient and Public Involvement*

**Funding and time** to undertake PPI were most frequently identified as barriers (described by 21 CTUs). Comments included: "*Having to revitalize banks of PPI&E representatives with no infrastructure money allocated within the CTU*" and "*Although there is a dedicated person for PPI at the Trials Unit, the amount of their time dedicated to PPI is actually very small, meaning that the amount of work that can be undertaken is limited*".

A significant barrier identified by 20 respondents was that of **finding patients to involve in research and/or sustaining involvement**. In addition to finding people to involve there were concerns about involving the right people and the need for representativeness seemed a concern "*Finding the right people to involve – e.g. people from the target population, people who are 'representative'*" and not using the same people time after time "*Finding people who are not professional PPI as they have volunteered so often*".

Concerns about **lack of consistency and standardisation** in PPI was seen as a barrier by some: "*Linked up national guidance on how to get started: recruiting PPI and role profiles etc.*"

There were **institutional issues** raised with PPI, for example, "*University focus seems to be on engagement rather than involvement, although this seems to be changing*" and additionally "*New visa and immigration laws mean that PPI members may have to present their passports for every meeting"*.

Four respondents identified areas where there was **duplication of PPI** – including the Research Design Service "*Lack of demand from investigators for CTU involvement when Research Design Service already provides this support locally*" and from other PPI panels "*Balance between disease specific and generic PPI panels depending on type of trial*"

Some were concerned that the **types of the trials** within the CTUs portfolios meant that doing PPI was more challenging: "*The trials we support cover a wide range of different clinical conditions, so it wouldn't be feasible for us to link CIs directly to PPI members*" One respondent mentioned "*Sponsor reluctance - especially from industry*".

**Misconceptions about and buy in** for PPI were identified as challenges by 5 respondents: "*The misconception by researchers that PPI is very time consuming and will delay their submissions*" and "*Preconception/prior experience of ineffective PPI contribution*". Similarly there were concerns about lack of experience of PPI and lack of training with 9 respondents mentioning concerns in these areas: "*Lack of training/confidence from trial management staff and chief investigators*" and "*Poor chairing of meetings resulting in PPI members feeling left out*".

Four respondents mentioned the **need for greater structure and/or organisation for PPI**, for example: "*Lack of PPI organisational structure (n.b. this is currently under development in the form of a steering group)"* and *"Inconsistent approach with different CIs. Some CIs take responsibility for PPI&E and some expect us to take a lead".*

### *Public Engagement*

**Funding and time** to undertake PE were most frequently identified as barriers (described by 22 CTUs). Comments included: "*relies on people volunteering at weekends/evenings in addition to their work*"; "*Inconsistent approach across trials units - need collaborative work as PE can be both time consuming and costly*".

**Leadership and/or commitment to PE** was another barrier, for example, there were concerns that it is "*unclear what funders expect in terms of engagement*" and that there is "*Still a strong focus on 'academic' outputs rather than outputs important to 'people'*". A lack of prioritisation of PE was also acknowledged, as was the organisational structure to undertake PE.

There were issues around a **lack of training or guidance for PE** and a general **lack of experience** in this area "*many trials staff are simply not very good at it and don't feel they can contribute*". There was also concern around identifying opportunities for undertaking PE in relation to clinical trials, for example: "*Lack of opportunities to attend to promote the CTU to the public*".

### 3.1.10 Support from the UKCRC Registered CTU Network

The majority of CTUs felt that the UKCRC Registered CTU Network could better support PPI (n=33) and PE (n = 31). Areas of potential support suggested related to:

- developing standardised approaches to PPI&E
- being a central point for the sharing of resources and PPI&E case studies
- developing standardised training (potentially accredited)
- offering webinars
- bringing together PPI&E leads to share experiences
- developing and promoting best practice and linking with other PPI&E organisations

The following quote summed up a number of these areas, the respondent stated that what was needed was:

"*Collaborative learning and development of standard procedures - we are all spending a lot of time reinventing the wheel*".

## 3.2 The Workshop

### 3.2.1 Attendees

The workshop was attended by 39 delegates from 39 registered CTUs and four Public Contributors. A mix of CTU staff, Directors and PPI&E Leads and Coordinators attended. Some of the registered CTUs who were not represented at the workshop could not identify a single person with responsibility for PPI&E to attend or were not available on the day.

### 3.2.1 Discussion of the Survey results

Delegates were invited to reflect on the various involvement models used within CTUs as identified by the survey and to discuss the pros and cons of those different approaches. They were also asked to discuss how public engagement fitted into those models. Following this small group exercise the following comments and queries were raised:

#### *PPI Organisation*

- **PPI Lead:** It was considered that having a PPI lead had the following advantages: i) being able to communicate best practice and offer one point of contact, ii) help build up rapport with Public Contributors and advocacy groups, and iii) enhance efficiency by avoiding duplication of effort.

  However, a PPI lead has some disadvantages: i) the majority of PPI leads work less than 50% of time in their role, ii) they are often stretched too thinly and require support, and iii) a CTU's approach to PPI may be too influenced by a single person, whereas a committee with responsibility for PPI might enable shared ideas.

- **PPI Steering Groups:** Several CTUs reported having PPI Steering Groups in the survey. This was seen as positive in that it enabled a range of experiences to be brought together and expanded the knowledge base for PPI in the CTU. It was acknowledged that the meetings for such groups may be infrequent and may not include the patient voice.

- **Institutional support for PPI:** There were concerns that Universities placed emphasis on public engagement rather than involvement.

- **Recognition for PPI work:** Delegates felt that PPI work should be recognised more as part of personal development and promotion.

#### *Working with Chief Investigators (CI)*

Support for PPI from CIs was described as mixed. It was suggested that some CIs should be encouraged and supported more to engage with PPI activities. Suggestions included managing the expectations of CI in relation to the PPI and improved planning and communication of PPI activities and its role from the outset.

#### *Working with Public Contributors*

- **PPI throughout the trial:** It was widely acknowledged that Public Contributors should be involved earlier and continue in all stages of the trial, but lack of funding for early involvement was a major obstacle.

- **Flexibility in PPI roles:** It was noted that not all Public Contributors were happy, able or have the necessary skills to contribute in the same way as other Public Contributors. For example, one person may be more creative to produce patient information or more able to do public speaking to support dissemination activities. Therefore, PPI opportunities should be tailored appropriately to the individual(s). It was suggested that PPI&E should be driven by the Public Contributors, explaining, for example, how they want to be involved.

Creative and flexible approaches to involvement were also described (e.g. video calling rather than a face to face meeting, social media, meetings in the community, etc). To widen the diversity of Public Contributors, it was felt that different approaches are needed to ensure a greater range of perspectives and experiences are included, and not excluded.

**Support for Public Contributors:** It was emphasised that we should be aware that Public Contributors can become isolated from every-day decision making in the research process (e.g. casual decisions made during the course of a working day rather than being discussed at Steering Committee meetings). CTUs should ensure that Public Contributors are given timely, regular and appropriate feedback on how their input has been used and what impact it has had.

- **Availability of Public Contributors:** As PPI&E work increases it is important to increase the number and range of different Public Contributors. Where multiple Public Contributors are available they can take part in different work streams, where appropriate. For example, a Programme Grant might have several smaller groups of Public Contributors working on different trials or other aspects of the Programme.

### *Support from the UKCRC Registered CTU Network*

It was suggested that it might be beneficial for the Network to have a single, consistent strategy and vision for PPI. Currently individual CTUs develop their own, which may be inconsistent with the rest of the Network. A unified approach to PPI would follow the examples of the various Royal Colleges who often lead in their specialist disease area, and may create a culture that views PPI in clinical trials as the norm.

### *Resources to Support PPI&E*

There was a broad recognition that sharing experiences and documents between CTUs (and individual institution departments) can help CTUs make the most of existing resources. Though, it was noted and should be emphasised that different CTUs have different research strategies and focus.

### *Public Engagement Approaches*

- **Public engagement development:** Public engagement was described as an emerging area. It can occur in a number of ways including Open Days, drafting patient summaries, and the use of Twitter and other social media. It was usually disease specific and conducted nationally, but initiatives such as 'I am Research' 'OK to Ask' and the 'Trials Change Lives' were also highlighted. It was acknowledged that Public Engagement was now important at a university level so it was suggested that CTUs should link in with them. In some instances university engagement teams did not feel that working with CTUs on their PPI was part of their remit. Some further work in this area may be indicated if a broader view of public engagement is taken.

- **Clinical trial participants**: It was suggested that capturing the views and experiences of trial participants about research might help with both future PE and PPI. For example, we can learn from the work of the RfPB funded PAtient-Centred Trials work, being led by Professor Peter Bower (University of Manchester). This group are developing and piloting a patient

experience measurement tool around clinical trials delivery and developing guidance and materials for trials units, investigators and other stakeholders to respond to feedback from the measure so as to improve trial delivery.

- **Clinical trials results**: A lot of communication about trial results was clinician focussed and it was emphasised that patients needed to know what treatments were available so that they could make informed choices about treatments, hence a broader, more patient focussed approach to engagement is needed regarding the dissemination of trial results.

### 3.2.2 - Mapping and Gapping Exercise

Delegates were asked to work in small groups to identify, along the timeline of a clinical trial, any resources they either used or were aware of to support patient and public involvement or engagement. The resources could be ones developed by the trials unit or by external organisations such as INVOLVE. They were also asked to identify any resources they felt might be helpful to have. Appendix 4 provides the full details of resources identified; the following is a summary.

#### *Existing resources*

Numerous resources already exist in the PPI& E community but these are not always trials specific. There are many around general guidance for PPI, but less about supporting PPI in particular activities, for example, in dissemination or data analysis or interpretation. Several examples of training were identified both for Public Contributors and trials teams, but these focussed on PPI rather than PE. The small number of PE resources identified included explaining trials to patients and some general public engagement resources.

There appeared to be inconsistency about people's awareness of external resources available. For example there was a request for guidance on the use of social media, whilst another group identified this as an existing resource produced by INVOLVE.

#### *Gaps in resources*

The group exercise highlighted some key gaps in resources:

- Guidance on PPI in analysing and/or interpreting data
- Specific guidance on PPI in clinical trial design
- How CTUs can effectively engage with the public

In some cases a group would identify a potentially useful resource that someone in another group had described as one their unit had developed. Alternatively, similar resources had been developed by more than one CTU, for example PPI training. It was difficult to determine exactly what all the CTU resources were from the descriptions given, therefore further exploration is needed.

The clear lack of resources for engagement suggests that this is a developing area for CTUs.

In addition to discussions about resources and gaps in resources, there were some notes documented during this activity that highlighted some specific issues or concerns. These included:

- **PPI in prioritising research questions** – Lack of networks to identify questions of relevance for the community; the need for early patient and/or public input in prioritising questions for research and issues around the design and funding of the James Lind Alliance process
- **Organisations and PPI** – The challenge of navigating organisational structures around PPI

- **PPI standards** – What are the minimum standards of quality for PPI? What does it look like?

### 3.2.3- Collaborative Working Discussion

A large group discussion then followed about potential collaborative working. Participants were informed that the recommendations and feedback from the workshop discussions, the survey and the Mapping and Gapping session, would be used by the PPI&E Group to develop an action plan which would be submitted to the Network's Executive Group for review. The report and the Executive Group's feedback would then be used to inform future work by the PPI&E Group.

It was noted that a number of key areas had been identified through the survey and through discussions earlier in the workshop:

- There are a wide range of models by which PPI&E was delivered, suggesting no overarching strategy.
- Resourcing is an issue no matter which model.
- Even dedicated PPI leads often have only a small percentage of time in their role.
- The level of public contributions vary at strategic level and it can be difficult to get the voices of Public Contributors heard.
- Where Public Contributors were not properly involved their full impact was not realised.
- The work of PPI staff and Public Contributors should be more fully recognised.

#### *Future Communication*

The communication methods used by the Network secretariat to support its Network Operational and Task & Finish Groups were described. Delegates were enthusiastic about maintaining a CTU network for PPI&E and explored the best ways of doing this. Suggestions included:

- A dedicated mailing list accessible by one representative from each CTU. This could be used for targeted emails such as requests for feedback on consultations or for meeting arrangements.
- A dedicated online forum for discussions hosted on the Network's website. Forums were usually open to staff at registered CTUs only which could potentially pose a problem for Public Contributors. However, there was possibly a way in which the forum could be made publicly accessible.
- A dedicated webpage for PPI&E on the Network website, containing updates and shared resources
- A list of contacts across the Network showing key areas of expertise was considered helpful in terms of sharing experience.
- The use of a closed Facebook group would enable practitioners to post pictures of things that they had done and share case studies etc.
- A newsletter for Public Contributors containing news, information and opportunities for PPI&E CTU, as well as PPI&E methods research findings.

#### *Sharing Resources and developing shared training*

Mechanism for developing and sharing resources and materials, included:

- A central repository of documents. Though, consideration about the following would be needed:
    - How to quality assure the resources

  - How to keep the resource up to date.
  - How to evaluate the use and usefulness of the resources – It was noted that the UKCRC Registered CTU Network is looking to introduce a form of managed access for its outputs, allowing the Network to determine the utility of its resources.
- It would be helpful to develop a 'map' of a trial, similar to the clinical trials toolkit. This could outline what should be included throughout the clinical trial and best practices. An existing PPI Toolkit (Bagley et al 2016) could be the starting point for this resource. A request was made to share the reference to the article about this toolkit.
- Information on relevant PPI&E journals could be circulated.
- A core PPI&E training pack could be developed for CIs.
- Annual PPI&E training sessions could be held for both staff working in PPI and Public Contributors.

### *Impact when working with other organisations*

By establishing and sustaining a collaborative PPI&E CTU group may be beneficial when making recommendations or lobbying for change with other organisations and funders. For example, it was noted that funding for PPI&E at the early stage in developing was a significant and on-going problem. A unified UKCRC Registered CTU Network voice on PPI&E would support those discussions with other key stakeholder groups including funders.

## 4 Discussion

### *PPI&E – growing areas*

The interest and enthusiasm in responding to our PPI&E survey (90% response) and attending our workshop suggests that this is an area where potential to work collaboratively is welcomed.

The results of our survey and the discussions and activities within the workshop suggest that activity and developments in PPI in clinical trials is greater than public engagement. Nevertheless, collaborative working in the future offers the chance to progress both of these areas.

PPI in clinical trials is increasingly a requirement of funder requirement. This has helped to drive progress in this area, but we need resources to support best practice across registered CTUs based on evidence of what works best. Indeed the recently published METHODICAL study (Kearney et al, 2017) identified priorities for research into PPI in trials and working groups around these priorities are establishing. Furthermore, the NIHR Public Involvement National Standards are starting to be tested and implemented in 2018. Both of these provide opportunities for the Network to get involved in advancing PPI in clinical trials. It is anticipated that the newly developing HEFCE Knowledge Exchange Framework will include PPI well as PE, which may increase the institutional drive for PPI.

Funders are likewise placing greater emphasis on public engagement, indeed the recent update of the EU Clinical Trials Regulation 536/2014 (Article 37) requires that sponsors provide summary results of clinical trials in an understandable format to laypersons. (EU Regulation No 536/2014 of the European Parliament and of the Council of 16 April 2014). The emphasis on public engagement as part of the Research Excellence Framework (REF) 2021 process has also become a key driver for public engagement across a number of CTUs and the newly developing HEFCE Knowledge Exchange Framework will no doubt further catalyse this.

### *Infrastructure for PPI&E*

Our survey showed that infrastructure to support PPI&E across the Network of Registered CTUs clearly varies, with only around a third of the CTUs having someone with overall responsibility for this area, with most in part time roles often stretched too thinly and requiring support. Using a PPI Working or Steering Group to support the strategic development of PPI&E is an approach also used in less than a third of CTUs, and not all these groups had Public Contributors as members, potentially due to funding constraints. Additionally some CTUs have their own PPI panel or access to specific PPI panels within their University offering advice to trialists which may be particularly helpful in the time pressured early stages of study design, given the difficulties described in finding Public Contributors to involve.

Sharing of more detailed information about PPI coordinator roles, PPI committees and Public Contributor panels may enable other trials units to develop similar approaches to suit the needs of their CTU or trials run in their CTU. For example, if there were a top tips document about how to establish, fund and run a PPI panel for a trial or for a CTU, other trials units may benefit from this. In addition there is a need for more detailed analysis to explore which approaches and models work best to support PPI&E in CTUs and how this is influenced by the CTU's portfolio.

### *Resources for PPI&E*

A wealth of resources were identified in the mapping and gapping exercise, produced by both CTUs and external organisations, although it was noted these are not always trials specific, so there may be potential for tailoring the resources more to the CTU context. However, it was not always clear exactly what each resource related to and therefore we need to find further detail about these resources to ensure their relevance.

The survey demonstrated that the majority of CTUs have used external organisations such as INVOLVE and the Research Design Service for their PPI resources. It was, however, noted that when the mapping and gapping exercise was completed, there were not many commonly identified resources across groups, suggesting that signposting to what is already available may be beneficial. This signposting approach was used in the Bagley et al (2016) PPI Toolkit. One potential issue with this, however, is that there is already much duplication of resources by external organisations. The Research Design Service, Collaboration for Leadership in Applied Health Research and Care, patient organisations and regional PPI networks have developed their own resources in very similar areas, for example there are numerous PPI Handbooks and 'how to' guides. By signposting we would not wish to swamp people with resources, therefore we would need to develop an approach to exploring the content of what is available and identifying the resource that best meets the needs of CTUs.

It was noted there are resources addressing the same area that more than one trials unit have developed indicating duplication of work and there were some resources that some trials units wanted to see developed, that had already been developed by other trials units. This suggests that there is potential for greater efficiency by future sharing of resources.

In terms of pooling resources that have been developed by CTUs, further work is needed to find out more about their resources and potentially collate them. Alongside this would need to be an agreed approach for how to share resources, for example:

- Clarification about how shared resources would be credited
- Potential processes for further potential piloting shared resources in other CTUs

- What to do where more than one CTU has developed a similar resource – is there a way of combining the good points into one document and if so what process would be required?
- Methods for proposing potential improvements to existing resources.

The enthusiasm for sharing resources indicates that, providing there is a means of collating the resources efficiently and keeping them up to date, sharing is potentially achievable.

Working collaboratively across the Network and with Public Contributors on PPI resources would enable us to:

- Develop a strategy for the identifying, sharing, developing, evaluating and updating PPI resources suitable for use in clinical trials
- Prioritise PPI resources that require adapting, improving and/or developing
- Explore a means for sharing PPI resources, for example a central repository

This work has highlighted that resources for public engagement with clinical trials are lacking and new resources are needed, such as 'how a CTU can engage with the public'. Those that existed tended to be videos and leaflets describing clinical trials to patients, or in relation to public engagement campaigns such as the Trials Change Lives and the "I am Research". Whilst there seemed to be considerable interest in the area of reporting trial results to study participants it was surprising that there was only one mention of the recent HRA Guidance on Information for participants at the end of a study in the mapping and gapping work.

### *Chief Investigators and PPI&E*

It was noted that CI enthusiasm for undertaking PPI&E was variable and there were calls for greater consistency in the role CIs take in this area. There also appears to be potential confusion for CIs in the early stages of a study when numerous organisations can offer PPI advice. Greater streamlining of this process, with organisations potentially using a shared 'PPI planning' tool such as that developed by Bagley et al (2016) may help.

### *Training in PPI&E*

Training in PPI had been developed by some CTUs for both Public Contributors and staff. There were particular calls for PPI training to be offered to CIs, which may help to address the aforementioned request for greater consistency in PPI approaches used by CIs. Some PPI training for CIs is currently available (e.g. The North West Clinical Trials Collaborative (NWCTC) Improving Health by Improving Trials training). There may be opportunities to learn from such courses, share training opportunities across the Network and to explore in greater detail what the training needs of CIs are.

Training for Public Contributors was also described by a number of CTUs, and Keele CTU had a notably large training programme for its Research User Group. Future training resources for Public Contributors should also take into account INVOLVE's new Learning and Development resources.

Little training was described in relation to PE in CTUs although two CTUs had developed training relating to the communication of projects to patients and to involving patients in the process of developing end of study information. Whilst this reflects PE in higher education in general (Burchell et al 2017), training for PE is not always well accessed by researchers (Wellcome Trust, 2000; Royal Society, 2006; Ruth et al., 2005; Vitae-CROS, 2013).

PPI training needs and limitations for researchers and Public Contributors were highlighted by Dudley et al (2015) in their work investigating PPI in a cohort of NIHR HTA funded RCTs. The Network could potentially use this to assess current training offered against those needs identified,

in order to inform any future potential training plans. Furthermore, given that little training about PE in clinical trials was reported, a standalone PE training needs exercise might help identify PE training priorities across the Registered CTU Network. Exploring best ways to deliver training will also need to be considered.

### *Support, reward and acknowledgement for PPI&E*

***Public Contributors***

Most CTUs reimbursed or paid Public Contributors. Some had a specific payment policy and a few lacked institutional payment processes for PPI. Sharing of payment policies and processes may prove helpful to other CTUs. Funding to support PPI, in particular in the early stages of PPI was a major issue raised. Funding for early PPI can be sought externally (e.g Involving People Network in Wales, NIHR Research Design Service) though budgets are limited. As a Network there may be opportunities, by working collaboratively, to explore the PPI funding issue further with major research funders.

***Professionals involved in PPI&E***

A number of CTUs recognised the support of senior management, CTU staff and institutions as important in driving PPI&E forward. Sharing examples of potential types of reward such as prize schemes, recognition in appraisal and promotion reviews, attendance at conferences and authorship of papers may prove helpful to other CTUs. Accreditation for PPI&E training might be a further consideration for the Network given the enthusiasm for training.

### *Recruiting Public Contributors and working with patient organisations*

One of the key challenges of undertaking PPI was finding Public Contributors, a common problem in PPI (Gamble et al 2015, Price et al 2017). One way to address this might be through greater collaboration. Whilst it was suggested that the Network might be able to develop a pool of Public Contributors with different types of experience, there may be challenges to this including overburden for Public Contributors, reluctance of teams to share and the need to constantly refresh the pool. An alternative approach might be to share information about PPI opportunities with Public Contributors across our CTUs. Likewise, there may be opportunities, through collaboration, for building relationships with key patient organisations which may help address the issue of recruiting Public Contributors, for example it was suggested that we may develop a list of research active organisations. Additionally if the Network of CTUs collectively reported successful approaches to recruiting Public Contributors there may be shared learning opportunities.

A further resource suggested for development was a series of materials to support the selection of Public Contributors for the occasions where there is only funding for a limited number of Public Contributors and yet interest from more people than there are places. Acknowledging that INVOLVE offer documents such as "Strategies for diversity and inclusion in public involvement: Supplement to the briefing notes for researchers", CTUs could work together to develop standardised processes that offer fair selection procedures. Although it should be recognised that formal selection procedures can sometimes put people off public involvement (Health Talk Online: Barriers to involvement).

### *Dealing with challenges in public involvement*

Whilst public involvement in research has the potential to bring a range of benefits, there can at times be challenges (Buck et al, 2014). Many of these challenges were highlighted in our survey and in the workshop discussion. Challenges can be from the perspective of Public Contributors, for

example, the language used in committee meetings may be inaccessible or patients and the public might not get to hear about PPI opportunities (Health Talk Online: Barriers to involvement). Some resources and website facilities do exist to address some of these challenges , for example, guidance on chairing research meetings involving Public Contributors and websites for advertising PPI opportunities (NIHR People in Research; Health and Care Research Wales Involving People Network)

There can also be sensitive challenges with engaging Public Contributors in the trial, for example, managing a relationship if a Public Contributor is a patient under the care of the CI or if a Public Contributor does not actively get involved, despite full support being provided. One potential resource mentioned in relation to this latter point was a 'ground rules' document for all members of oversight committees, including Public Contributors. Working collaboratively and with Public Contributors might help to develop a standardised set or template of ground rules for registered CTUs, which also align with forthcoming National Standards for Public Involvement.

### *Public engagement in trials*

Good public engagement can be a driver to improving public awareness of research, maintain good public relations and maximising recruitment into clinical trials (Bower et al, 2009). However, public engagement is lacking in many CTUs. There were clear opportunities to work together to better establish the area of PE in clinical trials. There were few resources around this area, presenting an opportunity for the Network PPI&E group to drive forward work in this area.

Whilst resources exist out in the PE community, these have not, to our knowledge, been extensively utilised in the area of clinical trials. Working together may provide opportunities to learn collectively from existing resources and from PE experts, such as Delia Muir, a member of our PPI&E Task and Finish group who is both a PPI coordinator in a registered CTU and a Wellcome Trust PE fellow. This will help CTUs to improve their PE activities, give people new skills to influence initiatives to raise public awareness of clinical trials, and ultimately improve the participation of people in CTU studies. There may also be opportunities, working as a network, to learn from or be involved in research studies testing out the effectiveness of public engagement approaches in the dissemination of clinical trial results. For example, the "Feedback matters: How should trial results be reported back to participants?" work at the University of Aberdeen (https://www.abdn.ac.uk/hsru/research/methodological/feedback-matters/). Likewise, we may, collaboratively, be able to take part in and potentially influence further development of initiatives to raise public awareness of clinical trials

A strategic approach to public engagement in clinical trials does not currently exist across the UKCRC Registered CTU Network and developing such an approach may help trials units communicate better and more consistently with patients about clinical trials, and may also help shape the knowledge base about the most effective ways of communicating trial results to patients and the wider public. Working with organisations such as the National Co-ordinating Centre for Public Engagement may also prove helpful for the Network in the future.

### *Developing and delivering best practice in PPI&E*

There were numerous calls for developing and delivering best practice in PPI&E. One potential resource that could prove helpful to the network is the NIHR Public Involvement National Standards, which have been developed in response to the recent NIHR Strategic review of PPI. These standards are currently being piloted in test bed sites and it will be important for the Network to raise awareness of these standards amongst PPI leads in registered CTUs and to consider what they mean and how to work with them.

### *Working collaboratively, communication and potential support of the Network*

Responses both in the survey and the workshop demonstrated clear enthusiasm for working collaboratively in the future, recognising this a more efficient way of doing PPI&E. Indeed one of the biggest barriers to conducting PPI in trials was identified, both in this survey and in a previous review of PPI in clinical trials, as being lack of time (Gamble et al, 2015). Sharing resources may be one way of supporting and facilitating PPI in trials. Collaborative working was also recognised as a potential way of supporting those who are PPI leads in CTUs.

The workshop group and survey respondents indicated that they were keen to stay in touch and suggested numerous ways that they would like to do this. Further work on the most effective and sustainable communication approaches is required.

# 5 Recommendations and conclusion

Given the importance of PPI&E in clinical trials and the limited resources available, there is clearly a need to work efficiently in how we develop and support PPI&E across registered CTUs. Currently there is little collaboration, aside from some sharing of news items by a smaller group initially developed by Bagley and Muir a few years ago. Within the workshop there was certainly a strong desire to work collaboratively. It is proposed that the PPI&E Task and Finish Group should continue and with that in mind, the following recommendations are made along with the related action plan for an initial three year period.

## 5.1 Recommendations

### Priority recommendations

1. Support the continuation of the PPI&E Task and Finish Group to deliver the agreed action plan, including workshops to advance the sharing and development of PPI&E models and resources.
2. Provide funding to support the crucial involvement of Public Contributors in the PPI&E Task and Finish group's activities.
3. Establish a communication strategy and methods for the PPI&E community and Public Contributors
4. Develop a UKCRC CTU strategic approach to public engagement, working with other PE clinical research campaigns and initiatives to raise awareness of clinical trials.

### Secondary Recommendations

5. Provide a central repository for sign-posting to relevant external PPI&E resources and sharing CTU developed resources and training including within the developing International PPI Network.
6. Promote a positive core message and vision for PPI across the UKCRC Registered CTU Network, aligned with developments in the NIHR Public Involvement Nation Standards and potentially engage with funders of clinical trial research and registered CTUs (NIHR, MRC, charities) to consider providing PPI infrastructure and delivery costs for the design of studies.
7. Review existing PPI training and mentoring for CIs, trial staff and Public Contributors in relation to the training needs identified in previous research. Explore the potential of a core set of PPI&E training materials and a mentoring system for both Public Contributors and for CTU professionals.
8. Raise awareness of existing resources to support the process of disseminating clinical trials results to patients and showcase examples of approaches to the dissemination process through the UKCRC Registered CTU Network.
9. Explore potential ways that the UKCRC Registered CTU Network might work with patient organisations both to promote PPI opportunities and to engage their patient communities around clinical trials in general and in relation to disseminating study results.
10. Develop a system of sharing opportunities for Public Contributors to be involved in studies throughout the Network.

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