UK CLINICAL RESEARCH COLLABORATION

igniting our potential

A critical assessment of the development of patient and public involvement in the UK Clinical Research Collaboration:

Lessons learned

Report by TwoCan Associates

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UK Clinical Research Collaboration
20 Park Crescent
London
W1B 1AL
United Kingdom
Tel: +44 (0)207 670 5452
Fax: +44 (0)207 637 6067
info@ukcrc.org
www.ukcrc.org

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Executive Summary

Introduction

This is a report of a critical assessment of the development of patient and public involvement (PPI) in the UK Clinical Research Collaboration (UKCRC). The aim of the assessment was primarily to draw out lessons learned for people who have a responsibility for taking forward PPI within a research organisation.

The assessment focused on the work that was undertaken to promote and support PPI both internally within the UKCRC and externally amongst its Partner organisations. It does not provide an evaluation of the many PPI projects that have been carried out. Nor does it provide an assessment of the impact that patients and members of the public have had on the organisation. It is a commentary on a complex journey to develop PPI within the environment of the UKCRC – a strategic partnership of many different national research organisations.

The work was carried out by TwoCan Associates between August and November 2009. The methods used included:

- A review of relevant internal documents
- Development of a timeline of activity linked to the development of PPI
- Interviews with key stakeholders
- A survey of UKCRC Board members

Carrying out this assessment proved challenging because of the nature of the UKCRC's PPI-related activity. There were a number of different individuals involved over time, either working alone or within various groups and committees. It is widely acknowledged that assessing the impact of any such complex social intervention can be difficult. We therefore aimed to understand the context to each step along the way and to identify the factors that either hindered or facilitated taking PPI forward. We also assessed the outcomes at each stage and the overall impact on the UKCRC and its Partners[1].

1 We based our approach on the model of realistic evaluation developed by Pawson and Tilley – see R. Pawson and N. Tilley (1997) Realistic Evaluation. London: Sage Publications.

Findings

The key milestones in the development of PPI within the UKCRC were:

1. First year plans for PPI
2. Establishing a UKCRC PPI Project Group and the successor Board Subgroup
3. Provision of a ring-fenced budget for PPI
4. Creation of a development and support post in the UKCRC Secretariat
5. Development of a pilot scheme to recruit patient / public members to UKCRC groups
6. Development and implementation of a three-year strategic plan for PPI
7. Development of proposals for PPI in 2010 and beyond

In this summary, we provide a brief overview of what happened at each milestone, what assisted the development of PPI, what were the challenges and where appropriate, what were the outcomes.

1. First year plans for PPI

For the first year PPI was not given a high priority and very little work was taken forward. However, a plan for PPI was developed and approved by the Board in the second year. The factors that **assisted** this development were:

- The knowledge and experience of the staff and members of Partner organisations who worked on the plan
- Careful briefing of Board members so that they were fully informed of the plan before it was discussed at a Board meeting
- A growing acceptance of a patient / public member on the UKCRC Board

The **challenges** were:

- PPI was not seen as a priority for the Board, given its demanding and crowded agenda
- Partner organisations had different objectives for PPI
- Those who were seen as potential champions of PPI did not always agree on the way forward
- There was often a failure to recognise a distinct PPI agenda

2. Establishing a UKCRC PPI Project Group and the successor Board Subgroup

The PPI plan called for the establishment of a PPI Project Group. This group worked collaboratively on a number of PPI activities under the UKCRC umbrella. It became a Board Subgroup in 2008.

The factors that **assisted** the work of this group were the knowledge and expertise of its members and support from a dedicated member of staff.

The **challenges** were:

- Getting the 'right people' involved in the group
- A perceived lack of interest and commitment from some members
- A lack of clarity about the group's aims
- Concerns about the UKCRC's role in relation to PPI
- The challenging nature of the projects the groups agreed to take forward
- The initial lack of resources available
- Differences in opinion as to how best to proceed and on priorities for action

The **positive outcomes** from this group not only included successful PPI projects, but also opportunities for group members to undertake joint projects and to share learning and ideas. This led to changes in people's attitudes and gave more credibility and legitimacy to PPI within Partner organisations.

3. Provision of a ring-fenced budget for PPI

The provision of a ring-fenced budget from 2006/07 onwards made a big difference to the development of PPI across the UKCRC. However Partner organisations could have decided to increase funding for PPI through further pooling of their resources. Such opportunities were either not identified or ignored or missed.

4. Creation of a development and support post in the UKCRC Secretariat

A Programme Manager for PPI was appointed in 2006. This greatly accelerated the work to promote PPI as there was a dedicated member of staff to carry out tasks for the PPI Project Group.

Identified as crucial factors to the postholder's **success** were:

- Good networking skills
- A willingness to lead from behind
- An ability to collect relevant information and to disseminate this to the right people in an accessible and useful form
- An ability to be 'professional'
- A commitment to involvement, but with an ability to make decisions alone where this is necessary

Openness and honesty, sensitivity, approachability, enthusiasm and warmth were also seen to be key attributes to the success of an individual in such a post along with good skills in facilitation and administration. Some people expressed frustration that this post had not been established earlier.

5. Development of a pilot scheme to recruit patient / public members to UKCRC groups

In 2006 the Board agreed to pilot PPI in the UKCRC's advisory groups. The recruitment process was rigorous and eight PPI members were appointed in June 2007. The impact of this PPI has been evaluated and reported elsewhere[2].

The factors that **assisted** the development of this pilot scheme were:

- An effective recruitment process
- Patient / public members were assigned clear tasks
- Effective administrative systems were put in place to support patient / public members
- Effective mechanisms were put in place to enable information sharing and peer support

The key **challenge** was recruiting people from a range of backgrounds, particularly people from black and minority ethnic communities – the UKCRC was not able to achieve this.

An important **positive outcome** is that the UKCRC has gained credibility in terms of its PPI activity.

2 See *An evaluation of the process and impact of patient and public involvement in the advisory groups of the UK Clinical Research Collaboration*, TwoCan Associates 2009'. http://www.ukcrc.org/patients-and-public/ppi/ppiinukcrcgroups/

6. Development and implementation of a three-year strategic plan for PPI

The PPI Project Group set up a working group to develop a PPI strategy as they recognised that their work needed a clearer focus and direction. Over a year, a wide range of stakeholders were involved in developing the strategy, which was presented to the Board in 2008.

The factors that **assisted** the development and implementation of the PPI strategy were the creation of an effective working group, senior level support from the Chair of the Board and a sense of ownership from relevant stakeholders.

The main **challenge** was developing a strategy that everyone could sign up to at the same time as developing a strategy that would actually direct change.

A **positive outcome** was that the strategy provided greater clarity and transparency for the UKCRC's PPI work. Some people felt it also provided the impetus to drive PPI forward, although others questioned whether this opportunity had been fully realised.

7. Development of proposals for PPI in 2010 and beyond

From January 2010 the UKCRC will operate through a Partner-led model with all future activities led and supported by UKCRC Partners. The size and function of the Secretariat will be much reduced. As part of this process, it was agreed that INVOLVE would be the lead Partner for PPI, and would provide continued support for a number of key activities. The Board Subgroup for PPI was formally disbanded in October 2009.

The factors that might **assist** further development of PPI are the commitments that have been made to taking forward PPI across the Partner organisations, and the efforts that have been made to learn from the UKCRC's recent experience.

The **challenges** will be:

- The onus is now on INVOLVE as the lead organisation working with Partners to take forward PPI
- There are many other competing priorities for action
- The reduction in dedicated resources for PPI within the UKCRC Secretariat

Impact of the development of patient and public involvement

The work that has been undertaken to promote and support PPI has led to changes within the UKCRC itself. There have been changes in organisational culture, especially at Board level, which have meant that PPI has become more of an integral part of Board activities. There is also much more PPI activity in UKCRC working groups and committees.

The factors that have **assisted** these changes include:

- Senior level support
- Board and other advisory group members having had direct experience of PPI
- An increase in the number of PPI champions
- The appointment of a patient / public member as a deputy chair of the UKCRC Board

The **challenges** to taking this work forward were:

- The pace and complexity of the UKCRC's agenda
- The difficulty of turning commitment to PPI into action
- The different attitudes of Partner organisations to PPI
- The time it can take to bring about culture change

A **positive outcome** has been that the development of PPI has also had an impact on Partner organisations. It has created an opportunity to:

- Learn from others
- Take the learning about PPI into their own organisations
- Work with other organisations to take forward projects of shared interest

Lessons learned

The lessons for people with responsibility for taking forward PPI in research organisations are summarised below:

What to think about when developing PPI:

- Make PPI a priority early on
- Identify clear aims and develop a shared understanding of PPI
- Ensure you have dedicated resources and the right staff as early as possible
- Develop a strategy that has broad ownership, but also directs and coordinates action
- Develop a programme of work that allows for quick wins and for long-term projects
- Ensure that all PPI-related activity is visible and adds value to other activities
- Demonstrate good practice, model high quality PPI and report what you have done, so that others are encouraged to do likewise
- Consider how you will measure any impact of PPI when you are at the planning stages

Building relationships:

- Ensure you have senior level commitment
- Build strategic alliances
- Keep sight of the bigger picture and don't consider PPI to be the only issue of importance
- Develop positive strategies to challenge sceptics:
  a. Demonstrate how PPI can help research organisations to achieve their goals
  b. Introduce change at an appropriate pace

Being realistic:

- About what can be achieved
- About the time it takes to achieve a culture change

Introduction

1

1.1. The aims of this report

This report aims to give a critical assessment of the development of patient and public involvement (PPI) in the UK Clinical Research Collaboration (UKCRC) and key lessons learned in order to:

- Describe and reflect on key aspects in the development of PPI
- Provide a critical assessment of the impact(s) of work to develop PPI
- Provide examples of what has worked well and what hasn't
- Add to current evidence / knowledge of public involvement in research
- Demonstrate accountability to the funders of the UKCRC

The key target audience for this report is people who have some responsibility for taking forward PPI in a research organisation. The main question we have therefore tried to address throughout this report is:

If you were to set up, or take forward, PPI within an organisation with an interest in research, what useful lessons could be learned from the UKCRC experience?

This review focuses on the work that was undertaken to develop PPI in the UKCRC. It does not provide an assessment of individual projects that were carried out (e.g. the development of a web based resource to help people get actively involved in research[3]), nor of whether or how individual patients and members of the public had an impact on the UKCRC[4]. This is not a report of a research project. It is a commentary on a complex journey to develop PPI within a partnership of organisations.

3 The People in Research website helps members of the public make contact with organisations that want to actively involve them in clinical research. See http://www.peopleinresearch.org/

4 This has previously been reported on in *An evaluation of the process and impact of patient and public involvement in the advisory groups of the UK Clinical Research Collaboration*, TwoCan Associates 2009. See http://www.ukcrc.org/patients-and-public/ppi/ppiinukcrcgroups/, as well as in a number of other reports – see http://www.ukcrc.org/patients-and-public/ppi/

1.2. About the authors of this report

This report was written by Bec Hanley, Carolyn Morris and Kristina Staley from TwoCan Associates. TwoCan Associates carry out research and evaluations, and provide training and support to help voluntary and statutory organisations involve people who use services in their work. Almost all of our work is undertaken in partnership with service users or carers. For further information please see www.twocanassociates.co.uk

1.3. Definitions used in this report

In this report, we frequently use the term '**patient and public involvement**' abbreviated as '**PPI**'.

The term '**patients and the public**' covers patients and potential patients; people who use health services; informal carers; parents / guardians; disabled people; members of the public; groups asking for research and organisations that represent people who use services[5].

Patient and public '**involvement**' in research is the term used to describe the active involvement of patients, service users, carers and / or members of the public in research for example as members of management committees or advisory groups. Many people describe PPI in research as doing research with or by patients and the public rather than about them[3].

1.4. About the structure of this report

The remainder of this report is structured as follows: In section 2 we describe our approach to this critical assessment and the challenges of evaluating work to promote PPI. In section 3, we describe the background to the development of PPI in the UKCRC. Section 4 addresses the key milestones in the development of PPI. In section 5, we discuss the impact of PPI on the UKCRC and its Partner organisations. Finally in section 6, we consider the lessons that can be learned from the development of PPI within the UKCRC. There are a number of appendices containing further information.

> In this report, quotations from people we interviewed and survey responses are in boxes like this.

1.5. Thanks

We are grateful to all of the stakeholders who agreed to be interviewed for this project, and to the UKCRC Board members who completed the survey. We would also like to thank the members of the UKCRC Board Subgroup for PPI – John Hughes (Chair), Maryrose Tarpey & Sally Crowe - who formed the Project Advisory Group and helped in steering this project.

5 This definition is adapted from the definition used by INVOLVE, see http://www.invo.org.uk/About_Us.asp (downloaded 26/10/09)

How we carried out this critical assessment

2

2.1. Our approach to this assessment

This project has involved carrying out an assessment of the work undertaken within the UKCRC to support and promote PPI both internally within its own activities and externally amongst its Partner organisations.

This work has involved a number of different individuals, either working alone or in a number of groups and committees and as such represents a complex, social intervention.

It is widely acknowledged that assessing the impact of any social intervention can be a challenge. We have based our approach on the model of realistic evaluation developed by Pawson and Tilley[6]. This involves asking the question: What works for whom and in what circumstances? Our questions have therefore explored context, mechanisms and outcomes. We have asked questions about:

- The aims and objectives of any activity, who was involved and when, what factors hindered or facilitated success - in order to assess the context
- What work people did and how well they were supported – in order to assess mechanisms
- The difference the activity has made both practically and also less tangibly, for example in terms of affecting attitudes and awareness – in order to assess outcomes

As the views of different stakeholders may not be the same, we talked to a number of people involved in each activity. We asked about their expectations and objectives as well as what they actually experienced and observed.

2.2. Methods used

This assessment was undertaken between August and November 2009. It consisted of the following stages:

- A review of relevant internal documents
- Development of a timeline of activity (linked to the development of PPI)
- Interviews with key stakeholders
- A Survey of UKCRC Board members

6 R. Pawson and N. Tilley (1997) *Realistic Evaluation*. London: Sage Publications.

- Data analysis
- Production of a final report

Each of these stages is discussed in more detail below.

Review of internal documents
After an initial meeting with the Programme Manager with responsibility for supporting the development of PPI in UKCRC activities, we reviewed all the relevant internal documents in order to:

- Draw out key lessons / reflections for this report
- Identify a list of potential interviewees
- Help shape the interview schedules
- Ensure we were fully informed of the context prior to conducting interviews
- Develop a timeline of activity

Development of a timeline of activity
We conducted an in-depth, exploratory interview with the PPI Programme Manager to identify key activities and milestones for the work that the UKCRC carried out to develop PPI. Along with the review of the internal documents, we used the findings to develop a timeline of the UKCRC's PPI-related activity. This timeline has been used as a:

- Prompt to remind interviewees of key events during the interview
- Framework to structure the analysis of the data from the interviews
- Structure for the final report

A summary of the timeline is provided on page 22 of this report.

This timeline also helped to identify the most relevant people to interview, as we were able to select those people directly involved at each milestone. To ensure the most efficient use of our time we selected individuals who would be able to comment on two or more milestones. We also selected individuals who would be able to reflect on the success / failure of PPI-related activity based on their knowledge and experience of PPI.

Interviews with key stakeholders
We drafted a general set of interview questions around each milestone. We then adapted the questions for each individual to take into account their particular experience and level of involvement. The Project Advisory Group considered our proposed list of interviewees and

the broad structure of our interviews. During September 2009 we undertook 13 interviews. Interviewees included current and former members of the:

- UKCRC PPI Project Group and the Board Subgroup for PPI
- UKCRC Board
- UKCRC Secretariat

We undertook five face-to-face interviews and eight telephone interviews (this was determined by the preference of the interviewee and the time available).

We also undertook two group interviews. The first took place in September 2009, with five patient / public members of UKCRC advisory groups. The second took place in early October 2009, with 13 members and observers at a meeting of the Board Subgroup for PPI.

Where permission was given, interviews were recorded. Otherwise the interviewer made written notes.

Survey of Board members
In order to obtain an overview of UKCRC Partners' views of the UKCRC's PPI-related activity, we conducted a survey of the UKCRC Board members. Each Board member was sent an email which asked:

1. What, if any, were your organisation's objectives in supporting PPI within the UKCRC?
2. Have these objectives been met?
3. Have the UKCRC's PPI related activities had any impact in your organisation? If so, what is or was that impact?

Seventeen responses were obtained following emails to all 25 Board members. The responses were analysed and included in the report.

Data analysis
Recordings of each interview were transcribed by the interviewer. The interviewer then reviewed all the transcripts / notes and highlighted key themes. All of the interviewers read all of the transcripts to check for consistency of views on emerging themes.

The data was organised using the timeline as a framework. We then analysed the data around each milestone by asking the following questions:

- What work was done to support / promote PPI?
- What factors hindered or supported this activity?

- What were the outcomes?
- What are the lessons for others who might be developing / implementing PPI?

Throughout several iterative stages of data analysis, all team members took part in telephone conferences to discuss and agree common themes as well as the main points for the final report.

Production of a final report
Some interviewees expressed concern that quotes could be attributed to them, even though all quotes are reported anonymously. Where this was the case, we sent draft extracts of the report to individuals to check they were happy with the use of any of their quotes.

A draft report was sent to the Project Advisory Group for comment. Many of their suggestions for changes were incorporated and a final report was produced. It was agreed that all recordings and notes would be destroyed one month after the report was published.

2.3. The challenges of undertaking this critical assessment

As with all evaluations of complex, social processes, there were a number of challenges to conducting this assessment and reporting the findings. These included:

- The most valuable contributions to the development of PPI within the UKCRC often came from key individuals and were heavily influenced by personalities and personal interactions. These kinds of interactions are hard to capture and it also proved difficult to draw out any generalisable lessons
- Work often took place within the context of committees or working groups. The complexity of decision-making processes in most groups makes it very difficult to analyse the thinking behind any group decision, and not all members of the same group will share the same opinion as to what happened. This made it difficult to link activity directly to outcomes
- This kind of PPI-related activity often results in subtle and intangible changes, such as changes in attitudes. These kinds of changes are again hard to capture. Their impact may not lead to immediate or obvious differences, but as they are so hard to achieve and their influence is likely to become more significant over time, these kinds of changes do represent major achievements. They may not be easy to measure or describe, but may be one of the more significant indicators of success. We may not have captured all of these less tangible changes within the limits of this assessment

- PPI-related activities are interconnected and may take many years to evolve. This means that the assessment of the impact of any particular activity or milestone is time-bound and may well change over time
- Interviewees were not always able to clearly remember events from the past, especially as we asked them about events over a five year time-span

Another challenge was the reluctance of a small number of interviewees to have their comments included in any way that might be linked to them individually. This meant we were unable to use some of the interview data. Regretfully this included a few comments on some of the most valuable 'lessons learned'.

Background

3

3.1. Patient and public involvement in research

A systematic approach to promoting PPI in health research within the NHS began in 1996 with the establishment of a group to advise the then Director of Research and Development for the NHS on PPI[7]. As a result of its work, and the work of many others, PPI within health research has continued to grow and develop. PPI in research has become more accepted and more widespread. Government policy to promote and support PPI within health research has developed quickly – for example the NHS R&D Strategy, Research and Development for a First Class Service, published in 2001 and the Research Governance Framework (2001 & 2003), both called for PPI at all stages of the research process.

Since 2001, PPI in research has extended across all parts of the UK. In England, the National Institute for Health Research is committed to involving patients and the public in research at every stage of research[8]. In Wales, Involving People: Cynnwys Pobl, was set up in 2006 specifically to support the development of PPI in research. In Scotland, the Chief Scientist Office has a Public Involvement Group whose members sit on its advisory committees and are involved in other activities. In Northern Ireland, the R&D Strategy, Research for Health and Wellbeing 2007-2012, identifies PPI as one of five strategic priorities.

At the same time, research organisations in the UK and beyond have begun to actively promote PPI both in their own work and in the research they support[9]. It is in this broader context that the background to the development of the UKCRC must be seen:

> You do need to put this into a broader context… in the period from 2002 to now… there was a really significant sea change in opinion and acceptance of patient and public involvement… in a whole range of areas around research.

7 This group was initially called the Standing Advisory Group on Consumer Involvement in the NHS R&D Programme. It changed its name to Consumers in NHS Research and more recently to INVOLVE.

8 *Transforming Health Research the first two years*. National Institute for Health Research Progress Report 2006 – 2008 (2008)

9 See Telford R, Boote J, Cooper C (2004) *What does it mean to involve consumers successfully in NHS research? A consensus study*. Health Expectations 7, pp209-220

3.2. The UK Clinical Research Collaboration

In 2003 the Academy of Medical Sciences and the Bioscience Innovation and Growth Team produced reports [10] which highlighted the urgent need for further investment and a more collaborative approach to supporting clinical research in the UK. In response, the Government established a 'Research for Patient Benefit Working Party', whose remit was to make practical recommendations to the Government as to how to implement the recommendations in the two reports.

Significantly, the Working Party included a patient / public member, Nick Partridge, who was chair of INVOLVE and chief executive of the Terrence Higgins Trust.

> The fact that the title… was Research for Patient Benefit, that was the first time that patients had really been put into that formal centre and so it was symbolically very important.

Whilst the Working Party was meeting, the Government announced the establishment of the UKCRC. The Working Party made recommendations as to how the UKCRC should function.

The UKCRC was set up in 2004. It aimed: "to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth"[11].

The Collaboration brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges and academia, as well as patients and the public. Partner organisations are represented on the UKCRC Board, which provides strategic direction and oversight[12].

Over the past five years the UKCRC Partners have focussed on a rapid programme of activities to transform the environment for clinical research in the UK[13]. The UKCRC has provided a flexible framework for Partners and other stakeholders to work together to develop innovative solutions to complex and long standing challenges.

10 Academy of Medical Sciences (2003) *Strengthening Clinical Research* and Bioscience Innovation and Growth Team (2003) *Bioscience 2015: Improving National Health, Increasing National Wealth*

11 UKCRC website: http://www.ukcrc.org 20/10/09

12 List of UKCRC Partners: http://www.ukcrc.org/aboutus/theukcrcpartners/, UKCRC website 16/11/09

13 See *UKCRC Progress Report 2006-2008* Full Report, http://www.ukcrc.org/docs/UKCRC_PR_06-08

UKCRC Partners all have their own organisational approaches to PPI. However, working under the umbrella of the UKCRC has provided an opportunity to focus on issues that could not so easily be addressed by one organisation working alone and where a collaborative approach is of mutual benefit. A list of projects undertaken to support the development of PPI is included as **Appendix 1**.

The Collaboration is supported by a jointly funded, independent secretariat.

Milestones

4

In this section, we describe key milestones in the development of PPI within the UKCRC. These are:

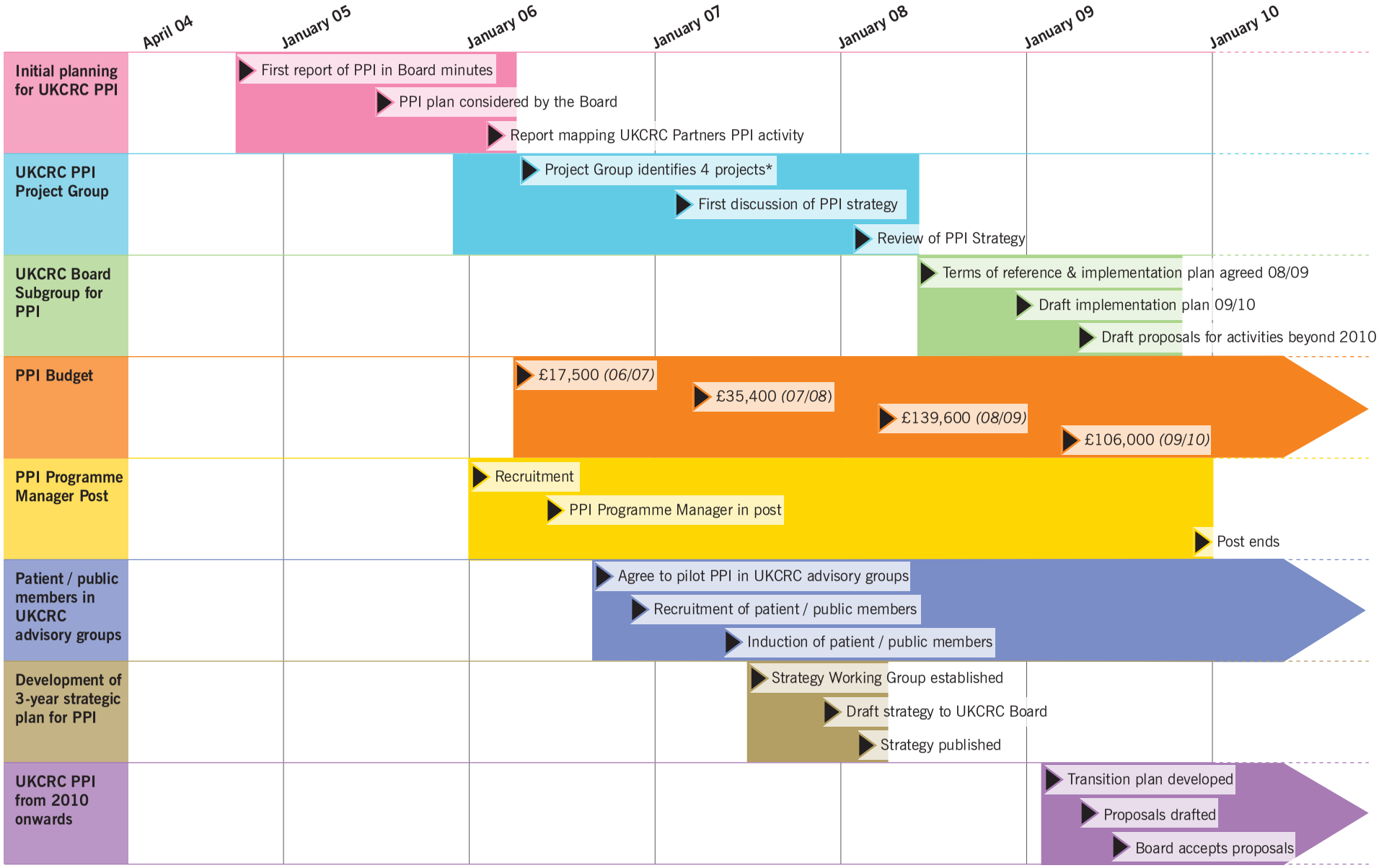
- First year plans for PPI
- Establishing a UKCRC PPI Project Group and the successor Board Subgroup
- Provision of a ring-fenced budget for PPI
- Creation of a development and support post in the UKCRC Secretariat
- Development of a pilot scheme to recruit patient / public members to UKCRC groups
- Development and implementation of a three-year strategic plan for PPI
- Development of proposals for PPI in 2010 and beyond

These milestones differ in nature and therefore the way in which we have reported each milestone is slightly different. With each one, we have aimed to describe what happened, what helped promote PPI, what were the challenges and (where appropriate) what were the outcomes.

When reviewing the history of the development of PPI in the UKCRC, it is important to bear in mind that this was an evolutionary and complex process, and that the work did not always follow a simple linear path. The timeline on page 22 illustrates the progress made over time and may help with following the narrative in this section.

PPI as part of the UKCRC is a real example of the politics and tactics of involving patients and the public in high level strategic decision making in clinical research. In this context PPI had to be flexible enough to cope with a constantly evolving clinical research landscape and complex partnerships. This critical assessment maps the journey of a collaboration of interested and not so interested parties. It has a start and a finish, but also some challenging twists and turns, so in this sense it is a realistic account of PPI, both the challenges and the achievements, and gradual change of attitudes over time.

Summary timeline of patient and public involvement activity since the UKCRC was established



*** see Appendix 1 for information about UKCRC PPI Projects**

4.1. First year plans for PPI

SUMMARY

There were a number of factors that assisted the development of PPI in the UKCRC in the early stages. These were:

- The knowledge and experience of the staff and members of Partner organisations who worked on the plan
- Careful briefing of Board members so that they were fully informed of the plan before it was discussed at a Board meeting
- The growing acceptance of a patient / public member on the UKCRC Board

The challenges were:

- PPI was not seen as a priority for the Board, given its demanding and crowded agenda
- Partner organisations had different objectives for PPI
- Those who were seen as potential champions of PPI did not always agree on the way forward
- There was often a failure to recognise a distinct PPI agenda

4.1.1. What happened?

PPI was not a high priority for the Board when it first met as it was faced with a very crowded and fast moving agenda. At this point, the only patient / public member of the Board was Nick Partridge, who had also been part of the 'Research for Patient Benefit Working Party':

> I was sitting there on my own and… if I had pushed it [PPI] all the time, I risked being marginalised… there's a balance between how much… you're there for the overall agenda and for that bigger strategic picture… it was important that I showed that I understood that… I felt I had to be much more 'statesmanlike'… in order to secure… the right to be at the table, not for me individually but for PPI and whoever succeeded me.

A suggested work plan for the UKCRC had been laid out in the Research for Patient Benefit Working Party Report. In October 2004, this was translated into a work plan by the UKCRC Board, identifying five major workstreams. PPI was not developed as a separate workstream.

However, the work plan stated that, "[A] key aim of UKCRC will be to ensure that the patient voice is heard in an appropriate fashion throughout each of the workstreams"

A paper on 'Mechanisms for Public Involvement', written by three UKCRC Partners, was presented to the UKCRC Board in January 2005. The ensuing discussions were contentious:

> I just remember being told… that… it sort of blew a hole in the side of PPI and caused all sorts of aggravation.

However, at the end of the Board discussion, it was agreed that the UKCRC Secretariat would "work with UKCRC Partners to further develop mechanisms for consumer involvement."[14]

Following the January 2005 Board meeting, the Secretariat met with relevant UKCRC Partners to discuss how PPI might be taken forward. In July 2005 the UKCRC Board considered and approved a plan for PPI, which proposed the establishment of a UKCRC PPI Project Group. This is discussed in section 4.2.

4.1.2. What helped the development of PPI at these early stages?

Three factors seem to have been crucial to the acceptance of the PPI plan:

- ***The knowledge and experience of the staff and members of Partner organisations who worked on the plan***
  Liam O'Toole, the UKCRC Chief Executive, had previously worked for the National Cancer Research Institute, an organisation with a proven track record in PPI. This meant he had knowledge and experience of PPI. He used his existing networks to bring people together to start the ball rolling.

- ***Careful briefing of Board members so that they were fully informed of the plan before it was discussed at a Board meeting***
  Liam O'Toole spent time talking with UKCRC Partner organisations before the plan was presented to the Board.

- ***The growing acceptance of a patient / public member on the UKCRC Board***
  Nick Partridge, still at this point the only patient / public member on the Board, was becoming more accepted and valued for his input.

> Liam and I were very careful about how it was presented… And I think also the fact that by that point I had been successful in ensuring that Board members didn't see me as a dangerous radical… I'd built up enough credit - I think is the way that I would put it - to get it through.

14 Taken from the minutes of the UKCRC Board meeting held on 04/07/05

4.1.3. The challenges to developing PPI at this early stage

The people we interviewed identified a number of challenges to the development of PPI. These were:

- ***PPI was not seen as a priority for the Board, given its demanding and crowded agenda***

> There was no [PPI] labelled workstream… And that said something basically… it suggested that this wasn't going to be… a high priority.

> There were five UKCRC workstreams and you can see that they are given prominence on a regular basis and attention - if PPI had been given the same kind of billing from the start, I think we would have got a lot further down the road than we have done.

- ***Partner organisations had different objectives for PPI***

  Some organisations were primarily interested in raising awareness amongst patients and the general public about the importance of clinical research, rather than actively involving them. For example, one UKCRC Partner organisation listed its objectives in supporting PPI within the UKCRC as follows:

> - Raise patient and public awareness of the importance of clinical trials
> - Show that it is good for patients to be involved in clinical studies (despite Northwick Park)
> - Increase availability of tissue samples (following fallout from Alder Hey)
> - Increase number of patients taking part in trials

Other Partners were primarily interested in the opportunities to work collaboratively on this issue, and to learn from one another, in order to inform work within their own organisations, or to develop shared resources, for example:

> Our support of PPI within the UKCRC forms part of a wider drive within our organisation to develop a strategy for PPI. Key to this is learning from other organisations' experiences and ensuring that our activity is complementary to others.

- ***Those who were seen as potential champions of PPI did not always agree on the way forward***

> Around that Board not everyone was a real fan [of PPI] so what you needed was leadership… What you needed was a champion. And the champions couldn't agree with each other.

- ***There was often a failure to recognise a distinct PPI agenda***
  The Board often discussed PPI and public awareness as a single agenda item. Although it was agreed in January 2005 that this would not be done in future, in practice this elision and a level of confusion continued. There was concern that PPI would be subsumed within the larger issue of engagement:

> Over the last couple of years, the number of times, you know it just doesn't get minuted, but the number of times I've had to remind the members that there is a significant difference between involvement and public understanding and engagement.

4.2. Establishing a UKCRC PPI Project Group and the successor Board Subgroup

SUMMARY

There were a number of factors that **assisted** the work of the UKCRC PPI Project Group, and later the Board Subgroup. These were:

- The knowledge and expertise of members
- Support from a dedicated member of staff

The **challenges** were:

- Getting the 'right people' involved in the group
- A perceived lack of interest and commitment from some members
- A lack of clarity about the group's aims
- Concerns about the UKCRC's role in relation to PPI
- The challenging nature of the projects the groups agreed to take forward
- The initial lack of resources available
- Differences in opinion as to how best to proceed and on priorities for action

The **positive outcomes** were:

- An opportunity to share learning, information and ideas
- An opportunity for stakeholders to undertake joint projects
- Changes in attitude
- An increase in legitimacy for PPI

4.2.1. What happened?

The PPI plan agreed by the Board in July 2005 called for the establishment of a UKCRC PPI Project Group. The aim of the Group was "to provide strategic oversight for PPI across the activities of the UKCRC, including the UKCRN and the new national framework for experimental medicine."[14]

The Board agreed that Roger Wilson, a cancer patient and the chair of the National Cancer Research Institute Consumer Liaison Group (and subsequently the Associate Director for PPI for the UK Clinical Research Network Coordinating Centre) should be invited to chair the Project Group. Current and former members of the Project Group and of the Board Subgroup for PPI are listed in Appendix 2.

In preparation for the first meeting, a mapping exercise was undertaken by UKCRC staff. This looked at PPI across UKCRC Partner organisations, and identified some activities that could be developed collaboratively under the UKCRC umbrella.

The PPI Project Group met for the first time in December 2005. At the Group's second meeting the following May, members identified four projects that they were willing to pursue jointly under the umbrella of the UKCRC[15]. Different members of the Project Group volunteered to take the lead on different projects.

In April 2008, following the adoption of a PPI strategy (see section 4.6), the UKCRC Board agreed to disband the PPI Project Group in order to establish a UKCRC Board Subgroup for PPI. The aim of this Subgroup was to oversee and monitor the implementation of the UKCRC PPI Strategic Plan 2008-11, to advise the UKCRC Board and to provide a forum for discussion of strategic issues relating to PPI in clinical research. Terms of reference for the Subgroup are included as Appendix 3.

The Subgroup met every three or four months. At each meeting, Subgroup members were able to exchange information about PPI activities within their own organisations, as well as to agree and monitor progress against annual implementation plans for the PPI Strategy. The last meeting of the Subgroup was held in October 2009 (see section 4.7).

4.2.2. What helped the work of the Project Group / Board Subgroup?

- ***The knowledge and expertise of group members***
  One of the key factors that helped the Project Group to develop its work programme was the knowledge and experience of its members. Many had previous experience of establishing PPI programmes and / or were experts in PPI. Others were relatively new to PPI, but made invaluable contributions through their ability to pose challenging questions and their commitment to getting involved.
- ***Staff support***
  The other major factor was the appointment of a PPI Programme Manager (see section 4.4). This made an enormous difference to taking forward tasks on behalf of the Group.

15 Projects undertaken by the PPI Project Group and later by the Board Subgroup for PPI are listed in Appendix 1

4.2.3. What were the challenges?

The Project Group (and later the Board Subgroup) faced a number of challenges, including:

- ***Getting the 'right people' involved in the group***
  Some members felt that the Project Group was missing some key stakeholders, especially in the early stages:

> We had good people around the table, but not all the right people… I think I'd have got more of the charities who were actively developing PPI and run a couple of workshops and learned some practical lessons…

> There was a very limited service user or carer involvement in that group… It seemed bizarre that we were taking about what's important in involvement without public involvement. And that I think was a problem.

- ***A perceived lack of interest and commitment from some members***

> The people were round the table because the Partner organisations felt like they had to be seen to be participating… it was no one's particular job or… particular interest… Either they weren't senior enough, or as I say, it wasn't their main role in life, and they thought 'well I'm not prepared to fight these battles'.

- ***A lack of clarity about the Group's aims***

> The Board hadn't thought through its objectives, what it wanted to get out of it [the Group]. It felt like a talking shop, an information exchange rather than something that was actually going to deliver something. The Board didn't give the Group a clear message about what it wanted.

> I was quite confused about… what the group was trying to achieve… I wasn't sure whether it was about PPI in UKCRC or PPI across the other organisations… which included mine of course… It had benefits for me… in understanding what was going on across all the different organisations but… I couldn't quite see what its impact would be within UKCRC.

- ***Concerns about the UKCRC's role in relation to PPI***
  There were also tensions around what PPI work could or should be taken forward by the UKCRC. Some stakeholders questioned whether all of the proposed projects were the

responsibility of the UKCRC, or were duplicating existing work. Others were concerned that the UKCRC was 'taking over':

> I think there was genuinely huge reluctance… from anyone who had anything to do with PPI, not wanting to get involved with the UKCRC. Because it was seen as, I think, this empire building organisation that was going to sweep things up and destroy them… So it would kind of overcome patient and public involvement, sweep it up and then turn it into rubbish. And so… actually just to get people to agree to participate in any way with UKCRC around PPI was really difficult.

- ***The challenging nature of the projects the groups agreed to take forward***

> I think what we found out was, it was much more difficult to deliver on them. It all sounded very good but they were not easy things to deliver on.

There were also differences in opinion as to the 'right' way to go about particular projects, for example in relation to the People in Research[16] project:

> People were saying we needed a database [that] people could dip into and pull people out as objects to be used… So that's where we tried to rephrase, or repackage… And so we thought if we… developed something…that enabled people who wanted to get involved to find out where the opportunities were… then it would leave the control, the power in a sense with the service users… It didn't make sense to try and have this sort of meta-group of people that could be called upon from different organisations, without necessarily knowing in what context or why.

- ***The initial lack of resources available***

Initially the Project Group lacked the resources (both in terms of budget and staff) to take their ideas forward:

> We got people to come together who all had an interest in public involvement but there wasn't really anybody to follow through and make things happen. So we were still at the stage of talking and not doing.

16 The People in Research website helps members of the public make contact with organisations that want to actively involve them in clinical research. See http://www.peopleinresearch.org/

- ***Differences in opinion as to how best to proceed and on priorities for action***
  Finally, there was a tension between people who wanted to 'get on and do something', and others who wanted to take a more considered approach:

> You say, this will move it forward, but they say it's not pure enough.... Don't let the perfect be the enemy of the good. You're trying to take one step forward and they're beating you up because it's only one step.

4.2.4. Outcomes

There were mixed views about what the Group achieved. Some interviewees felt there had been a number of positive outcomes, including:

- ***An opportunity to share learning, information and ideas***
  For some, the most important achievement was that it enabled stakeholders from across the UK with an interest in PPI to come together and share information and ideas around the development of PPI. It also enabled shared learning for example, the Group offered:

> A strategic view of how PPI was being implemented by UKCRC, [an opportunity to] be part of that process and also learn from the process... Good practice and learning from where things had gone wrong.

- ***An opportunity for Partners to undertake joint projects***
  It also enabled PPI to be taken forward by a range of organisations working together:

> To me it is this thing about being able to do things that were far greater than what the individual parts could do. It was that being able to think about where to move things forward, across the different Partners.

- ***Changes in attitude***
  The group also contributed to changes in attitude to PPI amongst some of its members:

> I think it was the gradual... trickle effect of making people start to think about these issues... some of it was that people were prepared to come and sit round the table, because not everybody was fully signed up to the ideas of involvement... it was that... slow process of bringing people on board.

- ***An increase in legitimacy for PPI***
  Some members felt that involvement in the Group gave some legitimacy to PPI within their own organisation:

> It gave me a strong protective element – anything [name of organisation] was doing with UKCRC and its Partners, it gave us added credibility. It [PPI] was a serious part of UKCRC's agenda, so we needed to take it seriously.

Other interviewees were not sure about what the Group had achieved. There was some disagreement as to whether becoming a Board Subgroup had made a real difference. For some people the change represented an important shift:

> I can see tactically how important that [Board Subgroup] was. And it was to ensure that PPI was a concern in UKCRC and was part of the discussions at the Board and I can see that that Group gave it weight because the people around the table were all very experienced people.

However, some people felt the change was not significant:

> I'm not sure anybody really appreciated there being any difference [between the PPI Project Group and the Board Subgroup]…it was more just [clarifying] the title of that Group … but I don't think it created anything different… I'm not sure how noticeable it was to people.

Some concluded that the Board Subgroup had very limited impact, beyond becoming a forum for sharing information:

> I don't think it's achieved anything… I think once you've got a strategy what you do next is to identify some quick wins, but the Board Subgroup didn't do it.

> I do recall disappointment, that having put in all this effort, made a contribution to the Strategy and having this real sense of support from the PPI Group, to the cause, for want of a better description, that it all kind of dissipated.

4.3. Provision of a ring-fenced budget for PPI

SUMMARY

The provision of a ring-fenced budget helped significantly in the development of PPI across the UKCRC. However, given the way in which UKCRC funding operated, opportunities for increased funding through the pooling of resources between Partner organisations were either not identified or ignored or missed.

4.3.1. What happened?

Initially there was no UKCRC budget for PPI activity. However a budget of £17,500 was put into place for 2006/2007 – this represented 1.5% of the UKCRC's total budget. This figure doubled for the financial year 2007/2008 and rose again to £139,600 in 2008/2009 – 12.9% of the total budget. (See Appendix 4 for further information.)

4.3.2. What helped?

The provision of a budget for PPI from the financial year 2006/2007 onwards helped significantly in the development of PPI across the UKCRC:

> [It made] a huge amount of difference in terms of being able to do things properly, due process in terms of getting people involved and advertising things, and being fair and transparent…so that was all fantastic.

4.3.3. What were the challenges?

Although the increase in spending on PPI between 2005/06 and 2009/10 is significant, it's important to see this in the context of how the UKCRC has funded other activities. If a project is identified as a priority by a number of UKCRC Partners, these Partners and other stakeholders may then contribute funds from their own organisations and create a shared 'pot', using the UKCRC as an umbrella. In this way, significant sums have been spent on issues that were a priority for a number of Partner organisations. For example, in 2007 £20m was contributed by a small number of UKCRC Partner organisations to fund the creation of five UKCRC Public Health Research Centres of Excellence.

There are no examples to date of UKCRC Partners identifying and funding any PPI activities in this manner.

4.4. Creation of a development and support post in the UKCRC Secretariat

SUMMARY

The interviewees identified the following set of skills of the postholder that made this post a **success**:

- Good networking skills
- A willingness to lead from behind
- An ability to collect relevant information and to disseminate this to the right people in an accessible and useful form
- An ability to be 'professional'
- Facilitation skills
- A willingness to get on with work between meetings
- Good administrative skills
- A commitment to involvement, but with an ability to make decisions alone where this is necessary

Openness and honesty, sensitivity, approachability, enthusiasm and warmth were seen to be key attributes to the success of an individual in this post.

The only **challenge** was that this post had not been established earlier.

The positive **outcome** was that the UKCRC had a dedicated member of staff who could take forward the PPI work across the UKCRC.

4.4.1. What happened?

In June 2006 Liam O'Toole reported to the UKCRC Board that he had appointed Philippa Yeeles as Programme Manager for PPI and nursing workforce research issues. (The nursing research portfolio was handed over to another member of the Secretariat in April 2007.) The impetus to create this post seems to have come primarily from Liam O'Toole and Roger Wilson. Philippa began work in July 2006 and her previous role at INVOLVE was seen to give her credibility:

Because of her time with INVOLVE she'd grown very familiar with the research environment so she knew the people and they identified with her as someone who was an advocate for patient involvement which gave her a real bump start when it came to actually talking about patient involvement.

4.4.2. What helped?

Many interviewees commented on the skills of the postholder that made this post a success. These included:

- ***Good networking skills***

I think the role's more about bringing people together than producing long papers.

A very good grasp of the broader networks of PPI outside UKCRC and particularly some of the key players in that.

- ***A willingness to lead from behind***

What it takes is drive and pro-activity. An ability to engage lots of different views. Someone behind the scenes kicking people, talking to people.

You actually need to exercise very skilful leadership…. When I say leadership it's not always leading up front. It's being a secret leader, in the background, influencing people.

- ***An ability to collect relevant information and to disseminate this to the right people in an accessible and useful form***

Drawing people's attention to other things that [are] going on, other consultations that [seem] relevant to PPI, sometimes things that [are] happening in other countries.

- ***An ability to be 'professional'***

Professional in the sense that although he or she might feel strongly about something and be, if you like, passionate about PPI, [they are] not emotionally led.

- ***Facilitation skills***

> A bridge you can use to contact other people, to be able to facilitate that, to get you known.

- ***A willingness to get on with work between meetings***

> Not only to do the leg work, but to do… some of the thinking, like put things in context, and try and map out projects, rather than just leaving it to a working party to do. But not taking responsibility away from them.

- ***Good administrative skills***

> A professional approach to expenses, the agenda, note taking… You do tell people they're important if you give them an agenda, if you tell them how you're doing it and that businesslike approach I think that was really important.

- ***A commitment to involvement, but with an ability to make decisions alone where this is necessary***

> That kind of approach in a situation where you are exploring new areas and evolving new ideas is actually very powerful.

The following attributes were also seen to be key to the success of this post:

- Openness and honesty
- Sensitivity
- Approachability
- Enthusiasm
- Warmth

4.4.3. What were the challenges?

Many of our interviewees shared the view that it would have been helpful if this post could have been created earlier in the development of the UKCRC:

> It would have helped to have had it in there from the start.

4.4.4. Outcomes

Everyone we interviewed was clear that having a member of staff dedicated to PPI had an enormous impact on the development of the PPI programme:

> If you've got a dedicated person, they've actually got the time and energy to feed things through and to ginger people up and persuade them to do it.

4.5. Development of a pilot scheme to recruit patient / public members to UKCRC groups

SUMMARY

The factors that **assisted** the development of the pilot scheme to recruit patient / public members to UKCRC groups were:

- An effective recruitment process
- Patient / public members were given clear tasks
- Effective administrative systems were put in place to support patient / public members
- Effective mechanisms were put in place to enable information sharing and peer support
- The process has been evaluated and steps have been taken to learn from this pilot

The key **challenge** was to recruit people from a range of backgrounds, particularly people from black and minority ethnic communities.

A **positive outcome** has been that the UKCRC gained credibility in relation to its PPI activity.

This section focuses on the pilot scheme to recruit patient / public members of UKCRC advisory groups – not on the impact the patients / members of the public had on these groups, as this has been covered in a previous report[17].

17 *An evaluation of the process and impact of patient and public involvement in the advisory groups of the UK Clinical Research Collaboration*, TwoCan Associates 2009. See http://www.ukcrc.org/patients-and-public/ppi/ppiinukcrcgroups/

4.5.1. What happened?

In September 2006 agreement was reached to pilot PPI in UKCRC advisory groups. Work began in late 2006 to take this project forward. This included:

- Development of job descriptions and person specifications
- Development of processes for advertising and selecting patient / public members
- Planning an induction process and mechanisms to offer support to patient / public members
- Development of guidance materials to support UKCRC groups that were part of the pilot
- Identifying appropriate training opportunities

In June 2007 eight patient / public members were appointed.

4.5.2. What helped?

A number of factors were key to the successful development of this pilot scheme. Those highlighted by the interviewees included:

- ***An effective recruitment process***
  This gave credibility to patient / public members of UKCRC groups and has enhanced the reputation of the UKCRC:

> I get the impression that increasingly the UKCRC is seen as a credible source of PPI… When you hear some of the senior operating officers… talking about ways in which they populate PPI positions on boards and groups and so on, one of the messages that comes through is that they … attach a lot of importance to the channel of recruitment... I get the feeling that increasingly the UKCRC in that role is regarded as sound and I think that's also an important marker in terms of saying it [has] had an impact.

- ***Patient / public members were given clear tasks***

> The PPI member [needs] to know what's expected of them…to be quite clear in what their contribution hopefully [will be]…what their remit is, and knowing that when [they] come in.

- ***Effective administrative systems were put in place to support patient / public members***

> …to have a system that supports us as PPI members to do various things… I think it's absolutely essential… people [need to] know what they're doing, what the groups and organisations are that they are going to and so on, that they are properly briefed, that they know how to reclaim their travel, all of those things that in the UKCRC has been properly done, and I think it's important that any other organisation doing PPI gets that right.

- ***Effective mechanisms were put in place to enable information sharing and peer support***
  Patient / public members met regularly to share information and to receive updates and training:

> Certainly for me in having had a group that I could come to… I found that a huge, huge value and it certainly helped me to do what I do better, because there's been questioning, there's been sharing of information, ideas, I've learned about other things that are going on.

- ***The process has been evaluated and steps have been taken to learn from this pilot***

4.5.3. What were the challenges?

Despite attempts to recruit patient / public members to broadly reflect the diversity of the population, all of the people recruited were white:

> The evaluation alluded to how difficult it was to get full representation. Although the process was very comprehensive, it was difficult to get people from ethnic minorities to join, [that's] one thing they could perhaps have done better. We all learned from that process and we could see where we could do it better.

4.5.4. Outcomes

The pilot project to involve patient / public members in UKCRC groups and its subsequent evaluation[17] has gained credibility for the UKCRC in relation to its PPI activity:

> We're beginning to see some tangible impacts of PPI in terms of some of the processes… in terms of the way PPI is organised… The UKCRC initiative is seen as competent and worth taking into account in that sense.

4.6. Development and implementation of a three-year strategic plan for PPI

SUMMARY

The factors that **assisted** the development and implementation of a strategic plan for PPI were:

- An effective working group
- Senior level support
- Ownership by relevant stakeholders

The key **challenge** related to the tension between developing a strategy that everyone could sign up to and developing a strategy that would lead to change.

The **positive outcomes** were:

- An increase in clarity and transparency
- An opportunity to drive PPI forward (although some questioned whether this opportunity had been fully realised)

4.6.1. What happened?

In March 2007, the UKCRC PPI Project Group discussed the fact that the lack of a PPI strategy was becoming a barrier to their effectiveness: "It [the group] has no terms of reference and as a result there is no agreed methodology / criteria for assessing any projects or ideas that come to the group... The group proposed that it would now be timely to develop a UKCRC strategy for patient and public involvement… [which] would give focus and direction to the role of the Project Group."[18]

The interviewees felt there was a sense that:

> Unless there was a strategy that actually linked what the PPI Group was doing to the rest of the agenda then the rest of the Board wouldn't sign up, and if the Board didn't sign up, then we were all going nowhere.

18 Taken from minutes of UKCRC PPI Project Group, 26/3/07

> We needed a clear set of statements that the Board could buy into, as a Board. And the aim was of course that by getting this agreed by the Board, you could then pin each of the Board members down on behalf of their own organisations.

Simon Denegri, Chief Executive of the Association of Medical Research Charities and a UKCRC Board member, agreed to chair a working group for the Project Group which would develop the strategy. Sally Davies, as Chair of the UKCRC, agreed to sponsor the development of the strategy. The working group sent a brief questionnaire to all UKCRC Board members to inform the development of the strategy. This was followed up by telephone interviews and two workshops for patients and the public, so that their views would also inform the strategy.

Several drafts of the strategy were circulated for comment to PPI Project Group members, UKCRC Board members, participants at the PPI strategy workshops and UKCRC patient / public members of advisory groups. The strategy was presented to the Board in April 2008. A copy of the strategy is attached as Appendix 5.

4.6.2. What helped?

- ***An effective working group***
  It was clear that the establishment of a small working group, with a clear mandate really helped the development of the strategy. The working group was made up of people who knew about and were committed to PPI, and was seen to have strong and skilled leadership.

- ***Senior level support***
  A second key factor, and perhaps the most important, was the support of Sally Davies as Chair of the UKCRC Board:

> I felt unless it had Sally promoting it and giving visible support to it at a Board level, it would be more easily ignored.

> The great thing about it was Sally pinned her flag to it and sold it. So everyone round the [Board] table knew it was going to go through.

- ***Ownership by relevant stakeholders***
  The working group worked hard to ensure the involvement of patients and the public in the development of the strategy, but also to ensure that it was owned by the Board.

> The way you went about the strategy... it did demand ownership by the [PPI Project] Group and by somebody like Simon leading on the telephone interviews and interviewing Partners it kind of shifted it, it wasn't a strategy that we just pushed out from here, it was named as something that the organisation as a whole had to own.

4.6.3. What were the challenges?

It seems there may have been some tension between developing a strategy that everyone could sign up to and developing a strategy that would lead to change. Some interviewees felt the strategy may not have been challenging enough and could have been stronger on action:

> The strategy when you read it, [was] almost idealistic not directive.

4.6.4. Outcomes

- ***An increase in clarity and transparency***
  The fact that the Strategy set clear priorities for action, and led to the development of an annual implementation plan, meant that there was a new clarity about the work that the UKCRC undertook to develop PPI. There was also more transparency – anyone could see what the UKCRC planned to do to develop PPI by looking at the UKCRC website and reading the PPI strategy and implementation plans[19].

> Through a relatively fair and open process we identified what the UKCRC says it will do in terms of PPI, which gives [us] a much more comfortable place to work from, because I can say this is our strategy, this is our work plan for this year.

- ***An opportunity to drive PPI forward***
  The strategy provided impetus and motivation for UKCRC Partners to take PPI forward, both individually and as a partnership:

> For us it was finding a way to join up with the rest of the UK initiatives… and I think the strategy helped to do that.

19 The UKCRC Strategy and implementation plans are at http://www.ukcrc.org/patients-and-public/ppi/ppistratplan/

However, one interviewee felt that these opportunities were not fully realised:

> When the strategy was done there was support at the top, but it needed something to happen quickly to engage them. But there's been a distinct lack of momentum.

4.7. Development of proposals for PPI in 2010 and beyond

SUMMARY

The factors that might **assist** the development of PPI in future are:

- Plans have been developed to take forward PPI across the Partner organisations
- Efforts have been made to learn from the experience

The **challenges** will be:

- The onus is now on INVOLVE as the lead organisation working with Partners to take forward PPI
- There are many other competing priorities for action
- The reduction in dedicated resources for PPI within the UKCRC Secretariat

4.7.1. What happened?

In February 2009, UKCRC Board members revisited the vision, aims and agenda of the UKCRC. It agreed that from January 2010 the UKCRC would operate through a Partner-led model. This meant that the role and function of the UKCRC Secretariat would change, with future work being led by the UKCRC Partners with a much reduced Secretariat supporting the UKCRC Board. The Board agreed that all existing UKCRC workstreams and associated groups should review their activities and define any proposed objectives for work beyond the end of 2009 and make recommendations for how these should be taken forward.

In June 2009, the UKCRC Board discussed and agreed proposals from the Board Subgroup for PPI. These were that INVOLVE would be the lead partner for PPI and would provide continued support for a number of key projects / activities. The Subgroup was formally disbanded in October 2009.

4.7.2. What factors might help PPI in the UKCRC in future?

- ***Plans have been developed to take forward PPI across the Partner organisations***
  The persistence of the UKCRC partnership will mean that those working to promote PPI (and especially INVOLVE as a member of UKCRC) will be able to continue working with a number of Partner organisations:

> It [INVOLVE] has a way in to, not all, but a significant number of the Partner organisations.

- ***Efforts have been made to learn from the experience***
  It's important to note that steps have been taken to reflect on the work that has been undertaken to promote PPI across the UKCRC. In addition to this report, evaluations were commissioned on the People in Research website and on PPI in UKCRC advisory groups.

4.7.3. What are the likely challenges to taking forward PPI in the UKCRC in future?

- ***The onus is now on INVOLVE as the lead organisation working with Partners to take forward PPI***

> It's going to be a test of whether PPI will stick, whether PPI really is taken seriously… within the UKCRC. I think it might, I'm not saying it won't. But clearly to do the kind of support job that Philippa and her colleagues have done it takes time and it takes effort and it takes a certain amount of money… I think that will be the test as to whether Partner organisations have taken on board that it's an integral part.

- ***There are many other competing priorities for action***

> Because the driver is keeping UK competitive and the argument about using PPI to enable the industry to do that isn't won by any means… From where I sit it doesn't look as if PPI's going to be a priority, apart for those organisations who sat around the [Board Subgroup for PPI] table.

- ***The reduction in dedicated resources for PPI within the UKCRC Secretariat***
  There was concern about the reduction of funding for PPI (both for the Programme Manager post and for PPI projects). Many interviewees were concerned about the potential impact on patient / public members of the UKCRC's Board and advisory groups:

> If you have a dedicated person like Philippa then there's no question that the thing gets done but if it's just tacked on to someone else's job description, well, the priorities may change.

There was concern about whether INVOLVE works in a way that will enable it to provide similar support for PPI within the UKCRC:

> INVOLVE has a series of projects as I understand it and… one of the questions I would have is whether in a sense taking up a series of projects is the same as having a sort of generic support framework.

The impact of the development of PPI within the UKCRC

5

SUMMARY

The development of PPI had an impact on the UKCRC as an organisation in different ways. These included:

- Changes in organisational culture, especially at Board level, which have meant that PPI has become more of an integral part of Board activities
- PPI in many more UKCRC working groups and committees

Factors that **assisted** these changes include:

- Senior level support
- Board and other advisory group members having had direct experience of PPI
- An increase in the number of PPI champions
- The appointment of a patient / public member as a deputy chair of the UKCRC Board

The **challenges** for the development of PPI were:

- The pace and complexity of the UKCRC's agenda
- The difficulty of turning commitment to PPI into action
- The different attitudes of Partner organisations to PPI
- The time it can take to bring about culture change

The development of PPI has also had an impact on Partner organisations. It has given them an opportunity to:

- Learn from others
- Take the learning about PPI into their own organisations
- Work with other organisations to take forward projects of shared interest

In this section we examine what impact the development of PPI has had on the UKCRC. In sections 5.1 – 5.3 we consider the impact of the programme to develop PPI on the UKCRC as an organisation. In section 5.4, we consider the impact on UKCRC Partner organisations.

5.1. Impact on the UKCRC as an organisation

In the early days of the UKCRC, the Board was faced with a very demanding and crowded agenda and PPI was not considered a priority for action. The Board also consisted of a wide range of organisations with divergent views and opinions on PPI. It is clear that members did not have a shared understanding of PPI, nor a shared set of objectives for PPI activity. This set a very challenging context in which to establish a shared agenda and develop a PPI programme. These challenges have been barriers to the progress of PPI at various stages in the UKCRC's history. The advances that have been made have therefore been highly significant, given the starting point five years ago.

The perceived changes within UKCRC include:

- ***Changes in organisational culture, especially at Board level, which have meant that PPI has become more of an integral part of Board activities***
  Many of the interviewees felt that the culture of the UKCRC Board has changed, and that PPI has become more of an integral part of Board activities. Board members are more accepting and understanding of its significance and importance:

> I would say that the idea of PPI and the concept…of accountability to the public… maybe this is wishful thinking, but I think it is more accepted around the table particularly at the Board now. Whilst it may not be the priority… for some [Board members] I think that they do now realise its importance in a way that perhaps they didn't take into account at the start.

  There is now a level of awareness of PPI that wasn't there in the beginning and this marks a major step forward:

> It's purely that it's in the consciousness of everyone. And that's not to say that's no mean achievement, that's quite an achievement.

- ***PPI in many more UKCRC working groups and committees***

> The good thing is that all the UKCRC, the decision making and consultative panels have patient and public involvement and I think it's seen now in a different way from what it was 5 years ago.

5.2. What factors have supported these changes?

There are a number of factors which have led to the growing acceptance of PPI. These include:

- ***Senior level support***
  For example, the support from Sally Davies, who chairs the UKCRC Board, was clearly crucial to the development and acceptance of the UKCRC Strategy for PPI.

- ***Board and other advisory group members having had direct experience of PPI***

> I think certainly at Board level… the presence of a PPI member - or more than one – it does perhaps have some effect on the attitude and thinking of the other participants… the thing about remembering the real purpose and the real role of research… I think that it helps them to remember the principle that there's this accountability to… patients and the public.

- ***An increase in the number of PPI champions***
  Over the years, as new members joined, there were more and more people who were able to champion PPI at Board level. This meant that these champions could work together and join efforts to promote more discussion at Board level:

> We were also sort of driving some agendas by getting questions asked [at the Board], using people like Nick Partridge to deliberately ask a question to get a particular topic aired more widely than it otherwise would.

> …because [X] and I were both on the UKCRC Board… if there was an issue or anything… occasionally we would talk to each other before a Board meeting and say you know it's your turn to bring this up today, I'll support you. There was a bit of that.

Importantly these champions were individuals who already had, or had earned the respect of other Board members, which gave their opinions more credibility:

> When PPI discussions came round there were… respected voices. We weren't the Barmy Army. We're quite consensual people. We weren't the Trojan horse.

- ***The appointment of a patient / public member as a deputy chair of the UKCRC Board***
  In December 2005, Nick Partridge (chair of INVOLVE and chief executive of the Terrence Higgins Trust) was appointed as a deputy chair of the UKCRC Board:

> There's something about Nick that he has the credibility and respect from people… He's seen as part of the solution and not part of the problem.

> [Nick is] seen to come from the voluntary sector and to be a sort of heavyweight within that and I think that brings a sense of respect for that sector but also for the idea of PPI which he's there to champion and I think… he does it well and that has had an effect.

5.3. What were the challenges to taking forward PPI within the organisation?

- ***The pace and complexity of the UKCRC's agenda***
  A major challenge to the development of PPI was the scope, complexity and sheer pace of work undertaken by the UKCRC:

> The agendas are very full for the meetings, the speed of the meetings is very fast, the chair is very keen to get on to the next item… So there's this driving agenda, this business agenda for the country.

> [PPI] was always in the corner of the room, no matter how hard we might work to sort of bring it centre.

- ***The difficulty of turning commitment to PPI into action***
  One interviewee felt that the Board, whilst sympathetic to PPI, did not give enough thought as to how best to implement it:

> Everybody on the UKCRC Board was supportive of the principle of PPI, and felt they were living by it. But little thought was given to what it actually meant. PPI was like the forgotten child in the corner of the room… The fact that Nick was vice chair was a very strong symbol of the Board's commitment to PPI. But there was only so much Nick could do.

- ***The different attitudes of Partner organisations to PPI***

> One of the issues of course is that the UKCRC is not some kind of blanket object… Not all parts of it have got the same history the same attitudes, the same objectives around PPI, so there's clearly vast differentials… between some member organisations which are very much ahead of the game and others dragged kicking and screaming into it.

- ***The time it can take to bring about culture change***
  A number of interviewees noted that it takes an enormous amount of time to bring about the kinds of cultural changes that have started within UKCRC:

> It's a very slow process, because you'd like them to have a kind of Damascene revelation about the whole thing I don't think that's going to happen, I think it's going to have to become part of the environment, part of the context that these organisations work in… it's going to take really a long time.

> The whole thing just moved on slowly. It progressed, but these things unfortunately just take time.

5.4. Impact on Partner organisations

We noted in section 4.1.2 that individual organisations had different objectives in relation to PPI at the UKCRC. There were different views about whether these objectives had been met. Some found it hard to measure. Others felt that at least some of their objectives had been met. These included:

- ***An opportunity to learn from others***

> There is no doubt that we have benefited from being part of the wider PPI community and from knowing what is happening in the field.

> What has been most interesting is the commonality of experience with both the UKCRC's PPI activities and our own, and other organisations. It has been both reassuring and encouraging that relatively disparate organisations do seem to approaching their PPI activities with the same techniques. More specifically, issues such as appropriate training of chairs of groups with lay members, has been an opportunity to explore our own approaches and learn from the experiences of the UKCRC.

- ***An opportunity to take the learning about PPI into their own organisations***

> Our organisation is now much closer to agreeing a strategy for PPI. We have received much support and advice from the UKCRC, in particular Philippa Yeeles, in the activity that we have undertaken and made links with other organisations in the field.

> [The UKCRC has] been helpful in enabling us to see good practice and, for staff involved in PPI strategy development, to understand clearly what can and cannot be achieved through PPI in a research-funding organisation.

- ***An opportunity to work with other organisations to take forward projects of shared interest***

> There have been… a number of one-off joint projects that have resulted in an expansion of the 'real-life' evidence-base around PPI as opposed to the theoretical approach in much of the academic literature.

However, some organisations expressed frustration that they had not achieved their objectives:

> [Our] aims of disseminating models of good PPI practice and developing a clearer understanding of when PPI is, and is not appropriate in research and research management have not been fully realised.

However, from the perspective of some interviewees, one of the major achievements of the PPI work within UKCRC was to encourage Partner organisations to reflect on their own practice:

> I think the main achievement was to put PPI really on the map, with the Board. And the Board of course are key – they run their organisations or they're senior people in their organisations, so they were hearing things. And there's no doubt that people were going back to their organisations and saying 'what are we doing? Are we doing anything along these lines?'

Lessons Learned

6

SUMMARY

There are a number of lessons that can be learned from the UKCRC experience. They come under three broad headings as follows:

What to think about when developing PPI

- Make PPI a priority
- Identify clear aims and develop a shared understanding of PPI
- Ensure you have dedicated resources and the right staff as early as possible
- Develop a strategy that has broad ownership, but also directs coordinated action
- Develop a programme of work that allows for both quick wins and for long-term developments
- Ensure that the PPI-related activity is visible and adds value to other activities
- Demonstrate good practice, model high quality PPI and report what you have done, so that others are encouraged to do likewise
- Consider how you will measure any impact of PPI when you are at the planning stages

Building relationships

- Ensure you have senior level commitment
- Build strategic alliances
- Keep sight of the bigger picture and don't consider PPI to be the only issue of importance
- Develop positive strategies to challenge sceptics:
  a. Demonstrate how PPI can help research organisations to achieve their goals
  b. Introduce change at an appropriate pace

Being realistic

- About what can be achieved
- About the time it takes to achieve a culture change

Our interviewees identified a number of lessons that could be learned from the work undertaken to develop PPI in the UKCRC. There were three key themes:

- What to think about when developing PPI
- Building relationships
- The need to be realistic

We illustrate each of these in turn below.

6.1. What to think about when developing PPI

- ***Make PPI a priority early on*** section 4.1.3

> I think the failure - if there has been one - was not to ensure that PPI was seen as a strategic priority from day one of UKCRC.

> I think it would have been useful to have it as an important priority right from the word go. It's understandable that it wasn't in a way because there were lots of things that needed fixing… So PPI didn't get the priority it deserved.

- ***Identify clear aims and develop a shared understanding of PPI*** section 4.1.3

> I think it could [have been] very much clearer about what it wanted to achieve with PPI… and then we could have moved towards it and [developed] more varied and creative ways of ensuring the patient and carer voice [is heard in] the work of the UKCRC.

- ***Ensure you have dedicated resources and the right staff as early as possible*** section 4.3 and 4.4

> I think it's a sufficient, dedicated resource in terms of time, that it is the focus of somebody rather than just the sideline. I think it is sufficient seniority and experience… by very nature of the post being what it is, they've got a bit of clout, and certainly top of the office support… I think… it's actually getting the right person for the stage of development that you're at.

- ***Develop a strategy that has broad ownership, but also directs coordinated action*** section 4.6

> A lot of the difficulties I've experienced in organisations have been when you don't have a thought through whole systems approach you get bits and pieces happening… It's an important lesson for the future, that organisations need to think through where these activities happen, how is it helping, how are they monitoring.

- ***Develop a programme of work that allows for both quick wins and for long-term developments*** section 4.6.3

> When we did have a strategy and group in place we did not capitalise on this quickly. We should have made some hard choices and focused on one deliverable.

- ***Ensure that the PPI-related activity is visible and adds value to other activities*** section 4.2.4

> It was really important that the Project Group became a Board Subgroup and that there was thought about who was going to chair the group and the idea of how does the organisation itself view this piece of work… and that process then gave loads more gravitas to what would otherwise be seen as a bunch of people who get together with their knitting… there's a form of culture change that was brought about through that process, it might not have been as all encompassing as I'd like but it made a real step change.

- ***Demonstrate good practice, model high quality PPI and report what you have done, so that others are encouraged to do likewise*** sections 4.5 and 4.6
  The recruitment and support of PPI members and the development of a PPI strategy have offered models of good practice that both UKCRC Partners and other organisations can follow. This modelling and reporting of good practice also enables those who may be sceptical to see the potential value of PPI for themselves.

- ***Consider how you will measure any impact of PPI when you are at the planning stages*** section 4.1

> The big thing that we've missed and I think we've only really become aware of it as a result of the work we've done in the UKCRC is that we need to embed measures at the very earliest opportunity so that we can evaluate it.

6.2. Build relationships

- ***Ensure you have senior level commitment*** sections 4.2.4 and 4.6.2

> One of the key issues in this: unless you get ownership at the top and it's clearly perceived ownership and ownership which sanctions and supports the approach, you're always going to be pushing upstream.

- ***Build strategic alliances*** sections 4.1.2 and 5.2
  Those committed to the development of PPI within the UKCRC identified potential allies (e.g. within the Board) and built relationships with them. This helped them to achieve specific goals.

> I think it's working out very early on who are your allies and working with them.

- ***Keep sight of the bigger picture and don't consider PPI to be the only issue of importance*** sections 4.1.1
  It's important for PPI members to focus on the broader aims of an organisation or a meeting, rather than solely focussing on PPI:

> I think sometimes they [the Board] have been surprised that a PPI member may ask about a budget or something of that importance… It's not just what you might call the softer, emotional, or patient-orientated things, that we are actually from the world as well and we would agree… that there have to be priorities and so on… I think it's important that PPI members… demonstrate that we do take a wider interest and that we're not just being a person affected by or a patient.

- ***Develop positive strategies to challenge sceptics:***

  a. Demonstrate how PPI can help research organisations to achieve their goals sections 4.1, 4.5 and 4.6

> I wouldn't criticise UKCRC at all for not making enough noise about it [PPI in research]. You've got to have people willing to hear, you've got to be able to say things that are helpful to them when they want to do it.

> My approach was very pragmatic… I thought, if we can pick one thing where the PPI thing is a solution, next time [a sceptic] will say PPI helped us with this.

b. Introduce change at an appropriate pace section 4.1

> In the Board it [PPI] was led by a number of Board members. If it was too radical you'd have lost [the other Board members]. It wasn't threatening enough for them to stop it and it has moved along a lot.

6.3. Being realistic

- ***About what can be achieved*** sections 4.1, 4.2.4 and 4.6

> I think there is something to take forward about other organisations starting small, work by stealth, up the anti gradually, because sometimes I tend to think we should launch things and be big and be bold, and I'm increasingly thinking that it's good to be on the edge, just watching going on and gradually just spotting the opportunities and being political about it actually, being more tactical.

- ***About the time it takes to achieve a culture change*** section 4.2.4

> In terms of lessons learned, and how things developed, some of the sort of things, things do take time and you can't rush things to happen.

6.4. Conclusions

The lessons learned through the process of undertaking a critical assessment of the development of PPI in the UKCRC are perhaps somewhat predictable. It is relatively easy to identify them with hindsight. It is also relatively easy to come up with a 'must-do' list and to be critical, from the outside or the inside, because what is identified as 'best practice' hasn't necessarily been followed.

Clearly it is valuable to try and reflect honestly on progress made, or the lack of it, within an organisation like the UKCRC. As this represents what can happen when trying to develop PPI in a complex, changing environment. Any approach to developing PPI will be heavily influenced by the specific individuals involved and the organisation they work in. The reality is that there may be power issues, politics and cultural barriers that prevent anyone taking forward PPI in the ways that are recommended. In practice, in order to even begin to move forward, there is a need to be pragmatic and to do whatever is possible:

> Sometimes when you're trying to take it forward in an organisation that's so far behind and not fully up to speed with PPI, then there's a wide gap… You can be galvanised here, and then when you go back there are so many barriers again - to make it quite frustrating.

It is also important to remember that the most intangible changes, for example changes in attitudes to PPI, are often the hardest to measure and may seem insignificant – but in fact they often represent the most radical changes. It is the changes to 'hearts and minds' that will have the greatest impact in the longer term. The work can be slow, frustrating and changes almost imperceptible, but it should remain an important focus:

> My impression of this is it did evolve, and it has grown, and that maybe gradual integration has been actually part of the success and that's what we tell other organisations.

Appendix 1

UKCRC patient and public involvement projects

The following projects were all considered for development by the UKCRC PPI Project Group and / or the UKCRC Board Subgroup for PPI. Further information about the PPI activities of the UKCRC can be found on the UKCRC website http://www.ukcrc.org/patients-and-public/ppi/

Project	Outcome / output	Link
People in Research - http://www.peopleinresearch.org/ A web-based resource for patients and the public connecting them to opportunities for PPI in research	*An evaluation of People in Research: a web based resource*, Minervation 2009 INVOLVE will lead on this project for the UKCRC from January 2010.	http://www.ukcrc.org/patients-and-public/ppi/pir/
Developing standard criteria for assessing patient and public involvement in research applications A project aimed to promote and improve the quality of patient and public involvement in research through the development of evidence based judgement criteria	Initially developed as a funding proposal by TwoCan Associates and the Association of Medical Research Charities (AMRC). The PPI Project Group eventually took this area of work forward in a different form as a joint project on prioritisation and commissioning of research between the James Lind Alliance, INVOLVE and the AMRC (see below).	
PPI clauses in research contracts A project aimed to embed PPI into the contracts of both research funders and the research workforce	After scoping this project UK-wide and in consultation with a number of research funders and research workforce development advisers, it was agreed not to take this project forward.	

Project	Outcome / output	Link
PPI Activities Log A database of current projects / activities that are in some way researching, evaluating or reflecting on the impact of patient and public involvement in research	The Activities Log was first produced and circulated in March 2007. An updated version was produced and circulated in March 2008.	http://www.ukcrc.org/patients-and-public/ppi/understandingppi/
A pilot project to involve patients and the public in the membership of UKCRC advisory groups and subgroups	*An evaluation of the process and impact of patient and public involvement in the advisory groups of the UK Clinical Research Collaboration*, TwoCan Associates 2009.	http://www.ukcrc.org/patients-and-public/ppi/ppiinukcrcgroups/
Developing a panel of patients and members of the public to contribute to the work of the UKCRC and UKCRC Partner organisations	This project was considered at length by the PPI Project Group. It was decided that there was not enough support or demand for this proposal to be taken forward. However another project was developed on the basis of the scoping undertaken - to explore the roles of patient / public members on strategic decision making bodies (see below).	

Project	Outcome / output	Link
A project to improve understanding of, and support for, PPI in research prioritisation and commissioning processes Led for the UKCRC by the James Lind Alliance working with INVOLVE and the Association of Medical Research Charities	A seminar for research funders and commissioners, building on the work of the James Lind Alliance, INVOLVE and the Association of Medical Research Charities, is planned for February 2010.	
	Related work: *Scoping research priority setting (and the presence of PPI in priority setting) with UK clinical research organisations and funders*, Staley and Hanley for the James Lind Alliance 2008	http://www.lindalliance.org/Scoping_research_priority_setting_PPI.asp
	A bibliography of research reports about patients', clinicians' and researchers' priorities for new research, Oliver and Gray for the James Lind Alliance, December 2006.	http://www.lindalliance.org/pdfs/JLA_Oliver%20and%20Gray%20report%2007_01_20.pdf
	The Association of Medical Research Charities' PPI Natural Ground Project.	http://www.amrc.org.uk/HOMEPAGE/Default.aspx?Nav=479,946&ith=20
A systematic review of evidence on the conceptualisation, measurement, impact and outcomes of PPI in health research Project undertaken by the NHS Centre for Involvement and the School of Health and Social Sciences at Warwick University	A report from this project will be made available on the UKCRC website in 2010.	

Project	Outcome / output	Link
Work with the UKCRC Board Subgroup on Public Awareness on the use of patient data for research purposes	The Board Subgroup for PPI provided advice and support to the Public Awareness Subgroup primarily through the activities of two shared members and the PPI Programme Manager.	
Work with the UK Clinical Research Network Coordinating Centre, the UKCRC Board Subgroup on Public Awareness and others, on improving patient and public access to information about clinical research	The Board Subgroup for PPI occasionally provided advice and support to the National Institute for Health Research on this issue.	
Work with relevant trade associations and other industry stakeholders to develop an action plan to increase PPI in industry activities This project was led by the Association of the British Pharmaceutical Industries (ABPI)	After consultation with members of the ABPI and other representative industry organisations it was agreed by the Board Subgroup that work was first needed to raise awareness and promote the value of PPI with industry before an action plan could be developed.	
An event to share knowledge and learning in support of the development of PPI in National Institute for Health Research (NIHR) clinical research networks at a local level, organised jointly with the NIHR Clinical Research Network Coordinating Centre	Report of workshop held in March 2009.	http://www.ukcrc.org/docs/PPI_LRN_WS_Report/

Project	Outcome / output	Link
Exploring the roles people are performing as patient / public members of strategic decision making groups within research organisation INVOLVE will lead on this project for the UKCRC from January 2010	Workshop held in March 2009 to: ▸ explore the roles people are performing as patient / public members of strategic decision making groups ▸ identify any core, shared challenges in performing those roles ▸ begin to consider how challenges could be tackled and what could help patient / public members carry out their roles more effectively.	http://www.ukcrc.org/docs/PPI_Strat_Decision_Making_WS
Developing guidance for chairs of research groups and committees that include patient / public members **A project developed in partnership with the National Cancer Research Network and the National Cancer Research Institute**	The guidance will be made available on the UKCRC website in 2010.	
Capture key learning from the experience of developing PPI in the UKCRC	*A critical assessment of the development of patient and public involvement in the UK Clinical Research Collaboration: Lessons learned*, TwoCan Associates 2009.	http://www.ukcrc.org/patients-and-public/ppi/understandingppi/

Appendix 2

Membership of the UKCRC Patient and Public Involvement Project Group & the Board Subgroup for Patient and Public Involvement

Hala Ahmed	Medical Research Council	Mar-07 - Jul-09
Nicole Barlow	Royal College of Physicians	Dec-05 - Feb-08
Hannah Brown	UKCRC (Secretariat)	Sep-06 - Oct-09
Sarah Buckland	INVOLVE	Dec-06 - Oct-09
Iain Chalmers	James Lind Alliance	Aug-06 - Mar-07
Mary Cooke	School of Nursing & Midwifery, Sheffield University	Jun-07 - Feb-08
Sally Crowe	James Lind Alliance	Jun-07 - Oct-09
Simon Denegri	Association of Medical Research Charities	Sep-06 - Oct-09
Dawn Duncan	Medical Research Council	Sep-06 - Mar-07
Susan Frade	Medicines and Healthcare products Regulatory Agency	Feb-09 - Oct-09
Craig Gilbert	Chief Scientist Office, Scotland	Mar-08 - Oct-09
Margaret Goose	Royal College of Physicians	May-06 - Feb-08
Lesley Griffiths	CRC Cymru Coordinating Centre	Sep-06 - Sep-07
Cathy Hamer	Patient / public member	Jun-07 - Oct-09
Sandy Herron-Marx	NHS Centre for Involvement	Feb-08 - Oct-09
John Hughes	Patient / public member	Jun-07 - Oct-09
Gail Johnston	Health & Social Care Research & Development Office in Northern Ireland	Jan-09 - Oct-09
Marcia Kelson	National Institute for Health and Clinical Excellence	Dec-05 - Oct-09
Marianne Miles	National Institute for Health Research Clinical Research Network Coordinating Centre	Dec-05 - Oct-09
Moira Nolan	Scottish Executive Health Department	Dec-05 - Dec-07
Liam O'Toole	UKCRC	Dec-05 - Jun-08
Kay Pattison	Department of Health, England	Feb-08 - Jun-08
Sophie Petit-Zeman	Association of Medical Research Charities	Dec-05 - Mar-07
Emma Louise Radway-Bright	Association of the British Pharmaceutical Industry	May-09 - Oct-09
David Rea	Clinical Research Collaboration Cymru	Sep-07 - Oct-09
Wendy Russell	Department of Health, England	Sep-06 - Jun-07
Sophie Staniszewska	NHS Centre for Involvement	Feb-08 - Oct-09
Roger Steel	National Institute for Health Research Clinical Research Network Coordinating Centre	May-08 - Oct-09
Maryrose Tarpey	INVOLVE	Sep-06 - Oct-09
Victoria Thomas	National Institute for Health and Clinical Excellence	Sep-08 - Oct-09
Richard Tiner	Association of the British Pharmaceutical Industry	Sep-06 - May-09
Alex Westmoreland	Wales Office for Research and Development	Apr-08 - Jan-09
Simon Wilde	Medical Research Council	Jan-07 - Oct-09
Tony Williams	Department of Health, England	Feb-08 - Jun-08
Tracey Williamson	Royal College of Nursing	Sep-06 - Feb-08
Roger Wilson	UK Clinical Research Network Coordinating Centre	Dec-05 - Feb-08
Philippa Yeeles	UKCRC (Secretariat)	Sep-06 - Oct-09

Appendix 3

UKCRC Board Subgroup for Patient and Public Involvement: Terms of reference

1. Purpose

The UKCRC Board Subgroup for Patient and Public Involvement has been established by the UKCRC Board to oversee and monitor the implementation of the UKCRC Patient and Public Involvement Strategic Plan 2008 – 2011.

The Subgroup will also advise the UKCRC Board and provide a forum for discussion of strategic issues relating to patient and public involvement in clinical research.

2. Responsibilities

The UKCRC Board Subgroup for Patient and Public Involvement will:

- Draw up an annual implementation plan to support the delivery of the Patient and Public Involvement Strategic Plan 2008 – 2011
- Oversee and monitor progress on the delivery of the Patient and Public Involvement Strategic Plan 2008 – 2011
- Request from the UKCRC Board a budget to support each annual implementation plan
- Provide the UKCRC Board with regular reports assessing progress and challenges of implementation
- Work closely with organisations that have a specific remit to support patient and public involvement in clinical research to ensure the best use of available resources, knowledge sharing and to avoid unnecessary duplication of effort
- Share information and work with a broad range of stakeholders to support and promote the development of patient and public involvement in clinical research across the UK

3. Accountabilities

The Subgroup will report directly to the UKCRC Board. The Chair of the Subgroup will be a UKCRC Board member or a UKCRC Board Alternate.

4. Financial Control

The Subgroup will oversee the expenditure of an annual budget set aside for patient and public involvement by the UKCRC Board.

5. Membership

The Chair of the Subgroup will be nominated by the UKCRC Board. This is currently Sarah Buckland (Director of INVOLVE).

The Subgroup will take on the role and broad membership of the UKCRC Patient and Public Involvement Project Group, which has ceased to function.

Membership will be drawn from the following stakeholder groups:

- Patients and members of the public
- UKCRC Partner organisations
- The UK Clinical Research Networks across the 4 nations
- Other organisations and individuals with knowledge and expertise in patient and public involvement in research, to act as 'critical friends'

6. Meetings

The Subgroup will meet three or four times a year, as required. It is anticipated that members will contribute to the work of the Subgroup outside of meetings through participation in smaller project groups or by responding to ad hoc requests for additional involvement.

Secretariat services will be provided by the UK Clinical Research Collaboration Secretariat team. Meeting papers will be circulated, by email, at least one week in advance of meetings. Paper copies of all documents can be posted out to members and alternative formats for information can be provided, if requested.

All reasonable expenses incurred in attending meetings will be reimbursed. An attendance fees is offered to members who are not working in the public sector and whose time would otherwise not be paid for.

Appendix 4

Patient and public involvement budgets and expenditure

The table below shows the UKCRC's planned and actual spend on PPI from the financial year 2005/2006 until 2009/2010, and also what percentage this represented of the UKCRC's total budget and spend. These figures do not include the salary of the PPI Programme Manager.

2005/06

	Approved budget	Final expenditure
Total budget	£953,582	£823,016
PPI budget	No PPI budget	n/a
PPI budget as % of total budget	n/a	n/a

2006/07

Total budget	£1,139,611	£970,564
PPI budget	£17,426	£19,272
PPI budget as % of total budget	1.5%	2%

2007/08

Total budget	£1,292,273	£967,909
PPI budget	£35,360	£36,737
PPI budget as % of total budget	2.7%	3.8%

2008/09

Total budget	£1,104,802	£978,904
PPI budget	£139,600	£92,293
PPI budget as % of total budget	12.6%	9.4%

2009/10

Total budget	£661,288	(not yet known)
PPI budget	£106,050	(not yet known)
PPI budget as % of total budget	16%	(not yet known)

Appendix 5

UKCRC Patient and Public Involvement Strategy 2008-2011

In addition to their own organisational approaches to patient and public involvement, the UK Clinical Research Collaboration Partners are jointly committed to the following three-year strategic plan.

Our vision

What we aspire to:

Patients and the public, actively involved in developing and sustaining a thriving clinical research environment in the UK, to improve the health and well-being of all.

Our objectives

What we will do to achieve our vision:

We will encourage and facilitate the development of patient and public involvement in clinical research, offering leadership in areas that will most benefit from our collaborative approach.

We will establish partnerships with others to deliver three key strategic objectives:

- To ensure that patients and the public influence and support the development of UK clinical research at a strategic level
- To improve public confidence in, and understanding of, clinical research through greater patient and public involvement
- To develop sustainable solutions to the barriers that can prevent or impede public involvement in research

How we will work

We will:

- Involve patients and the public in the work of the UK Clinical Research Collaboration, paying particular attention to the need for greater diversity amongst the wide range of communities, groups and individuals that could be involved
- Advocate the value of patient and public involvement to UK clinical research at local, regional, national and international levels
- Recognise the importance and value of patient and public involvement by offering people appropriate and continued support and reward for their involvement
- Work closely with organisations that have a specific remit to support patient and public involvement in clinical research (such as INVOLVE and Involving People: Cynnwys Pobl), to ensure that we make the best use of available resources, share knowledge and avoid unnecessary duplication of effort

- Monitor and evaluate our work both to improve our own practice and to add to the developing knowledge base describing the processes and impact of public involvement in research

Activities within the three key strategic objectives:

Ensure that patients and the public influence and support the development of UK clinical research at a strategic level
Over the next three years we intend to:

- Support opportunities for the development of patient and public involvement membership in structures and processes of organisations that have a strategic remit in clinical research
- Develop and support a network of patients / public with experience of patient and public involvement in research to act as broader reference group for a range of UK Clinical Research Collaboration activities

Improve public confidence in, and understanding of, clinical research through greater patient and public involvement
Over the next three years we intend to collaborate in:

- Developing resources for patients / public to inform them about the broad spectrum of research-related activities in which they can get involved
- Exploring the role of patient and public involvement in improving public confidence in, and understanding of, clinical research
- Influencing researchers' attitudes towards, and understanding of, the value of patient and public involvement in research
- Exploring, with relevant trade associations and other industry stakeholders, how to support patient and public involvement in industry

Develop sustainable solutions to the barriers that can prevent or impede public involvement in research
Over the next three years we intend to:

- Support the development of the evidence base for the impact of patient and public involvement in research through collaborating with others in reviews, mapping, monitoring, evaluation and related activities
- Work closely with the UK Clinical Research Network Coordinating Centre to support it in embedding patient and public involvement in the clinical research networks
- Collaborate with other organisations to facilitate seminars, workshops and other events, to share knowledge and learning

UK Clinical Research Collaboration
20 Park Crescent
London
W1B 1AL
United Kingdom
Tel: +44 (0)207 670 5452
Fax: +44 (0)207 637 6067
info@ukcrc.org
www.ukcrc.org