Patient and Public Involvement in Paediatric Research

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Agenda

1. My role
2. PPI definitions
3. Doing PPI
4. Examples of PPI – JLA, YPAG, Generation R
5. Web resources
My role

• PPI lead in research until March 2017

• Individual consultation for GOSH/ICH BRC researchers

• Facilitator of Young Persons Advisory Group

• Develop PPI training for GOSH/ICH BRC researchers, joint with GSTT BRC and online modules

• Map and document existing PPI resources around GOSH/ICH BRC

• Network and collaborate with other PPI leads, locally and nationally
Patient and Public Involvement in Research

- Research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them

- **Engagement**: raising awareness of research, sharing knowledge or engaging and creating a dialogue with the public

- **Participation**: Recruitment of patients or members of the public as participants in research.
Patient and Public Involvement in Research

Public
• Patients
• Potential patients
• Parents and carers
• People who use health and social care services
• People from organisations that represent people who use services
• Patient support groups
• Charities that represent specific health conditions
• Individuals with an interest in the topic being researched

• Patients vs. service users?
• Consumer involvement?
• “Citizen engagement in research and implementation”? 
PPI – Why do it?

1. **Necessity** – Because **you have to** (e.g. NIHR, funding policy, ethics approval)

   and /or

2. **Democratic principles** – Use of public money, ethical scrutiny, ‘nothing about us without us’ ‘placing patients at the centre’

3. **Pragmatism** – avoiding waste - improving quality and relevance of the research

4. **Valuing expertise** – knowledge, experience, patient, public perspectives
PPI – Why do it?

NRES application form:

'QA14-1: In which aspects of the research process have you actively involved, or will you involve, patients, service users and/or their carers or members of the public?

☐ Design of the research
☐ Management of the research
☐ Undertaking the research
☐ Analysis of results
☐ Dissemination of findings
☐ None of the above

Give details of involvement, or if none please justify the absence of involvement (free text box)
Joint INVOLVE/NRES study

Looked at the responses on IRAS forms regarding the nature and extent of public involvement planned

N = 646, forms submitted in 2010
Joint INVOLVE/NRES study

Responses to the NRES question on public involvement (N=646)

- No involvement box ticked (N=248)
- Involvement box ticked, confirmed by free text (N=124)
- Involvement box ticked, not confirmed by free text (N=274)

Joint INVOLVE/NRES study

Answers to free-text responses describing involvement:

“patients will be involved during the research as subjects”

“I will be asking my patients to take part in my study”

“patients will be asked to carry the sampling storage equipment (bottles and paper) and present them to staff at delivery”

“the intention is to report the findings in peer review journals”

“participants will be offered a copy of the results of the study.”

“I will be giving talks about the research”

“I see patients all the time, I know what their views are on this”
Joint INOLVE/NRES study

Answers to free-text responses describing involvement:

“service users helped develop the research topic and what research questions should be asked”

“named members of the public as co-applicants who will continue to be involved in the study”

“we have involved patient user groups in writing the information sheets, questionnaires and other research materials”

“we have invited patients on the trial steering group/management group”
Needs and expectations

1. Why do you want to involve people in your research?
2. Who will you involve? Where will you find them?
3. What do you expect of the people you involve?
4. What skills are needed by those you wish to involve?
5. Should you write a role description?
Identifying and prioritising

Design

Development of the grant proposal

Undertaking/managing

Analysing and interpreting

Dissemination

Implementation

Monitoring and evaluation
Consent and ethics

• Do I need consent to do PPI? No!

“If patient and public involvement in research is carried out to a high standard, it is more likely to result in ethical research. This is because the research is more likely to be:

• Relevant to the people it is trying to help;
• Beneficial in terms of delivering meaningful outcomes for patients and/or;
• Conducted in a way that is sensitive to the needs of the participants – through better patient information, recruitment processes and general management of the project.

It is therefore in the interest of RECs to promote and support high quality active involvement in research.”

• (INVOLVE 2009)
Levels of involvement

1. Consultation – One-off or on-going. Researcher seeks advice, views/opinions of involved people.

2. Collaboration – Researcher and involved people work together to make decisions about aspects of the research.

3. User-lead/controlled – Involved people make decisions about the research.
Identifying the people to involve

- In clinic
- Patient groups and charities
- Individual connections
- RDS London
- Clinical Research Networks
- Involving London website
Costs involved in PPI

- Meeting costs:
  - Room hire?
  - Refreshments
  - Transport
  - Childcare cover
  - Involvement

- Payment for involvement
  - £150/day
    - £75/half day
  - Vouchers for C/YP

NB: Different for people on state benefits
MHRA guidance: Benefits Conditions and Systems around Paid and Voluntary Involvement
Training and support

- What skills do you require from the people you want to involve?
- What training will you need to provide?
- How will you provide this training?
- What support do you need to offer the people you want to involve?
PPI example: James Lind Alliance

- JLA funded by the NIHR, coordinated through NIHR Evaluation, Trials, and Studies Coordinating Centre (NETSCC)

- Focusing on specific conditions or healthcare settings, JLA Priority Setting Partnerships aim to:
  - bring patient and clinician groups together on an equal footing
  - identify treatment uncertainties which matter to both groups
  - work with both groups to jointly prioritise the uncertainties
  - produce a final list (often a ‘top 10’) of jointly agreed research priorities,
  - publicise them widely, and make sure that other uncertainties they have discovered are recorded and available for researchers and research funders to access
  - provide a rare and valuable opportunity for patients and clinicians to shape the health research agenda.

- e.g. Cleft lip and palate PSP top 12, Type 1 diabetes PSP top 10, ENT aspects of balance PSP top 10
PPI example: Young Persons Advisory Groups

• National initiative, regional groups
• Members aged 8 – 18
• Consultation and collaboration service for researchers
• Meet every 6-8 weeks
PPI example: Generation R

“Ordinary children doing extraordinary things”

You’re invited to join us for

Generation R
young people improving research

11th September 2013, Science Museum, London, 10am - 4pm

The award winning NIHR Medicines for Children Research Network Young Person’s Advisory Group invite you to an event to showcase how children, young people & families have improved the design, development and delivery of paediatric research.

Topics led by Young People

- Benefits of Collaborating with Children & Families
- Impact & Evidence in the Design & Delivery of Research
- Disseminating Research Results
- The Future of Research / Educating the Next Generation

Special Guests

- Professor Dame Sally DaviesChief Medical Officer
- Sir Iain Chalmers Editor, James Lind Library
- Simon Denegri Chair of INVOLVE
- Dr Jonathan Sheffield CEO, NIHR Clinical Research Network

To register your interest please log on to http://sms.mcrn.org.uk/public/events/registration.aspx
Round-table discussions

• Afternoon session on challenges in consumer involvement

To discuss:
1. The ethical challenges of paediatric research

1. Disseminating research results

1. The future of research and educating the next generation
Recommendations

Recommendation 1:
Work with key stakeholders including parents and young people to identify solutions on tackling the major challenges. This could be achieved in collaboration with organisations such as the Nuffield Council for Bioethics and the Royal College of Paediatrics and Child Health (RCPCH).

Recommendation 2:
Summary level results should be made publicly (open access) available for all clinical trials.

Recommendation 3:
A patient specific (confidential) results feedback sheet mandatory part of the research process (as is the Patient Information Leaflet).

Recommendation 4:
We agree with the House of Commons Select Committee inquiry that peer review is vital to the reputation and reliability of scientific research and we agree that journal articles remain the primary instrument for the publication of summary-level trial results.
**Recommendation 5:**
Researchers and sponsors should ensure provision for the on-going supply of a treatment shown to be successful in a clinical trial to the study participants.

**Recommendation 6:**
To explore alternative and innovative ways of engaging with more young people and families, building our links with charitable organisations and parent/young people’s groups.

**Recommendation 7:**
MCRN PPI work-stream to work closely with the MCRN Children’s Research Industry Group (CRIG) to explore how models of closer collaboration with industry partners can be implemented.

**Recommendation 8:**
Build on collaborations with NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) to encourage involvement of young people and families in the identifying and prioritising of research studies.
**Recommendation 9:**
Develop an effective communications strategy that showcases involvement activities and sustains the objectives highlighted at GenerationR. This will require the use of innovative communication tools, such as a dedicated GenerationR website, E-Magazine and the use of social media.

**Recommendation 10:**
To develop a systematic way to measure the impact of involvement activities.

**Recommendation 11:**
Work with the education sector to promote clinical research education in schools, sharing resources such as Testing Treatments Interactive, resources developed by NHS England, and Centre of the Cell.
Research cycle

Engagement → Involvement ← Participation
Principles of involvement

• Plan user involvement as early as possible
• Be clear about what users will be able to do
• Be clear about what users will not be able to do
• Ensure all staff understand the reasons for involving users and attend training where necessary
• Support users with training and information
• Identify a key person within the research team for users to contact
• As a minimum reimburse users’ travel expenses
• Where possible offer childcare or carer expenses and cover other incurred costs such as telephone calls and stationery
• Acknowledge users’ input and be sure to feedback on the research and what you feel their contribution meant
• Ask for users’ feedback on their experience of being involved so you can make improvements for next time
• Ask users if they would like to remain involved if other opportunities are available

• RDS London
Conclusion - What is ‘good PPI’?

• Relevant to the project
• Appropriate for patients and public
• Allocated proper funds
• Well thought out
• Integrated throughout your research project
• Methodological approach
• Not tokenistic
• Documented
• Aims to have an impact
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Resources

RDS London PPI Resources:
http://www.rdslondon.co.uk/Patient-Public-Involvement/Resources.aspx

INVOLVE:
www.invo.org.uk

University public engagement:
http://www.publicengagement.ac.uk/

Involving London
www.involvinglondon.co.uk

Generation R report:
http://viewer.zmags.com/publication/62b8f2e9

People in Research
http://www.peopleinresearch.org/

James Lind Alliance
www.jla.nihr.ac.uk

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