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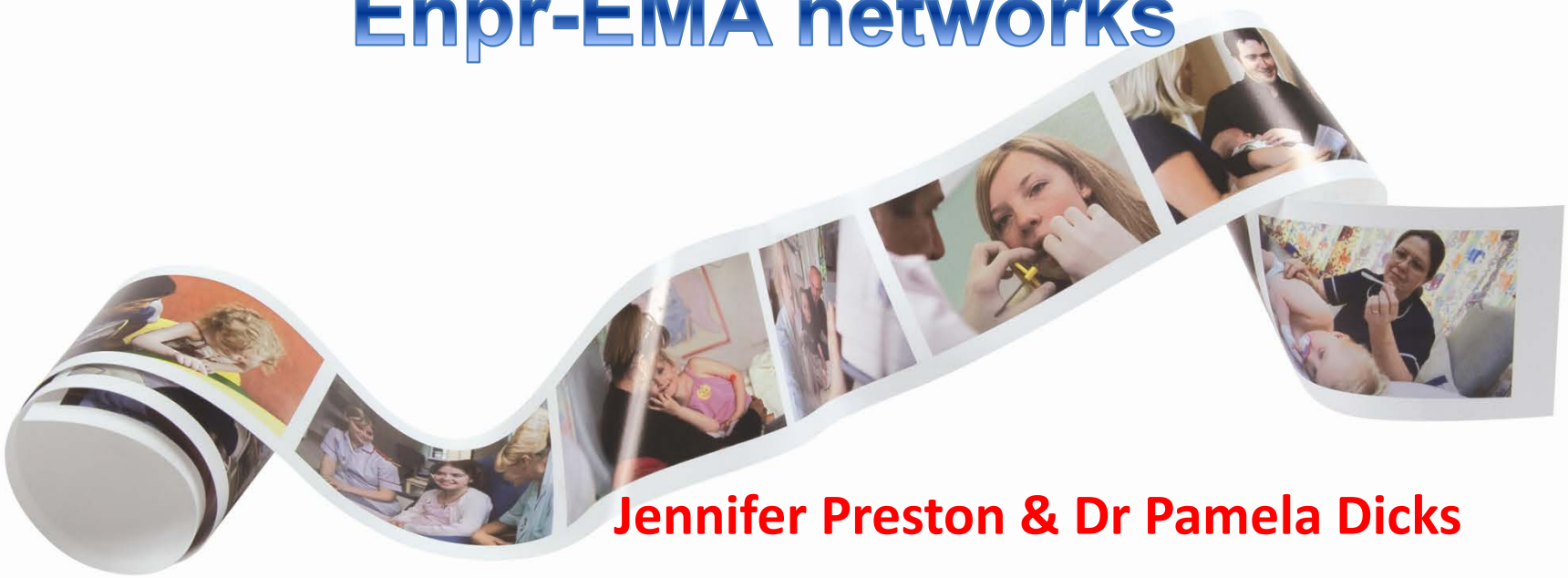
Involvement of young people in Enpr-EMA networks



Jennifer Preston & Dr Pamela Dicks

27 June 2013

Enpr-EMA Annual Workshop

Presentation overview

- MCRN Vision
- Two case studies
- Role of the groups
- Training
- Running the groups
- Key Outputs
- Challenges

Our vision

“Our vision is for real collaboration with young people and parents/carers at every feasible stage of the research process”

MCRN YPAG

Our PPI

Young Persons Group aged
8-18yrs

Meet monthly (Saturdays)

Receive relevant training in clinical research

Practicalities

- All young people received written information about the group
- Application forms and parental information sheets were sent out
- Parents were asked to sign consent forms prior to membership commencing
- Dietary requirements, travel arrangements, access issues and emergency contact details were noted

Getting started

Open information day (2006)

Pragmatic approach - invited yp via various routes, local schools, youth groups, specialist clinics

13 young people expressed an interest in joining the group but only 7 attended the open day

90 yp in National group

Scottish Network YPG

Our PPI

Young Persons Group aged 11-17 – senior school

Meet regularly

Receive relevant training in clinical research

Club/ membership and certification

Getting started

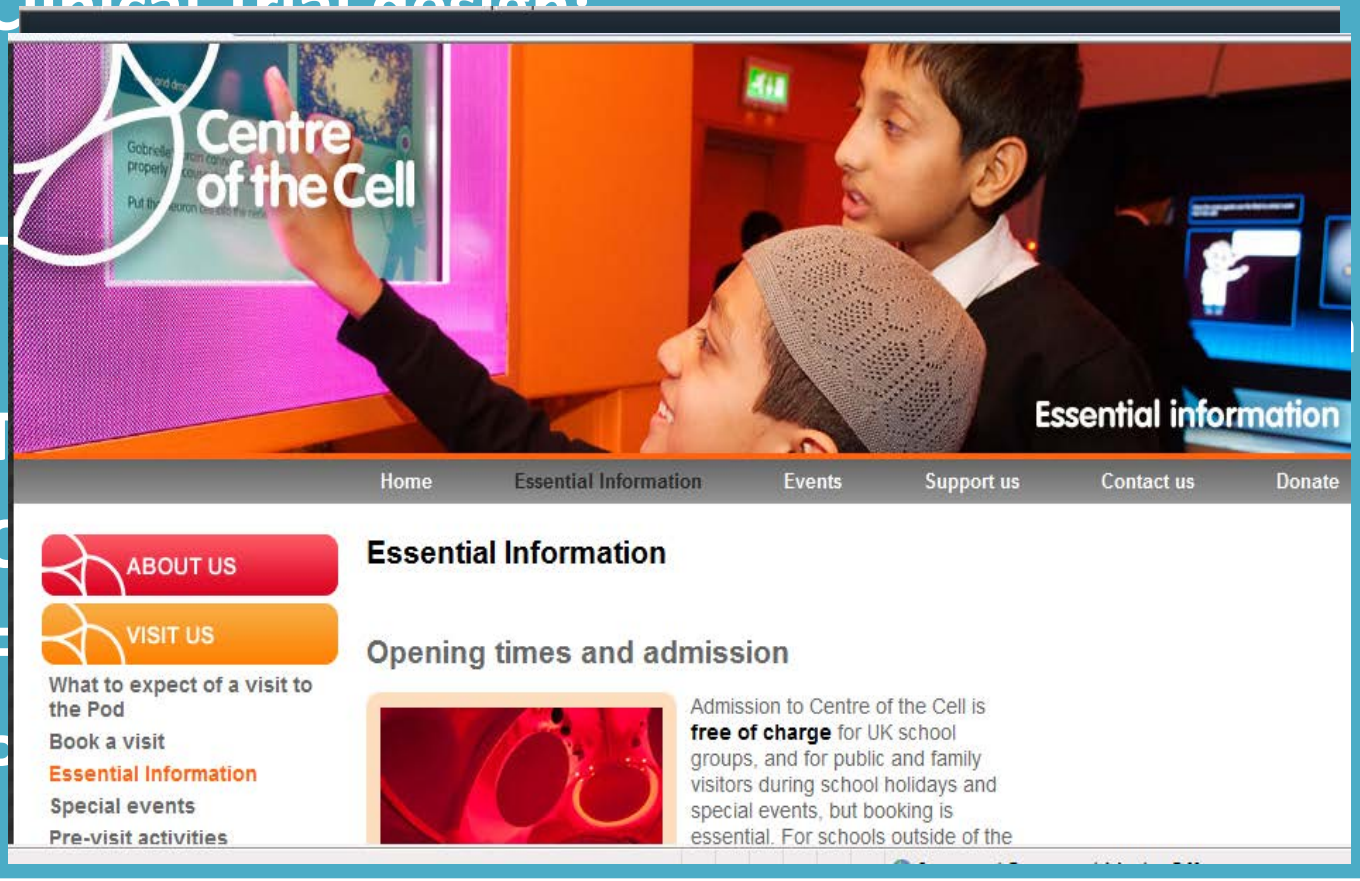
- Open information day
- Invited pupils via local schools and specialist nurses.
- 45 arrived and 44 applied for a position on group.
- 24 were selected to provide as broad a range of age and experience as possible.

Role of the groups

- Ambassadors for young people in research.
- Consultees e.g. NRES Guidance on information sheets.
- Comment on language, terminology, design and content of research documentation i.e. protocols, reporting forms, information sheets, methods, schedules and questionnaires.
- Comment on age appropriateness of information sheets, consent forms and assent forms.
- Comment on materials, apps, diaries, produced for children in clinical trials.
- Learn about research

Training

- Clinical Trial design:
- L
- T
- C
- F
- P



Running the group

- Balance between enjoyable and informal activities- providing valuable comments and opinions on research materials (dry)
- Payment of £20 voucher per meeting
- Provide lunch, snacks and drinks
- Ice breakers- beginning and end – adults too
- Name badges
- Flexible timing
- Break groups down for feedback – facilitators
- Open questions – researchers
- Report changes back to the group, reaffirms participation is meaningful

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Any Questions so far?

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Key achievements to date

- Contributed to the national consultation on the NRES – Guidance for information sheets for children 5-12 and 12-16
- Focus group for preparation of Guidance being produced by UK CRF on transition to adult clinics
- Seaton study – incentives
- Commented on information sheets and consent forms for several trials
- Redesigned and written information sheets for tissue banking information
- Presented at the British Science Festival Aberdeen 2012

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Working with Industry

medicines for children

Young people help researchers to "get real"

Clinical research is evolving. Increasingly, there is pressure on the research community to ensure that treatments are relevant and effective in daily life. This is driving more researchers to seek the input of service users in the development of their work, which is leading to a transformation of the cultural and regulatory environment for children's research.

▲The Young Persons' Advisory Group is growing in size and influence

The NIHR Medicines for Children Research Network (MCRN) has been at the forefront of patient and public involvement in research for some time. In 2006, the Network started its first Young Persons' Advisory Group in Liverpool. Since then, four more groups have been established in London, Nottingham, Birmingham and Bristol.

The initial remit of these groups was straight forward: to engage young people with research and to work in partnership with, and offer support to, researchers. Jenny Newman, NIHR Medicines for Children Research Network Consumer Liaison Manager, explains how this role has evolved:

"We set up the group to provide a forum for young people to learn about, and comment on, various aspects of the research cycle from the identification of research questions to the dissemination of research findings. We are now working with national governing bodies and helping to remodel the guidance they provide to researchers to help them design and deliver ethically robust research for children, as well as support researchers in the design and deliverability of their studies."

> "Young people... want to know what the study will mean to them."

Parents are able to consent for children to take part in clinical research if they are under 16 years of age. But researchers have to gain the assent of children too, which is why they receive guidance on how to produce materials to help young people understand a study.

The National Research Ethics Service (NRES) is responsible for producing this guidance. When they decided to review their materials, NRES approached the Medicine for Children Research Network about working with the Young Persons' Advisory Group:

"We conduct training for researchers in the area of ethics guidance and over the last five years the MCRN's Young Persons' Advisory Group has become an important part of our meetings", explains Dr Hugh Davies, consultant paediatrician and Research Ethics Advisor at NRES. "As a result, we wanted their input in our guidance review, which has led to a major statement of how we should approach children."

Group members felt that NRES guidance was producing study materials that failed to meet their needs. Holly Lamden is 18 years old, and a member of the Liverpool Young Persons' Advisory Group:

"A lot of the materials we see are highly formulaic. They are clearly designed to tick legal and governmental boxes, but they produce assent forms that are 15 pages long. An eight year old is not going to read this. Researchers need to make a distinction between child and adult studies. Paediatric studies need to stand alone."

Holly and her fellow Young Persons' Advisory Group members left NRES in no doubt that researchers had to work much harder to seek children's assent to clinical research. Dr Davies continues:

"We learnt that one of the guiding principles for producing information for young people is that they want to understand research and how it will impact on their lives. They want to know what the study will mean to them."

The result is that NRES will be incorporating the Young Persons' Advisory Group's feedback into a section of their guidance designed specifically to help researchers understand how to write and produce study materials for children.

This is a significant success for the Medicines for Children Research Network and a major step for the broader paediatric research community. The Network has worked hard to place young people at the heart of this community and the NRES collaboration shows this hard work is bearing fruit.

This shift in culture is further evidenced by the number of life-sciences organisations now approaching Medicines for Children for support from the Young Persons' Advisory Group. The Group has worked with 10 life-sciences organisations, but half-a-dozen of them have approached the Network in the last six months.

Mitsubishi Pharma Europe Ltd is one of the organisations that has benefitted from partnering with the Young Persons' Advisory Group. It spent over four months developing patient resources for its first paediatric study, but made significant progress when its representatives spoke to the Group. Anna Muroni is a Clinical Research Scientist at Mitsubishi Pharma Europe Ltd:

▲Actually finds young people have an important role to play in the development of children's research

"We benefitted from a range of advice from the Group. Based on their advice we developed a colourful and child-friendly flip-chart to accompany the assent form.

"They also advised us to reduce the length of the form itself... we made a number of alterations including simplifying the assent text and increasing its font size. This advice contributed to us gaining ethics approval at our second attempt."

Mitsubishi Pharma Europe Ltd is now reviewing its processes, with a view to producing paediatric patient information only after meeting with service users. But the Medicines for Children Research Network is keen to get young people involved in the conception of the research question itself.

Dr Enitan Carrol is a Reader in Child Health and Consultant in Paediatric Infectious Diseases at the University of Liverpool Institute of Child Health. She recently used a workshop with the Young Persons' Advisory Group to determine whether the research question she was proposing was valid. She feels that, in an increasingly competitive environment, this input can prove vital:

"It's powerful that the people experiencing a diagnostic device have helped to shape it. Their involvement makes a study more competitive because it provides us with perspectives that we can't find anywhere else. It makes the product more likely to succeed and helps us avoid the development of expensive products that children do not want to use."

Dr Davies agrees that involving children at the beginning of the research process is crucial:

"The research community is concentrating on studies that are relevant and shaping the right question is key to this. The opportunity for genuine influence is limited, which is why it needs to be embedded in the early stages of research development."

With the paediatric research community increasingly focusing on the real-world relevance of research, the influence and impact of the Young Persons' Advisory Group is set to grow. In September this year it is holding its first national event for the life-sciences industry in which a wider range of organisations will gain an insight into how young people and families can have a positive impact on the development of clinical research.

www.mcrn.org.uk

Watch a Young Persons' Advisory Group member's video diary by visiting: **www.crn.nihr.ac.uk/researchpeople**

> "Researchers need to make a distinction between child and adult studies. Paediatric studies need to stand alone."

Streamlining & simplifying the research approval process– HRA Consultation March 2013

Key topics the HRA wanted our views on included:

1. How young patients should be recruited and consented for clinical trials.
2. The extent to which we might feel protected by the newly proposed approval process or even at risk
3. The measures needed to ensure trust in the system and a feeling of safety.
4. And generally, to get our views on the proposed process and ask us how best to include young people and families in research

"I was very impressed by the group. They gave serious consideration to some complex issues and were clearly very well informed about research. It was a pleasure to work with them". Amanda Hunn HRA

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Designing information fit for purpose – working with NRES

What we do and don't want to know:

✓

- How long will it take?
- What is the aim?
- What is the drug?
- What will I have to do?
- Do we have to go ahead with it?
- Who will it benefit?
- Are there any side effects?

Leaflets or A5 booklets
Colour
Relevant pictures
Concise text
Break it down
No acronyms
Don't lie to us.
Don't patronise.

✗

- Ethics
- Invitation Paragraph
- Other medicines
- Who is funding the study
- What happens when the study ends
- What is research
- Why were we chosen

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Funding

Appropriate Staffing

Workload

Safeguarding

Keeping meetings interesting

Challenges are what make life interesting.

Overcoming them is what makes it meaningful.

Further Information

Involving Children and Young People in Health and Social Care Research

Edited by *Jennie Fleming* and *Thilo Boeck*

20% Discount!*

Led by both children's rights perspectives and methodological arguments, there is an increasing emphasis on children and young people's participation in health and social care research by researchers, policy makers and funding bodies – with many now considering the active involvement of children and young people a requirement. There is little exploration of how to address and overcome the many challenges arising from their participation, however.

Divided into five parts, this practical book begins by considering what research with young people is and why we should do it, before leading the reader into how to undertake it. The book then provides practical examples of action and finishes with reflections about the whole process. Bringing together a variety of experienced researchers, from a wide range of backgrounds in health and social care and including young people, the chapters provide insight for practical action, as well as critical and theoretical reflection. *Involving Children and Young People in Health and Social Care Research* includes issues on:

- Understanding the reasons and processes for involving children and young people in research
- Making sure that involvement is meaningful and not merely tokenistic
- Developing research methods that are commensurate with different ages and abilities
- Ensuring adequate training and preparation, for children, young people and adults to make involvement meaningful
- Power and relationships between young people researchers and adult researchers
- Sustaining young people's interest and motivation
- Addressing ethical issues that arise throughout the research journey.

Selected Table of Contents

Introduction **Part 1: What** 1. What Is Research With Young People? **Part 2: Why** 2. Sociological Theories Of Childhood: Reasons For Involving Children And Young People In Research 3. Why Participatory Research? Exploring Principles And Practice 4. Using National Standards For Children And Young People's Participation To Inform Health Research **Part 3: How** 5. Moving To The Inside – Employing Young People As Researchers 6. An Exploration Of How Ethics Inform The Design Of Social Research With Children Under Eleven Years Of Age 7. How To Make Involvement A Positive Experience – Ensuring Adequate Training, Preparation And Support 8. Transforming Relationships Between Adults And Young People Through Improvisation And Performance **Part 4: Action** 9. Young Women Researching Access To Sport 10. The Transition From Practitioner To Researcher: Physiotherapists Undertaking Research With Disabled Children And Young People 11. Offering Children Confidentiality In Research – What Are The Limits? 12. Getting The Message Across – Working With Young People To Change Perceptions Of Health Research 13. Young People's Participation In Service Evaluation 14. A Long Term Partnership – Adults And Young Researchers Working Together On The Evaluation Of The Children's Commissioner For Wales **Part 5: Reflection** 15. Medicines For Children: Reflection On How Young People Improve Research 16. Peer Research With Children And Young People Reflecting On The Impact Of Adopting A Rights-Based Rationale 17. What Is It Really Like To Be A Researcher? Dilemmas, Role Conflict And Reflections On Interviewing Children And Young People 18. Youth And Adult Researcher Reflections On Participatory Research In Australia And The United Kingdom 19. "I've Always Had A Passion For Being A Part Of Something Unique" Young People's Reflections On Being Researchers 20. Conclusion – Emerging Processes For Maximizing The Involvment Of Children And Young People In Reserach

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Newman et al (June 2012) Medicines for Children: reflecting on how young people improve research in this area. The Active Involvement of Children and Young People in Health and Social Care Research. (Routledge)

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WORKING IN PARTNERSHIP WITH YOUNG PEOPLE

We are here to help!

jennifer.preston@liv.ac.uk