mcrn
Medicines for Children Research Network

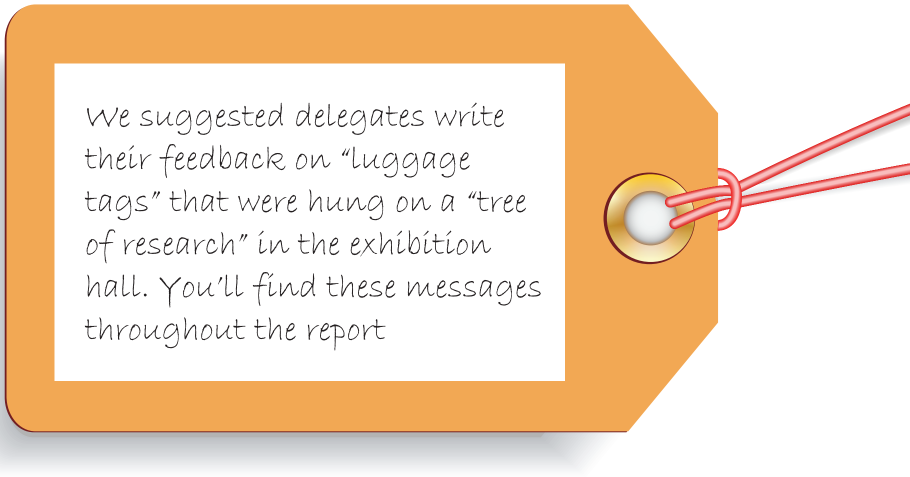
NHS
National Institute for
Health Research

GenerationR

young people improving research

2013 Meeting Report

Contents



We suggested delegates write their feedback on "luggage tags" that were hung on a "tree of research" in the exhibition hall. You'll find these messages throughout the report

Executive summary

Over the last eight years, over 100 children and young people have contributed to the activities of the NIHR Medicines for Children Research Network (MCRN) Young Persons Advisory Groups (YPAG). In addition a network of parents and families have contributed to local and national MCRN activities, including; advised researchers and pharmaceutical/biotech companies sponsoring research, commented on patient information, provided guidance to National Research Ethics Service, engaged in formulations research and lobbied for a greater involvement in the research process. Yet in 2013, many researchers, charities and companies had little knowledge of their award-winning achievements and, for many, involving children and parents was a token exercise.

So we set about to change their understanding of the value of involving our young people and parents in children's research. We empowered and funded our young person's groups and parents to develop and run a national meeting. Their title: GenerationR (for research) emphasised their commitment to learn more about research and the importance of correcting some of the public misperceptions about this sensitive topic. Their strapline: 'Young people improving research' spoke to their belief that meaningful involvement of children in the design of research would improve its quality, delivery and impact.

We were delighted that the meeting was over-subscribed, supported by some of the most senior figures in medical research in the UK and by major research charities and companies. As ever, the Young Person's Advisory Groups (YPAG) and parents delivered: stunning delegates with professional films, presentations and interviews. But what we really remember is the clarity of their message: that they can help us to do research better, that they are the GenerationR whom research might benefit but also that it might benefit others. As the opening film was entitled: Ordinary children doing extraordinary things…

Dr. William van't Hoff
MCRN Joint Interim Director

Introduction

On the 11th September 2013, the National Institute for Health Research (NIHR) Medicines for Children Research Network (MCRN) held a fantastic event promoting the involvement of young people and families in research. It was an amazing day and we were overwhelmed by the positive feedback we have received. In this report we share with you the highlights of the event, which included interviews with leading researchers and pharmaceutical companies and many influential figures in the medical world.

A key moment for us was the opportunity to interview the Chief Medical Officer, Professor Dame Sally Davies, who fully supported our message. We asked Dame Sally why she thought research involving children is important:

"Of course it is! We all know that! But let's just unpack why. I caught the point about equity and fairness and of course it's that, but there's also a very important reason that not all medicines work the same in children as they do in adults. You can't just assume it's a smaller package of an adult and do it by weight. We do need to investigate whether treatments work as well. And then there are significant issues about growth, and how treatments may impact on that and development. And then the psychosocial issues are quite different. How do we give you the autonomy and power to make your own decisions and join in, and that is quite a different way of going about it. So not important, essential!"

We thoroughly enjoyed organising and participating in the event. We hope that everyone who attended felt our incredible passion for the subject and that this report does the day justice.

Enjoy reading! Look out for our first edition of the GenerationR magazine...coming soon!

Shani, Georgia, Luca and Mihari
Members of the Young Persons Advisory Group (YPAG)

Click here to watch interviews with the public, on the subject of clinical research, conducted by YPAG members

Planning and objectives

Planning for the GenerationR meeting started in October 2012. The meeting was planned to 'Showcase how children, young people and families have improved the design, development and delivery of paediatric research' 'Improve the success of studies in partnership with children, young people and parents.'

A planning group made up of representatives from each regional young person's group alongside five parent representatives and a core team of MCRN staff was created. The group was responsible for ensuring young people's and parents' perspectives were core: setting the agenda, inviting the speakers and their topics, planning the activities, sessions, format and meals/refreshments, contributing to the publicity and communications.

Objectives

Three core objectives were prioritised for the event:

- Demonstrate how children, young people and parents support/improve the design and feasibility of studies
- Choosing the right patient-reported outcome measures
- Showing how bringing patients and researchers together can improve research

View the programme for the event here: http://bit.ly/genr-programme

Quotes from charities

"We will start to ask our grant applicants if they have consulted children in the design of their study."

"Use the group to suggest areas for future research and involve them from initiation stages of all CYP projects"

About the meeting

We chose to host the meeting in the London Science Museum and adopt a low-key, relaxed, informal, fun approach to the day. MCRN staff and young people wore red T Shirts to highlight the NIHR 'Red for research' campaign, and all delegates were personally greeted by young people. Delegates were invited to wear casual clothing to fit in with the informal and fun vibe to the day, an important request from the young people, who were mingling with and interviewing some very high profile guests.

The meeting was designed to be a fun, action-packed, one day event with inspiring and thought- provoking topics relating to 'Showcase how children, young people and families have improved the design, development and delivery of paediatric research.' Members of the YPAG wanted to steer away from the conventional style of presenting, and were very clear they wanted something stimulating and influential. The meeting started with a short powerful film, featuring two young people who explained why they are participating in research studies, and why it is beneficial. You can view the film using a link in the Resources section on page 6.

The meeting was jointly chaired by Ms Sheena Burlton, a member of the MCRN YPAG and Dr William van't Hoff, Joint Interim Director of the NIHR Medicines for Children Research Network. The format of the day was divided into two parts; TV studio style in the morning session, and round table discussion and feedback in the afternoon. The programme topics were designed to initiate discussion and feedback to help inform the MCRN and others about young people and families improving research. Topics for discussion included:

- Setting the national scene
- Reducing waste in clinical research
- Red for research
- Research case studies – pharmaceutical, academic and a parents view
- The importance of medical research for children
- Is public involvement the new black?

A focus on networking was important to the young people, who designed and participated in some interesting and fun refreshment/lunch break activities to encourage interaction. This included hand painting, and a fun 'mocktails' session! The West Midlands YPAG had produced fabulous art work around the topic of Randomised Controlled Trials (RCTs), which generated a lot of interest.

Delegates

The meeting was attended by over 160 stakeholders, representing various organisations and key partners, from pharmaceutical companies to charities.

There was keen interest from the pharmaceutical industry – 16% of delegates were from the Pharmaceutical Industry, which enabled further networking to develop stronger links, including generous sponsorship, which we were extremely grateful to receive. Other delegates attending were from charities, the NHS, regulators and other professional bodies interested in children's research.

The meeting opened with a short, but inspirational film featuring young people involved in clinical research. Click here to watch

Speaker interviews

A synopsis of each speaker's interview is below, which highlights "key points" in places.

1. Sir Iain Chalmers - Coordinator, James Lind Initiative

Sir Iain's discussion focussed on waste in clinical research, and the national picture, initially touching on immunisation for measles, which through bad research, has recently caused a measles epidemic.

Preventing bad research

Sir Iain commented that bad research can be prevented if funders only fund research that is addressing important questions, and journal editors seek peer review to ensure they don't publish bad research.

Reducing uncertainty and waste

Sir Iain talked about his latest book 'Testing Treatments' and the need to reduce uncertainty about the effects of treatments by professionals doing more research. This led on to the issue of waste in research, which Sir Iain felt could be reduced by asking whether the research question has already been answered, and encouraging researchers of good studies to publish their results.

Involvement in research

Sir Iain went on to talk about the importance of children being involved in research, and the link between the book 'Bad Science', and the 'Testing Treatments Interactive' website, which has links to videos, games and other resources. Iain invited members of the YPAG to help make sure that they produce material that is relevant to children and young people.

Improving the design of research

Sir Iain's message for young people's groups trying to improve the design of research is to ensure that the question that is being asked is a sensible one, and to do systematic reviews to look at what's been done already.

Asking the right questions

Sir Iain advised the YPAG members not to imagine there is any question which may seem too stupid to be asked when having a role in asking the right questions.

Key points:

- When referring to the 'Bad Science' book and 'Testing Treatments Interactive' (www.testingtreatments.org) Sir Iain invited members of the YPAG to help ensure they produce material that is relevant to children and young people

Click here to watch Sir Iain's interview

Quote from MHRA

"Would be interested in involving the YPAG in a project we are working on our yellow card scheme about improving reporting on side effects from paediatric medicines."

2. Keeley Brook - Project Manager, GW Pharmaceuticals

Keeley spoke about her first paediatric study, and how the YPAG helped to develop an informed consent form.

Approaching the group

The study investigates a therapy to help spasticity due to cerebral palsy in 8-18 year olds, and at a later time, 0-8 year olds. Keeley was recommended by sites to approach the MCRN for advice, and came to the first YPAG meeting not knowing what to expect. From coming empty handed to the meeting, Keeley was pleased to leave with six or seven different versions of informed assent/consent forms and other ideas, including the use of different technologies such as apps which was surprising.

Discussing a difficult topic

Keeley was unsure how to discuss the delicate topic of Cannabis, which was a component of the drug in the study, and was referred to as 'plant based' in the assent form. The level of understanding of the group was much higher than she expected, which encouraged her to be open and frank, and the response was much more grown-up than some adult responses she had previously received.

Outcomes from involvement of YPAG

There were some really good outcomes from the meeting, including a good structure for an informed assent/consent form, a review of the diaries, and some good ideas about keeping children motivated throughout the trial with stars and certificates. The ethics committee highlighted that the assent/consent forms were very good, and the study rapidly received ethics approval.

3. Dr Calum Semple - Senior Lecturer in Child Health, University of Liverpool and Consultant in Paediatric Respiratory Medicine, Alder Hey Children's Hospital

Calum talked about a study looking at the biology of two viral illnesses and how they affect people, lifestyles and their genes.

Presenting a protocol to YPAG

Calum attended a YPAG meeting where members were presented with the protocol and asked for their feedback. Although the study was not going to directly benefit the children or adults and involved blood samples and secretions, all 17 members of the group thought it was a worthwhile study. The process around consent was also discussed and the protocol was changed to reflect the YPAGs request of the right to refuse assent at a later stage, due to the critical condition of the patients.

Redesigning Patient Information

The feedback from the group was unexpected but very helpful and resulted in the following outcomes; the patient information leaflet was redesigned and broken into two age groups – a cartoon was developed for age 12 and under. The terminology within both the parents and children patient information leaflets was also simplified, and words such as pooh instead of stools, and wee instead of urine used, which is a language children understand.

Positive outcomes

The study plan necessitated gaining Ethics review within a tight timetable. Within 3 weeks, discussions with YPAG were held and the Oxford Research Ethics Committee accepted the patient information leaflets without any difficulties.

Click here to watch Keeley and Calum's interview

Quotes from industry

"I will encourage my department to involve the YPAG earlier and more often when writing protocols and documents"

"I will use YPAG to help with study design and feasibility"

Dr Silvia Guillino, Parent and Researcher

Silvia's story:

In Silvia's pregnancy scans and health checks revealed that something was wrong and subsequently Silvia's daughter was born prematurely at 28 weeks. Silvia's daughter received care from the Neonatal unit at St Thomas' Hospital for 4 months. The baby came home and received extra oxygen for 8 months. It was very difficult and challenging, but family life resumed, although there were huge difficulties managing the portable oxygen cylinder with the baby. Her baby is now a healthy 3.5 year old girl and doing extremely well. Her experience led her to an interest in research in this field.

Premature babies and the influence of the urban environment

Silvia talked about the grant she has recently been awarded to investigate the experience of mothers with Premature babies and the influence of the urban environment. As a Social Scientist and an academic, Silvia is interested in urban space and design, which gave her an awareness of how selective she was about the routes and transport she took, when travelling with a vulnerable baby with a portable oxygen cylinder. This inspired Silvia to investigate the experience of first time mothers with premature babies of the urban environment in inner London – the catchment area of St Thomas'. "My idea is to explore how they negotiate the environment, so they are very much part of the process at different stages. At the moment they are asked to hold an electronic diary to keep track of where they are going."

The importance of collaborating with parents and their children in research

Sylvia feels medical research is absolutely fundamental and has consented for her daughter to participate in many studies whilst she was in hospital. It is important that parents and children are part of the research process and kept informed about what is going on and that data about the study is shared. "Involvement in medical research is good not only for the research, but for the children as it is extremely empowering."

Approach for Investigators working with parents on premature baby research

In Silvia's case, the involvement of patients is not clinical; it's about sharing their own experiences. "I hope there will be a good response for this project and they will see the benefit. It's good not to feel isolated and have the opportunity of sharing their emotions and experience. It's good not to feel lonely."

Click here to watch Silvia's interview

Dr Jonathan Sheffield - Chief Executive Officer, National Institute for Health Research Clinical Research Network (NIHR CRN)

Jonathan first talked about what led him to a career in research, which led to his views on how young people can influence research, and why clinical research involving children is important.

Importance of research involving children

Jonathan talked about making sure we've got a healthy population of children, getting the right care for them and making sure their lives are much more enriched later on. The more we do with making sure that children are fit and healthy and well throughout their childhood and through their growth spurts, the far more likely it is that we're going to see a healthy population later on in life.

Young people's role in raising awareness

Jonathan stressed the importance of the GenerationR event and of young people's involvement in it. Jonathan commented that children have a particular important role to play in persuading peer groups, friends at school, family members, and getting them to think about how important research is, which will make a huge difference to their attitude in life.

Southampton Clinical Research Facility:

"Better design of research to improve research, recruitment and outcomes, which will improve the health of our children. I want to develop a YPAG group in Southampton."

Influencing education

Jonathan emphasised that the responsibility should be for the people who are involved in research to go out and meet with the schools, adding that we should have an active role in schools and science awareness days, opening ourselves up so that young people can see the fascinating work and research that goes on in hospitals.

Preventing poor research

Jonathan agreed with Sir Iain Chalmers' points about the publication of all the results, and making sure the data is open and having a responsibility to publish that data. He also stressed the importance of having patient and public involvement in research. Jonathan's view was that the more openness and transparency we can have with our research, the far more likely we are to get really high quality research, and that critical appraisal can also come from the public - in children's research, it should come from children.

Improving study information

Jonathan is a big fan of plain English to help make information clear, and also encouraging the active use of PPI groups which he noted as being a transformational thing in the last ten years. "The pressure must also be on the research sponsors; pharmaceutical companies and the charities, they must be clear in their constitution that the way they conduct research is by making it plain, open and transparent to the people that are being involved in research on their behalf."

Mystery shopper campaign

Jonathan explained that a mystery shopper campaign was developed by the NIHR CRN communications team thinking about how NIHR CRN could raise the profile of research in the NHS. "The message via the campaign was that you should be proud that your institution and patients and public are involved in research, and you must keep them informed. It was amazing what response we had and it also engaged some very senior NHS leaders which was really good for us."

Message to Industry and charities

Jonathan talked about the changes to children's research in the coming months, combining the Medicines for Children Research Network with the Paediatric (non-medicines) Specialty group, to unify all children's research. "One of the great strengths of things we have done with the networks is that we've made the availability of, particularly for the pharmaceutical companies, Paediatric Investigation Plans (PIPs) to be tried out and used. It's a huge opportunity with the strides that are being made with genetics disease and increasingly we will be able to tailor our medicines in the future, to individual diseases and individual sub types of the disease, and in actual fact, children are a very important group in that population because if you get it right when children have a genetic abnormality in early childhood, then they will have a long successful life in adulthood. So I would say you must pay attention to children's research and that includes a whole range of diseases"

Key point

YPAG has a role in schools and science awareness days, so that young people can see the fascinating work and research that goes on in hospitals.

Professor Dame Sally Davies - Chief Medical Officer for England

Dame Sally discussed 'the importance of medical research for children'. This was a highlight for the event, and included some powerful questions from the young people, including what young people can do to raise awareness, where young person's groups will be in five years, and how we encourage Industry to undertake more studies involving children.

Importance of children's research

Dame Sally was asked if research involving children is important, and agreed that it is not important, but essential! She emphasised that not all medicines work the same in children as they do adults. "There are also significant issues about how treatments impact on growth and development. And then the psychosocial issues are quite different; How do we give you the autonomy and power to make your own decisions and join in, and that is quite a different way of going about it."

Quote from a nurse:

"I will try to link into the MCRN on behalf of the Trust and our paediatric teams (Cambridgeshire Community Services NHS Trust)

Raising awareness

Dame Sally explained that we need to get doctors and nurses to understand that patients are our partners in research, and take it to an ideal stage where children demand their right to join in research. When talking about how young people can raise awareness, Dame Sally suggested social media; "You could Tweet, you can have Facebook pages, you can talk to your friends and actually if you do that and you strike a chord at the right moment in the right way, we could see it go viral. What about some YouTube videos as well about why you did it, or its fun, or it's importantance. I think you could use social media to spread the work much more effectively than we can through our routes."

Influencing education for the next generation

Dame Sally would like to see more modern and savvy discussions about living and life in schools, which research could come into, as well as biology and chemistry. "Have you got a biology club, can you use it to have a session on research?"

Preventing poor research

Dame Sally talked about the definitions of good research and that peer review and ethics committee processes can help to ensure research is good. "We involve from the NIHR, patients and public, healthy and ill, I hope at every stage of that process, because it is the patients and public right to feel part of it."

(l-r) Professor Dame Sally Davies and Dr Jonathan Sheffield answer questions from Dr William van't Hoff and YPAG members

Click here to watch Dame Sally and Jonathan's interview

YPAG input on Dame Sally's Penguin E-book

Dame Sally introduced her new book 'The Drugs Don't Work' which however wasn't primarily intended for a children's audience. Sally explained that she will be publishing a book about early years and adolescence, which will be more relevant, and welcomed YPAG input into that

Message on research in children to Industry and Charities

"Yes. It is that its right to do, it's important to do, but we will only get it right if we make it work with children and for children. We have to do it as a partnership."

Plain English for researchers

Dame Sally agreed this was a very difficult challenge, and that plain English should start in schools. "We are trying to put in order the NIHR house, to make sure that the summaries are in good plain English, but how do we educate researchers to do it? It starts in school."

Access to studies

Dame Sally initially suggested the group could develop a toolkit for researchers, and that social media could also have a role to play, as long this was done in an appropriate, ethical manner. Dame Sally also explained there could also be two other ways in; "One is through the healthcare professionals looking after the children, and that's our standard way, but the other is through children's groups, and we all know the medical charities play a role in that, and the support group can play a role."

Industry undertaking children's studies

Dame Sally noted that there had been changes since the European Regulation on children's medicines was implemented. "We need to push Industry to use that patent extension for completing studies in children to do the right thing, and we need to step in and fund some of the work that should have been done historically but wasn't."

Support from Industry and Charities for young people's activities

Dame Sally commented that this issue was complicated, and that it is a balance between appropriate social behaviour, and undue influence on people. She suggested one option for pharmaceutical companies to all continue to a fund that supported children's groups; "So let me ask the pharmaceutical industry whether you would be prepared to contribute, all of you, to a central pot that could then support this activity. Not just to the early and on-going engagement around industry studies, but for charity studies and public sector studies, because it would be helping to deliver a better quality product that would be more relevant..."

Young person's group in 5 years time

Dame Sally suggested two main roles for the group; "One part, being a supportive one to make sure that research is high quality, that young people know about it and join in, and the other part a role in advocacy, demanding your rights, more research in specific areas and more involvement."

Key points

- YPAG input into a book Dame Sally is writing about early years and adolescence.
- Develop a toolkit for researchers to improve access to the views of children and young people.
- Discuss concepts and models of accessing the expertise and support of young people in pharmaceutical research to improve research.

Simon Denegri - National Director for Public Participation and Engagement in Research, NIHR

Simon Denegri, NIHR's National Director for Public Participation and Engagement in Research, was also interviewed about public involvement being the new 'black'?

Journey through public involvement

Simon explained how he first became involved in public involvement through the Alzheimers Society, which was inspired through a family experience and his work in various high profile campaigns. "I was very struck by the very strong bond that families and researchers had formed in raising awareness of dementia to make it a research priority."

Click here to watch Simon's interview

Simon Denegri explored the notion of public involvement as "the new black"

Public involvement is the new black

Simon commented how NIHR has led the world about how we think about public involvement in research, and gave an example of the momentum building for INVOLVE and the increasing website hits it has received in a 9 month period. “I really get a sense that people are becoming interested in this, they want to do it, they want to do it better, and there are major opportunities for driving very political things like health and wealth, but more importantly by driving better care and treatment for people by involving patients and the public.”

YPAG work in the future of NIHR networks

Simon talks about the complexity of the networks from 5-6 years ago, and how well they have been led through that. Simon adds that the network changes are about simplification and matching research onto what’s happened in the local health services. He explains that the changes create lots of opportunities. “We’ve always been a movement that’s refreshed the way we think, that’s been open-minded. I think the network change is another opportunity to do that and just go up to a whole different level, and I think young people will be at the forefront of that, and you’re going to teach us and help us do new things that we haven’t even thought of yet.”

Working on a national scale

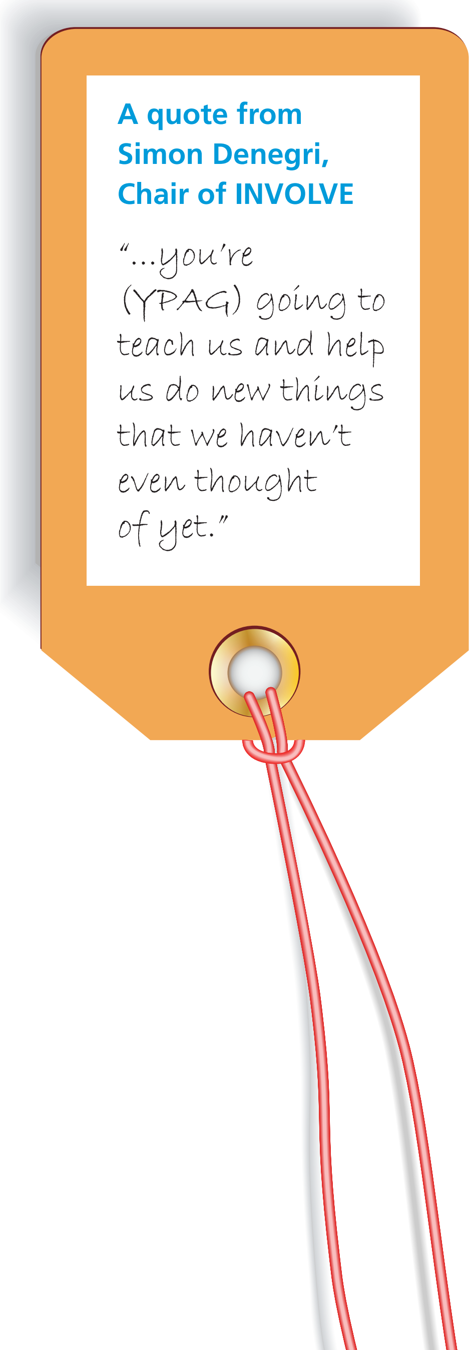
Simon felt public involvement on a national scale would work though acknowledged the challenges. This would include portfolio development; “Sally has already asked me to look at that from a PPI point of view and I think it’s going to be a case of asking colleagues here and young people, how can we do that nationally across the NIHR. And I think the other thing is, I think it relies and depends on people being leaders, and I include young people in this absolutely, leading, sharing, making connections, crossing boundaries.” Simon went on to invite YPAG to take part in his work, and give their ideas on how PPI might work on a national scale.

Young people supporting clinical research

Simon commented that there needs to be better use of social media for this work, and NIHR have ideas about using social media for ‘clinical trial in a day’ as a topic for next year’s Clinical Trials Day. “Help us support clinical research using social media.”

Key points:

- Work with Simon to look at how YPAG can work nationally to improve and raise awareness of research across the whole of the NIHR
- Work with Simon to raise awareness of research and support initiatives such as “Ok to Ask” and “We do clinical research” using social media



A quote from Simon Denegri, Chair of INVOLVE

“...you’re (YPAG) going to teach us and help us do new things that we haven’t even thought of yet.”

Round table discussions

The afternoon session of the meeting was focussed on challenges in consumer involvement in a round-table discussion format. Three significant topics were put forward to delegates for them to discuss and provide their feedback.

Key feedback and recommendations

This section lays out key recommendations based on the feedback from round table discussions. Three significant topics were put forward to delegates for them to discuss and provide their feedback: the ethical challenges of paediatric research; disseminating research results; the future of research and educating the next generation.

a) Ethical challenges of paediatric research

Delegates were asked to rank in importance (1 being the most important and 6 being the least important) six major ethical challenges (Undertaking research in emergency settings, carrying out pregnancy tests for research purposes, offering payments for participation, lack of parental awareness of research, gaining fully informed consent or assent and balancing the risks of research versus benefits) associated with research involving children that are commonly highlighted [On reflection we realised that the wording should have been clearer as importance or difficulty are two separate issues so an explanation was given that what we really wanted to know is; what are the most challenging aspects of undertaking paediatric research?] We were able to distinguish responses from delegates separately to those from parents/ children and professionals.

Although feedback indicated that all issues are challenging, the highest ranking challenge for parents was undertaking paediatric research in emergency settings. Whilst for researchers, the biggest challenge was offering payments for participation. Both parents and researchers felt balancing the risks versus benefits to be the second highest challenge, followed by obtaining consent and assent.

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).

Click here to watch interviews with attendees

b) Disseminating research results

The issue of transparency and dissemination of research results has been a long-standing concern for both researchers and patients taking part in research. This lack of transparency, say campaigners, undermines public trust, breaks the ethical pact between scientists and those participating in research and leads to clinical decisions being made on the basis of incomplete evidence, potentially leading to poorer outcomes for patients.

Patients and families stress to us how important it is to find out the outcomes of research they have participated in. We posed the question of what responsibilities do researchers have towards child participants and parents when the study is over in relation to open access to results and on-going access to treatment.

In response to open access to results several strong themes emerged; duty, expectation and good practice, interim updates and personal feedback.

Delegates felt really passionate about the duty of researchers to share data and results with patients, several felt it was a:

"Moral ethical responsibility irrespective of whether results are positive or negative".

Others mentioned that "there should be an obligation from company/investigators to feedback to participants, not necessarily in paper format but with a formal letter, lay summary and personal acknowledgement".

One suggestion that delegates put forward was the idea of researchers producing summary feedback in the form of patient-specific results sheets. Several highlighted the importance of having access to interim updates as this affects participation in a study and that patients and families should receive personal feedback as one statement indicates

"Parents and children should have access to their results just as they are entitled to in their clinical care, as long as confidentiality is maintained. They are partners in research trials and hence are entitled to see the results of the trial".

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

A quote from the Dutch clinical research community

"The example of involvement in research of young people in the UK is really an inspiration for researchers in other countries."

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.

c) On-going access to treatment

It was clear in the discussions surrounding on-going access to treatment that delegates (including parents/children) felt that there was an ethical or moral standpoint in allowing access to treatment once a study had finished (assuming it was beneficial)

Several people felt that "if a treatment is beneficial it is unethical to then stop treatment when the trial stops" and some felt that "pharmaceutical companies may be viewed in better light, especially if the drug is not covered by NICE Insurance (sic)".

The decision to participate in the first place can be influenced by the availability of the medicines after trial completion. Delegates also commented that funding may be an issue but that drug companies should be obliged to provide these drugs at a reduced cost to participants if found to be successful.

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.

d) The future of research and educating the next generation

One of the many benefits of collaborating with patients and families in research design and delivery is that the research is more likely to meet the needs of patients who participate in trials. However, it was important to explore what the research community can do to build on these collaborations and how we can educate the next generation about paediatric research.

The first discussion point raised issues that can be divided into five themes; developing/involving more young people, proactive approach to industry/ funders, involving young people and families in priority setting and in the design of research, sharing best practice and having appropriate funding to support involvement activities.

It was clear that delegates felt that patient involvement and engagement should be the norm not the exception as several delegates suggested: "In five years all studies designed in children should be reviewed by young people and this should be made compulsory".

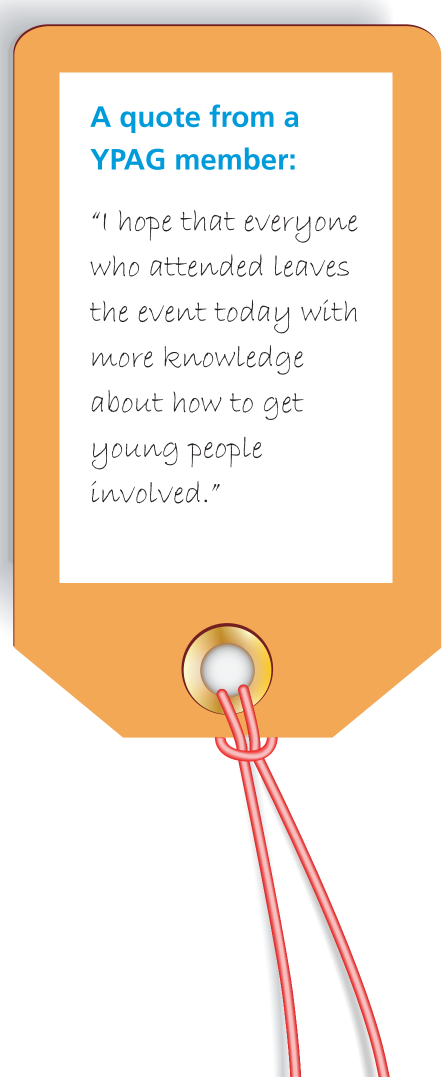
More needs to be done to build on the MCRN model of involving young people and to encourage involvement of young people from disadvantaged backgrounds and disabled groups of young people. This could be achieved by exploring alternative and innovative ways to involve them, for example using social media, virtual forums and working closely with charitable organisations and patient groups.

Delegates felt that more work needs to be done with industry to promote user involvement and one delegate suggested: "Go directly to industry, don't wait for them to come to you… maybe training industry colleagues about user involvement is the way forward".

It was very clear that involvement should be integral to the research process and that more research originating from young people and families is essential. Early involvement in protocol development and paediatric investigation plans (PIPs) was also encouraged. This clearly fits with recommendation 23 in the Annual Report (2012) of the Chief Medical Officer:

"The National Institute for Health Research (NIHR) Clinical Research Network, including the NIHR Medicines for Children Network, should work with children and young people to input to the design of clinical studies in order to facilitate increased participation of children and young people in drug and other trials".

One of the clear benefits of holding an event such as GenerationR was to showcase the excellent work undertaken by young people and families. For some delegates this was their first opportunity of hearing about the groups. Delegates felt that more needs to be done to promote the work of young people and families and that there needs to be a systematic way to measure the impact of such involvement.



A quote from a YPAG member:

"I hope that everyone who attended leaves the event today with more knowledge about how to get young people involved."

Although there was a clear consensus that further work is required to ensure effective involvement at every level there was a realisation that this requires further investment in both resources to run groups and staff responsible for involvement activities. A possible solution was put forward that investment could possibly come from pharmaceutical companies.

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.

e) Educating the next generation

Feedback from this discussion was split into two categories: better awareness of research opportunities in general and age appropriate information about research, and encouraging education in schools.

Delegates felt that more needs to be done to raise awareness about research to young people and families, providing appropriate information that people will understand in order for them to make an informed decision to participate in research if approached to take part.

GenerationR featured a set of sculptures developed by YPAG that explored the historical development of clinical research

Several delegates felt that finding information about clinical trials is often impossible despite Government initiatives such as Clinical Trials Gateway.

Several also felt that there has been a general reluctance within the NHS to promote research opportunities, which has led to patients and families often being excluded from participating in trials.

Many young people and parents lamented the lack of education about clinical research in schools for instance in the Personal Social and Health Education (PSHE) and Citizenship topics.

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.

Nuffield Council on Bioethics:

"I hope to approach the group to help us with our current investigation into the ethical issues arising out of research with children/young people."

Moving forward

The purpose of GenerationR was to showcase how children, young people and families have improved the design, development and delivery of paediatric research. This was a unique opportunity for various stakeholders to learn more about how engaging and involving young people and parents impacts upon the quality and safety of paediatric clinical trials.

National speakers and delegates reinforced some important recommendations for patient and public involvement in improving the design, development and delivery of paediatric research. We value all the feedback and ideas taken from the event, and feel a tremendous amount of enthusiasm and support for working in collaboration with key partners and stakeholders in the future.

Research Design Service

"I will seek to involve YPGs in every research study – I will encourage my colleagues to do the same."

Acknowledgements

We are grateful to have received such generous sponsorship from the following organisations:

- University of Liverpool
- Premier Research
- Garfield Weston Foundation
- King's College London; Centre for the Developing Brain
- Proveca

We are extremely grateful to parents and young people who became members of the stakeholder planning committee and gave so much time and support for the event. Members of the MCRN National Young Persons Advisory Group (YPAG) provided such an invaluable contribution, as did all members of the national YPAG, who contributed to other GenerationR projects. These included the various visual resources and artwork developed for the event [Resources can be viewed in section 11 of this report.] Without their vision and inspiration, the event would not have been as successful and meaningful as it was.

Thanks also to all MCRN colleagues and staff who contributed to the GenerationR event, including the following;

- Helen Paton, Youth Participation Officer, MCRN Coordinating Centre (CC)
- Jenny Preston, Consumer Liaison Manager, MCRN CC
- Dr William van't Hoff, MCRN Joint Interim Director
- Patient and Public Involvement (PPI) Leads in MCRN Local Research Networks (LRNs), MCRN Coordinating Centre staff: Claire Callens, Carly Tibbins, Anoushka Dureu, Kirsty Widdowson, Ruth Nightingale, Tracey Bingham
- NIHR Patient and Public Involvement (PPI) Leads: Derek Stewart, Roger Steel, Terry McGrath, Martin Lodemore.

A personal thank you is expressed to the speakers who kindly offered their time from busy schedules to play a part in the day. We would like to thank the following speakers in order of their appearance:

- Sir Iain Chalmers, Coordinator, James Lind Initiative
- MCRN YPAG members; Sheena Burlton, Thomas Hodgson, Shani De Soysa, Mihari De Soysa, Aatif Syed, Sophie Hamilton Foad, Ella Hamilton Foad, Courtney Hamilton Foad, Luca Wetherall, Georgia Semple
- Keeley Brook, Project Manager, GW Pharmaceuticals
- Dr Calum Semple, Senior Lecturer in Child Health, University of Liverpool and Consultant in Paediatric Respiratory Medicine, Alder Hey Children's Hospital
- Dr Silvia Guillino, Parent and Researcher
- Dr Jonathan Sheffield, Chief Executive Officer, National Institute for Health Research Clinical Research Network (NIHR CRN)
- Professor Dame Sally Davies, Chief Medical Officer for England
- Simon Denegri, National Director for Public Participation and Engagement in Research, NIHR

Finally, our grateful thanks are extended to the many delegates who attended this event. It was encouraging to see such enthusiasm and receive your valuable input, especially during the roundtable discussions.

Resources

We would like to share the following educational and inspiring resources from the GenerationR event with you:

Opening film

This short but inspirational film was played at the start of the event. Based around two patients who have been involved in our research. The film illustrates the importance of clinical research in children and young people.

Visit: http://bit.ly/genr-opening-film

Speaker interview clips

Guest speaker interviews were filmed. All five parts can be viewed by clicking on the titles below:

Part 1 – Reducing Waste in Clinical Research, Sir Iain Chalmers. Visit: http://bit.ly/genr-clips-part1

Part 2 – Setting the National Scene, YPAG members/members of the public. Visit http://bit.ly/genr-clips-part2

Part 3 – Case Studies, a) Mrs Keeley Brooke, b) Dr Calum Semple. Visit: http://bit.ly/genr-clips-part3

Part 4 – The Importance of Medical Research, Professor Dame Sally Davies and Dr Jonathan Sheffield. Visit: http://bit.ly/genr-clips-part4

Part 5 – Is Public Involvement the New Black, Simon Denegri. Visit: http://bit.ly/genr-clips-part5

Vox pops - delegates views

Young people at the GenerationR event were provided with video cameras to film short interviews with delegates at the event about their views on the event and children's research.

Visit: http://bit.ly/Genr-eventvoxpops

Vox pops - public views

A short collection of video clips were filmed for the event, to capture the general public views on what they thought about children's research, both positive and negative.

Visit: http://bit.ly/genr-publicvoxpops

Social media

Delegates were invited to use social media to make comments about the event. Comments were received on Twitter via the #GenerationR twitter feed. View the twitter feed comments here: http://bit.ly/genr-tweets

Luggage tags

Delegates were encouraged to write about how GenerationR has inspired them, on luggage tags which were pinned up at the event. View all the comments here: http://bit.ly/genr-tags

Blogs

Kate Harvey, Research Officer from the Nuffield Council on Bioethics, wrote a blog about the meeting, which captures the essence and atmosphere of the day. Read Kate's blog here:

http://bit.ly/genr-kate-blog

Simon Denegri, National Director for Public Participation and Engagement in Research, NIHR, wrote a blog about the event, which was very complimentary, and illustrated the impact the event had on him and others. Read Simons blog here http://bit.ly/genr-simon-blog

Glossary

Abbreviation	Meaning
NIHR	National Institute for Health Research
CRN	Clinical Research Network
MCRN	Medicines for Children Research Network
YPAG	Young Persons Advisory Group
LRN	Local Research Network
CC	Coordinating Centre
PPI	Patient and Public Involvement
TCRN	Topic Specific Network
RCPCH	Royal College of Paediatrics and Child Health
E-Magazine	Electronic Magazine
PSHE	Personal Social and Health Education

For more information about children's research, or how to access the Young Persons' Advisory Group, visit:

www.mcrn.org.uk
or email:
info@mcrn.org.uk

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