

Research
Centre



Evaluation of Consumer Involvement in the NIHR Clinical Research Network: Children 2013-2014

Overview report

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1. Introduction

This report presents findings from the evaluation of the National Institute for Health Research (NIHR) Clinical Research Network: Children Consumer Involvement Strategy 2013-2014. The evaluation was conducted by the National Children's Bureau Research Centre.

1.1 The NIHR Clinical Research Network: Children

Children deserve the same high standards as adults in the assessment of the safety and effectiveness of the medicines that they use, yet research suggests that the use of unlicensed or off-label drugs to treat children is widespread.¹

In 2007, a new EU Regulation on Medicines for Paediatric Use came in to force seeking to address this issue.² Following this, an NIHR research network was set up, with the specific aim of ensuring that studies relating to medicines for children in the NHS have the support they need to be delivered successfully.

Originally called the 'Medicines for Children Research Network' (MCRN), in April 2014 the 'NIHR Clinical Research Network (CRN): Children' was created. This network brought together MCRN and the Paediatric (non-medicines) Specialty Group to cover all children's research. The network is one of 30 Specialties which bring together communities of clinical practice to provide national networks of research expertise within the overarching NIHR Clinical Research Network. The primary objective of CRN: Children is to support and deliver clinical research involving children.

With the formation of the new Children's speciality, there were also changes in how the network operated at a regional level. Originally MCRN operated via six Local Research Networks which focused on supporting medical research for children in their region. In the new organisational structure, these have been replaced with 14 Local Clinical Research Networks which are intended to provide research support across all 30 specialities in the NIHR Clinical Research Network portfolio.

¹ Conroy S, Choonara I, Impicciatore P, Mohn A, Arnell H, Rane A, Knoepfel C, Seyberth H, Pandolfini C, Raffaelli MP, Rocchi F, Bonati M, Jong G, de HM, van den Anker J: Survey of unlicensed and off label drug use in paediatric wards in European countries. European Network for Drug Investigation in Children. *BMJ* 2000, 320:79-82.

² The regulation requires pharmaceutical companies to agree, with the European Medicines Agency (EMA), a Paediatric Investigation Plan for all new drugs at a very early stage in the development process.

This report is based on activity between 2013-2014 at a point when the structure was still formed of six Local Research Networks (LRNs), and prior to the network transitioning to 14 Local Clinical Research Networks (LCRNs).

The vision of the CRN: Children is to improve the health of children through research. Its purpose is to provide the best infrastructure within England to support the development and delivery of world-class research on medicines for children which is relevant and meaningful to children, families and other key stakeholders, and to contribute significantly to international medicines for children research.

1.2 Consumer Involvement within NIHR CRN: Children

NIHR CRN: Children supports the NIHR position that involving patients and members of the public in research can lead to better research, clearer outcomes, and faster uptake of new evidence.³

Consumer Involvement (CI) is a central thread running throughout the activities of the network. It is achieved via the delivery of a Consumer Involvement Strategy, which aims to:

- ensure that all aspects of the network's activity are informed and enhanced by the involvement of children and their families
- continue to build capacity to enable consumers working locally to inform the national research agenda and vice versa
- systematically map and evaluate the impact of CI activity on the research process
- widely publicise and promote the benefits of CI.

CRN: Children Consumer Involvement activities

Within CRN: Children, young people and families are actively involved in both local and national activities. The national co-ordination centre also seeks to establish links and share good practice internationally.

National level

The CRN: Children Consumer Liaison Manager, based at the national Co-ordinating Centre, is responsible for involving young people and families at a national level. This is achieved via the following activities:

³ NIHR CRN: Children Consumer Involvement Strategy 2012-2015.

- **Consumer Involvement Steering Group:** this group has two parent representatives on its membership and meets twice a year. The group is responsible for strategic oversight of consumer involvement across the network.
- **National Young Person's Advisory Group:** this group originated in the Co-ordinating Centre in 2006 and expanded across four local research networks in 2009. Current membership is approximately 90 young people aged nine to 18 years. This group inputs into specific research projects, but also participates in more general work to support effective research with children.
- **Clinical Studies Groups (CSGs):** there are 14 CSGs leading different portfolio areas of the NIHR children's research. Each CSG provides expert advice to help researchers develop high-quality research proposals. On average each CSG meets face-to-face twice a year and holds at least one teleconference. Each CSG has a minimum of two parent/carer/patient representatives as members, who are invited to attend all meetings. There are currently 33 parents/carer/patient representatives involved in CSGs.
- **Establish, manage and facilitate disease-specific focus groups:** additional funding from research studies can be sought to set up patient and family groups to inform the design and delivery of a research project.

Regional level

In 2013-2014 in each of the six Local Research Networks (LRNs) there was a member of staff responsible for undertaking consumer involvement activities in their region. Three networks employed dedicated consumer involvement staff for this purpose; in the remaining three, research nurses led consumer involvement and engagement as an add-on to their role.

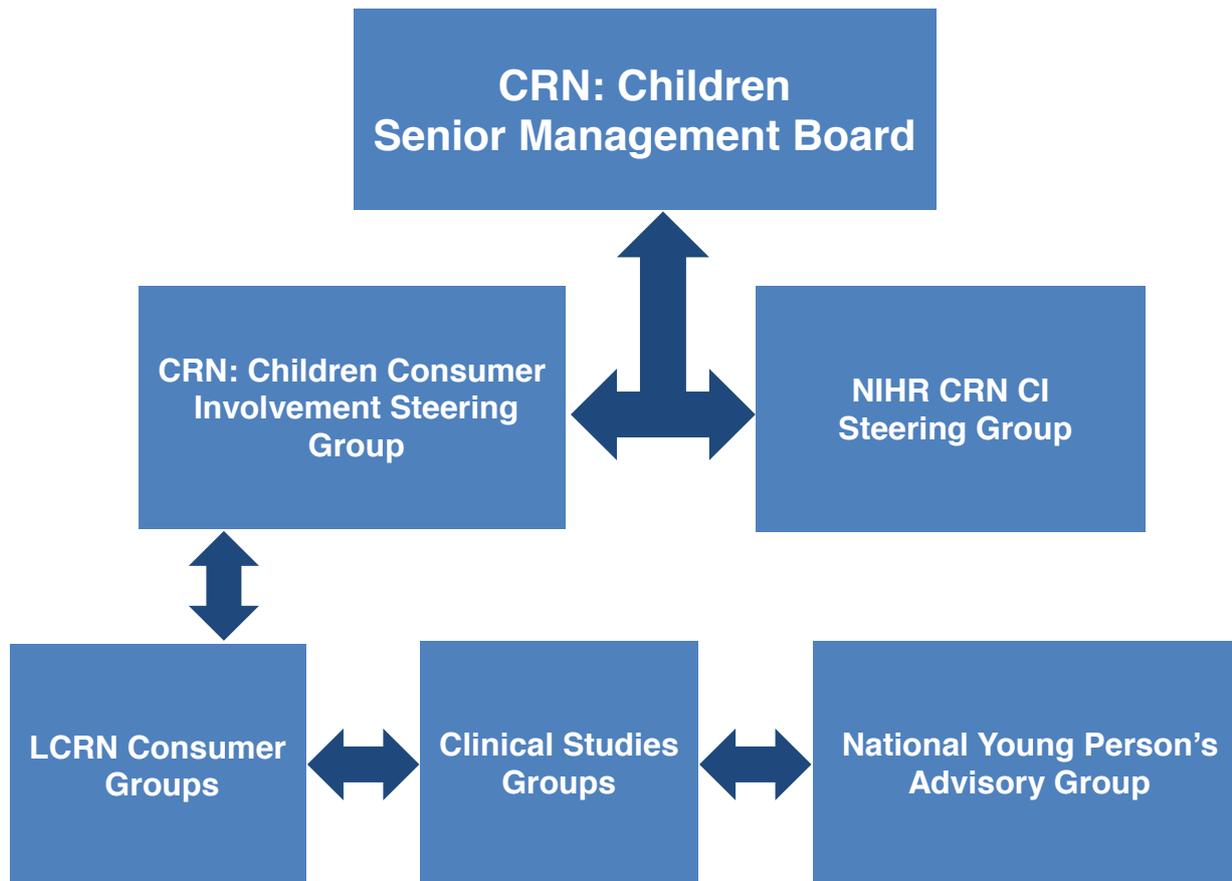
In 2009, four out of the six LRNs decided to set up their own young person's advisory group based on the model developed by the Co-ordinating Centre. These were in operation during 2013-2014. Each had a remit to support studies within their localities as well as multi-centre studies led by the Co-ordinating Centre and national projects, such as working with the National Research Ethics Service.

International work

The CRN: Children, Consumer Liaison Manager also supports European and international colleagues regarding the involvement of children and families. For example, she has been involved in supporting the set up of young people's groups in Canada and the United States, as well as within devolved nations in the UK.

Figure 1 Consumer Involvement Structure

Figure 1 shows how the various arms of the NIHR CRN: Children Consumer Involvement work-stream are structured and how they link into the broader CRN structure, including the CRN: Children, Senior Management Board and the NIHR CRN Consumer Involvement Steering Group which considers CI across all 30 specialities.



1.3 Evaluation aims

Monitoring and evaluation of Consumer Involvement (CI) activities is one of the four key aims of the Consumer Involvement Strategy. To help address this aim, the NCB Research Centre has been engaged to monitor and assess the impact of CI activities and to contribute to reviewing and revising the impact strategy and its implementation on an annual basis.

Key evaluation questions are:

1. In what ways does the network involve consumers⁴?
2. How have key stakeholders experienced the network?
3. What has been the impact of stakeholders' involvement with the network?
 - a. What difference has the network made to their research?
 - b. What were the outputs and outcomes of CI activities?
 - c. What do they consider to be good practice and why?

1.4 Evaluation methods

The evaluation is based on three areas of data collection activity:

- a. Collection and analysis of monitoring data for CI activities.
- b. Qualitative case studies of ten CI activities identified as effective practice.
- c. Collation of data from feedback forms for parents involved in Clinical Studies Groups (CSGs).

Brief details of each activity are outlined below. Further details are provided in Appendix C where we also highlight our thoughts about data collection in future years.

⁴ These are defined to include three groups: (i) children aged 18 or less, with experience of (or interest in) participating in clinical research, health conditions and/or health settings; (ii) parents/carers with experience of (or interest in) participating in clinical research, health conditions and/or health settings; (iii) organisations that represent children's and young people's interests.

a. Monitoring data collection and analysis

The scope of data collection

In 2013-2014, CI activity monitoring focused on the Co-ordinating Centre's and the LRNs' CI work with *children and young people*, for *specific individual research studies*. The intention was to pilot data collection on these specific types of activities, before rolling out to monitor data on all other CI activities.

Monitoring was designed to provide an overall picture of CI activities in terms of: number, types, outputs and reported outcomes. In addition, the evaluation aimed to profile the range of studies supported with CI work by region, type of research project and stage of project.

Sample

Whilst the intention was for monitoring data to be completed by each of the CI leads across the network and the Co-ordinating Centre for relevant CI activities, in practice, only the Co-ordinating Centre and the four CI leads who had a Young Person's Advisory Group (YPAG) provided data. The manager of the Co-ordinating Centre felt that this reflected the fact that the other areas do not have a dedicated staff member for CI work, and therefore have limited time to conduct or report on this.

As such, it needs to be borne in mind that the data presented in this report does not reflect the activities of two regions; though it is also likely that the level of activity was lower in these areas.

b. CI case studies of good practice

The scope and purpose of the case studies

Ten specific CI activities, identified as innovative or effective CI, were explored through qualitative case study work. The purpose of the case studies was to illustrate the range and nature of effective CI work taking place, explore stakeholder's experiences of this, and provide insight into how CI can be effectively delivered to make a positive difference to the quality of research study outcomes.

Sample

We asked the NIHR CRN: Children Co-ordinating Centre and six regional Local Research Networks (LRNs) to nominate examples of innovative or effective CI activities. Twelve examples were provided by the Co-ordinating Centre, South West LRN, East Midlands LRN and the West Midlands LRN. We then selected ten case studies to provide a regional spread across England.

All case studies selected involved CI work with children, but a small number also involved parents. In addition, whilst most case studies examined CI work relating to specific individual research studies, three of them involved more general work around involving children and young people in research.

For each case study the NCB research team aimed to conduct telephone interviews with the study's Chief Investigator, the researcher who led on the CI activity, and/or a participant. Between December 2013 and August 2014, ten case studies were completed involving a total of 17 stakeholder interviews.

Appendix A provides a full list of the case studies, and the range of stakeholder feedback obtained for each one.

c. Collation of data from feedback forms for parents involved in Clinical Studies Groups (CSGs)

The final aspect of data collection was feedback forms from parents who participated in CSGs. Every time a parent/carer/patient representative attends a CSG meeting, they are invited to complete a feedback form about their experiences of involvement in the meeting and any involvement they have had in reviewing individual research proposals since attending a meeting.

For this evaluation report, data was collected from 14 feedback forms completed by parents who participated in a meeting during the period October 2012 to March 2014.⁵

Whilst this data represents a small proportion of parents' experiences, it is useful in providing an indicative picture of experiences. However, responses may not be representative for example, parents who have been most effectively engaged within the CSG may also be those more likely to respond.

1.5 The content and structure of the report

Section 2, Overview of CI activities – This reviews the number and range of CI activities reported in monitoring data April 2013-March 2014.

Section 3, Learning from effective and innovative practice CI case study examples – This Section provides an overview of learning from the nine case study examples.

⁵ Whilst the evaluation period covers April 2013 to March 2014, the inclusion dates were expanded to include feedback from early meetings to maximise the sample size reported on, and because feedback forms have not previously been included in evaluation reporting.

Section 4, Parents' experiences of involvement in Clinical Studies Group meetings – This presents feedback from parents collated from parent feedback forms.

The Appendices provide further information about the case study activities reported in Section 3. Appendix A provides a numbered summary list of the case studies to aid cross-referencing and Appendix B details each case study. Appendix C provides further detail on the data collection methods employed for the evaluation.

1.6 Acknowledgements

We would like to thank the CI leads in the LRNs and the CRN: Children Co-ordinating Centre who provided monitoring information and helped us with the identification and set up of case studies. Importantly we would like to thank the medical research team representatives, CI research leads, and the young people and parents who provided feedback about their experiences of CI work.

2. Overview of CI activities

Consumer Involvement (CI) activity monitoring was designed to focus specifically on the Local Research Networks' (LRNs) and the Co-ordinating Centre's CI activities with *children and young people*, and for *specific individual research studies*. This Section reports on these activities.

However, note that other CI activities also took place in 2013-2014 and some of these are discussed in other Sections of the report. CI work with parents involved in the Clinical Studies Group (CSG) is discussed in Section 4. Two examples of CI work with children and young people to support effective approaches to research and involvement among children more generally (rather than for specific individual research studies) are also reported on in Section 3.

2.1 Scale and national spread of CI activities

During the year April 2013 to March 2014, details of 64 CI activities carried out with children and young people to support individual research studies were recorded in monitoring returns, each for a different research study. Given that there were 144 funded projects within the CRN: Children funded project portfolio during 2013-2014, it is clear that CRN: Children is supporting CI activities for a significant proportion of the research portfolio.

As shown in Table 2.1, around two-fifths of activities were led by the CRN: Children Co-ordinating Centre, whilst just over half (56%) were lead by individual regional LRNs⁶, with the West Midlands reporting the greatest number of the activities out of the four regions (22%).

⁶ Note that whilst a substantial number of projects are supported by individual regional LRNs, many of these projects are delivered nationally, or across multiple regions.

Table 2.1 Local Children’s Research Network area

	CI activity	
	N	%
CRN: Children Co-ordinating Centre	26	41
West Midlands	14	22
London	9	14
East Midlands	8	13
West of England	5	8
Not specified	2	3
TOTAL	64	100

Base: All reported project-specific CI activities undertaken with Young Person Advisory Groups between April 2013 and March 2014 (64)

2.2 Project stages at which CI was sought

Table 2.2 below outlines the different stages of projects at which CI support was provided.

Notably, whilst 38% of input took place following acceptance of projects onto the National Institute for Health Research (NIHR) portfolios, in a greater proportion of cases (57%) input was given prior to this, either during the initial design work to inform the funding application (48%), or to inform the ethics application (9%). This reflects the benefit of involving consumers from as early a stage as possible in the design of a project⁷ as well as the fact that CI is often assessed as part of funding and ethics applications. By and large, it was originally intended that CRN: Children should support projects which are confirmed for funding under the CRN: Children portfolio. However, given the above, there may benefit in considering how support with CI can be formally offered by CRN: Children prior to acceptance on an NIHR portfolio.

⁷ Boote, J., Twiddy, M., Baird, W., Birks, Y., Clarke, C. & Beever, D. (2013) Supporting public involvement in research design and grant development: a case study of a public involvement award scheme managed by a National Institute for Health Research Research Design Service, *Health Expectations*, 10.1111/hex.12130; Miller, E., Morrison, J. & Cook, A. (2006) Brief encounter: Collaborative research between academic researchers and older researchers, *Generations Review*, 16(3/4), 39-41

Table 2.2 Project stages at which CI was sought

	CI activity	
	N	%
In design (prior to funding application)	31	48
Ethics (following funding approval and prior to ethics review ⁸)	6	9
NIHR Portfolio project (post ethics, and once accepted onto an NIHR portfolio). ⁹	24	38
Children speciality	(12)	(19)
Other speciality	(7)	(11)
Speciality unknown	(5)	(8)
Blank/unknown	3	5

Base: All reported project-specific CI activities undertaken with Young Person Advisory Groups between April 2013 and March 2014 (64)

The Table also highlights that CRN: Children provided a useful role in supporting CI in projects in other CRN portfolios (for example, where they involved children) as well as in the CRN portfolio itself, meaning it provided benefit to the wider NIHR Clinical Research Network.

2.3 Methodological study types for which CI took place

Table 2.3 below shows the range of methodological study types for which CI activity took place, as identified in data linked in from the portfolio study database.

As the Table shows, the majority of studies were medical studies (81%). Among these the most common study types were randomised control trials (28% of all recorded studies) and observation studies (27% of all recorded studies). Around one in ten studies, or fewer, were qualitative (11%), pharmacokinetics (8%), or open label (6%).

⁸ These are coded "IRAS" (Integrated Research Application System) in the study database. (IRAS is the system through which ethics applications are reviewed.)

⁹ In some cases, more detail about the project stage was given in free flow text, for example: at the stage of feasibility testing and site selection; during early set up; during participant recruitment etc.

Table 2.3 Study type for which CI activity took place

	CI activity	
	N	%
All medical studies	52	81
Randomised control trial (RCT) <i>Participants studied are randomly allocated one or other of the different treatments under study</i>	(18)	(28)
Observation <i>The assignment of subjects into a treated group (vs. control if present) is outside the control of the investigator</i>	(17)	(27)
Qualitative <i>A method of inquiry to gather an in-depth understanding of behavior, experiences and reasons governing these</i>	(7)	(11)
Pharmacokinetics <i>Describes how the body affects a specific drug after administration through the mechanisms of absorption and distribution as well as the chemical changes of the substance in the body</i>	(5)	(8)
Open label <i>In which both researchers and participants know which treatment is being administered</i>	(4)	(6)
Extension <i>Allows continued prescribing of drugs providing information on long-term safety and tolerability of potential</i>	(1)	(2)
All non-medical studies (for example, surgical)	4	6
Other¹⁰	6	9
Blank	2	3

Base: All reported project-specific CI activities undertaken with Young Person Advisory Groups between April 2013 and March 2014 (64)

¹⁰ Unknown whether medical or non-medical and includes: two cohort studies; two mixed methods studies, and two feasibility/pilot studies.

2.4 Aspects of the research that the CI studies informed

There is potential value in facilitating CI across all stages of the development and design of a research study¹¹. This includes involvement in:

- strategic aspects that will qualitatively influence the *type and nature of data to be collected*, such as deciding the research questions or outcomes for measurement or overall methodology, for example, the mode of data collection.
- practical aspects relevant to determining the *quality of data collected and efficiency of study implementation*, for example, the detailed study protocols or the content and format of patient information leaflets (PILs) to be used in recruitment and consent processes.

Table 1 below summarises how the CI activity reported in monitoring data maps against the potential stages at which CI can play a role. Many studies sought input on one aspect, but some sought input on multiple aspects (as such the percentages column sums to more than 100%).

As the Table highlights, the CI work sought to involve young people across a range of different aspects of projects. However, most commonly their involvement focused on the more practical elements of projects, and involvement in more strategic issues, such as the outcomes to be measured in the study, was less common. For future activities, there may be benefit in promoting awareness of the benefits of CI across a wider range of project aspects, including the more strategic aspects in particular.

¹¹ Boote, J., Twiddy, M., Baird, W., Birks, Y., Clarke, C. & Beever, D. (2013) Supporting public involvement in research design and grant development: a case study of a public involvement award scheme managed by a National Institute for Health Research Research Design Service, *Health Expectations*, 10.1111/hex.12130; Miller, E., Morrison, J. & Cook, A. (2006) Brief encounter: Collaborative research between academic researchers and older researchers, *Generations Review*, 16(3/4), 6

Table 2.4 Elements of research projects which CI activities informed

	CI activity	
	N	%
Strategic	(19)	(30)
Membership of project steering committee	1	2
General views of the study (relevant/appropriate)	6	9
Research design/method	2	3
Data analysis	2	3
Relevant content/issues/outcomes	8	13
Practical implementation	(54)	(85)
Data collection tools	6	9
Procedures/processes/approaches to implementing data collection	14	22
PILs	31	48
Participant engagement	1	2
Participant retention	1	2
Assent forms	1	2
Dissemination	(3)	(5)
Plain English lay summary	2	3
Dissemination poster	1	2

Base: All reported project-specific CI activities undertaken with Young Person Advisory Groups between April 2013 and March 2014 (64)

2.5 Impact of CI activities

CI leads were asked to record the impact CI activity had on a project (if any) in an open text box in the monitoring spreadsheet. Positive outcomes in terms of changes or improvements made to the study approach were reported for just over half (52%) of activities. As might be expected, the types of impact reported reflected the areas where involvement was sought (e.g. reviewing patient information leaflets, or considering relevant content and outcome areas).

Here we provide some examples of outcomes at various stages of research. We explore the nature of this impact in more detail in Section 3.2, drawing on the case study analysis.

Study content

"The group helped with design of the questionnaire and raised issues regarding questions that should be asked about children with neurological disorders that the study team hadn't previously considered. Two young people will sit on the steering committee for the research study. The feedback has helped to design the research and has gone into the HTA grant application."

West Midlands YPAG, CI for an observational study

Research design

"The group's views have helped to design research and have gone into the funding application."

West Midlands YPAG, CI for an observational study

"Study design changed (inclusion of control group). One of the parents has agreed to be research co-investigator on grant submitted. Involvement with her and parent group to continue if successful."

East Midlands LRN YRAG, CI for an observational study

Data collection tools

"Questionnaire was amended by the Young Person Group."

National YPAG, CI for a randomised control trial

"The feedback from the group helped design the questionnaires to be used in the project. The feedback also fed into the main report for the research."

West Midlands YPAG, CI for an randomised control trial

Implementation of data collection

"Researcher listened and has documented concerns from parent/carers. Tablets since made smaller. Other concerns e.g. length of time in scanner to be looked at."

East Midlands LRN YPAG, CI for an observational study

Patient information and liason service

"All changes made to assent and patient information sheet."

National YPAG, CI for a pharmacokinetics study

"All feedback was sent over to the researcher with a view to the team changing the patient information leaflets based on the young people's comments."

East Midlands YPAG, CI for a non-medical study

"Changes made to patient information leaflet and consent process."

National YPAG, CI for an observational study

Dissemination

"The information gathered helped to produce a poster for the AYPH conference."

West Midlands YPAG, CI input for a qualitative study

3. Learning from effective and innovative practice CI case study examples

Our analysis of ten case study Consumer Involvement (CI) activities has provided insight and learning with regards to the following issues:

- **The role of CI** in different aspects of research projects, and the benefits of employing CI at different stages.
- **The practice of CI** in terms of the different methods employed and learning generated by experiences of the CI work, which may be helpful for informing CI work in the future.

3.1 The role of CI at different project stages

The majority of the case studies (7/10) focused on CI work relating to specific individual research projects – these are discussed here. The remaining three case studies focused on CI work relating to approaches to research with children and young people (CYP) in general and are discussed further in Section 3.2

As shown in Table 3.1 below, our findings reflect those on the coverage of CI activities reported in monitoring data - case study activities sought to involve young people across a range of different aspects of research projects, predominantly the more practical elements, though we did find a small number of cases where they were involved in more strategic issues.

Table 3.1 The elements of research projects which CI activities informed among the project-specific case studies

Aspect of research where CYP input	Total studies	Case study ref¹²	More detail on what the CI informed
Deciding the relevant outcomes to be measured in the study	2	3 & 8	The outcomes that should be measured when testing the medicine (both studies)
Study design	1	8	The overall design for the study 'control' sample
Study implementation approach	4	4 7 9 3	The design of wireless monitors to be worn by study participants How the medicine to be tested should be presented and packaged for participants (taste, colour and packaging) How medicine should be administered and compliance with taking the medicine supported The mode through which data should collected
Participant communication materials used in implementing the study	4	1,4,8 2	Patient Information Leaflets (PILs) PILs & child assent forms

Further information about the nature of CI input and the outcomes achieved for each of the four elements above across the case studies is provided below. The findings highlight the value that can be achieved from CI across different research project stages, and the potential benefit of ensuring CI is fully promoted across all stages, including the more strategic elements, where involvement is currently lower.

¹² Case study number allows cross-referencing to case studies in the Appendices

Content – defining relevant issues and outcomes

Two CI case studies (three and eight) involved young people and/or parents and carers in considering what outcomes should be measured when testing the efficacy of the medicine. In both cases the study team had initially been mainly focused on primary clinical outcomes, but young people and parents highlighted the importance to them of measuring secondary outcomes which are more meaningful in terms implications for quality of life. For example, in case study three, researchers were originally focused on measuring children's IQ, but young people and parents suggested that children's functionality should also be measured (they argued there is little point in being intelligent according to clinical measures if this did not translate into positive functioning in practice). Similarly in case study eight, doctors were focused on measuring the quality of tone in children's bodies, but parents and carers were more concerned with secondary outcomes relating to quality of life (e.g. pain and participation).

OUTCOME: In both cases, the research team expanded the range of outcomes measured as a result of the CI. They felt this helped to ensure the study was assessing the medicine against outcomes that were valid, important and meaningful for young people and parents themselves. Ultimately the research teams feel that this has improved the potential value of the research because the studies now address outcomes which are most important to patients themselves.

Study design

Case study eight involved young people and their families in helping to inform and finalise the design of a future study. Young people with increased tone were consulted alongside their parents/carers to discuss their preferred study design. The group agreed that they did not support a placebo controlled or crossover design, for fear of the pain that could ensue from increased tone. Instead, they agreed that their preferred method would be a feasibility study of the main current drug versus the new drug.

OUTCOME: The research team opted for the design preferred by participants. The CI helped identify the design that was most realistic in terms of enabling participant engagement in the trial, thus potentially supporting its overall success.

Implementation approach

Four case studies (three, four, seven and nine) asked young people to provide feedback on specific aspects of how the studies would be implemented. Case study three consulted parents about which of two modes (self-completion

questionnaires or face-to-face interviews) would be the most appropriate mode of data collection. For study four, young people were consulted regarding the best design for the monitors that might be worn by patients in the study. In case study seven, young people were consulted about the colour and flavour of medication to be used in a clinical study. Finally, in study nine, when where and how medicines should be taken, and how compliance might be maximised, was discussed with young people.

OUTCOME: Case studies four, seven and nine, researchers incorporated young people's suggestions into study protocols and implementation approaches, and these researchers felt this would support effective participant engagement in the study and/or compliance with protocols, and thus support the studies' overall success. For example, in case study nine, additional budget was built in to respond to young people's preferences for having blood tests at home, and many of their suggestions for how to incentivise compliance with the therapeutic regime were also adopted.

OUTCOME: Regarding case study three, the researchers concluded that, the approach taken to the CI (a 'one off' consultation meeting) was not sufficient to educate participants enough to fully consider methodological concerns. In this case, the study team opted for the data collection mode that was *less* preferred by participants, because the preferred mode was deemed less methodologically appropriate.

Taken together, these four case studies highlight that CI can help inform effective research study implementation approaches, but that this depends on ensuring that CI activities are fit for purpose in terms of facilitating young people's and parents' understanding of the issues. Some types of implementation design issue are more technically complex than others – it is important to match the CI methods with the complexity of the issue to be explored.

Participant communication materials

Four case studies (one, two, four and eight) focused on obtaining young people's views on various materials used to inform patients about the study, and support recruitment and consent and assent processes, for example patient information leaflets, assent and consent forms.

OUTCOME: In all four case studies, changes were made to the materials, in light of feedback provided by young people. Developing the materials alongside consumers is perceived by the research teams to have helped support effective engagement with the patients and their parents/carers, aided recruitment and ensured easier consent/assent processes, thus supporting the overall success of studies. Researchers found it relatively easy to facilitate realistic and actionable feedback from participants via light-touch involvement activities, such as one-off meetings, highlighting that this is an area where effective CI can be easily achieved.

3.2 The role of CI in informing research in general

Three of the ten case studies involved young people in activities designed to support effective research more generally. The success of these activities highlights the benefit of the CI Strategy involving proactive work to develop and promote best practice in research with children. Two of the three case studies achieved significant impact in influencing policy and practice around involving children in research.

Case study five was a large high-profile event that was designed, developed and led by young people and parents and aimed to promote effective CI among young people and families. The event was reported to have had a strong impact among attendees in highlighting what can be achieved via effective involvement of young people and families and motivating them to further promote this in wider work. It was also deemed to have influenced senior decision-making in the NHS. For example, Chief Medical Officer, Professor Dame Sally Davies, made highly vocal endorsements of, and commitments to, children's involvement at the event. And, reflecting this, the Chief Medical Officer's annual report in October 2013 made a specific recommendation for children and young people's involvement in clinical research.¹³

Case study six was run by the Health Research Authority (HRA), and worked with young people, as well other patient groups and the general public, to seek their opinions on how to improve the research process and the overall research approval system. Young people made a number of suggestions and recommendations which have directly informed and influenced a number of

¹³ <https://www.gov.uk/government/publications/chief-medical-officers-annual-report-2012-our-children-deserve-better-prevention-pays>

publications, strategies and policies. For example, this feedback has directly informed the HRA's transparency strategy and the findings triggered the HRA development of guidance for researchers on 'Information for patients at the end of a study', and informed the development of the '[HRA Strategy for public involvement](#)'. Dialogue findings are also informing revisions to the standard template Patient Information Sheet that is used by most health researchers, and being fed into the wider Research Governance Framework, which is being revised in 2014 and, in the longer term, into revision of the [Governance Arrangements for Research Ethics Committees](#).

3.3 The practice of CI

3.3.1 Overview of CI methods

Children and young people's involvement in CRN: Children supported projects was largely facilitated via Young People's Advisory Groups (YPAGs).

As outlined in Section 1.3, these groups were run by the national Co-ordinating Centre and four Local Research Networks (LRNs). They tended to bring together a specific group of young people (typically around 15-20 young people aged 12-18) via regular meetings to be involved in a range of different research projects over time.

As shown in the Table 3.2 below, all of the case studies featured in this report utilised the YPAGs for their CI activities.

Researchers often returned to the group several times in the study to consult on different issues. Whereas involvement of the YPAG on any one research issue usually involved just one meeting of the group, in some cases researchers returned to them more than once to develop a solution to the issue in a more iterative way. In some cases the one-off meeting with the YPAG was supplemented by other activities, such as involving patients with the relevant condition or meeting with parents and carers. In one case, young people were taken to view some medical equipment in a paediatric intensive care unit.

A further case study involved young people in a more fundamental way by supporting them to develop and deliver a youth-led event to help raise the profile of CI among young people in clinical research.

This way of working – providing a range of different ways for young people to get involved – fits well with what is known to be effective in supporting the

involvement and participation of young people in health and other services.¹⁴ More recent work on the value of co-production¹⁵ also provides further support for this way of working with young people.

Table 3.2 Overall methods of involvement

Method of involvement	Total studies	Case study ref no.	Detail
One meeting with a YPAG	3	4,6,10	Researchers met with the group to discuss a particular issue on one occasion. In one case, young people were additionally taken to view some medical equipment.
One meeting with a YPAG plus parent involvement	3	3,8,9	As well as meeting with a YPAG, researchers involved parents, either in the same meeting, or more commonly via separate follow-up meetings.
Multiple meetings with a YPAG	2	1,2	In some cases researchers returned to the same group more than once to gain input on the same issue.
One meeting with a YPAG plus consultation with patients	1	7	The YPAG was involved in initial consultation, and helped to develop consultation tools for use with patients. In-depth consultation then took place among patients via one-to-one interviews.
Youth-led event, extensive involvement	1	5	An event (GenerationR) was planned by several YPAGs across England over the course of several meetings, and then co-delivered by young people along side adult researchers.

¹⁴ Street, C. and Herts, B. (2005) *Putting participation into Practice: A guide for practitioners working in services to promote the mental health and well-being of children and young people*. London: YoungMinds

¹⁵ See for example, Boyle, D., Coote, A., Sherwood, C., and Slay, J. (2010) *Right Here, Right Now: Taking co-production into the mainstream*, London: New Economics Foundation

3.3.2 Key learning points

The case study interviewees identified a number of success factors for running effective CI activities based on their experience of taking part in CRN: Children CI work. These are summarised below:

- **Time meetings around young people's schedules.** Either tap into an existing group's regular meeting(s) and/or schedule sessions for after school or at weekends. This removes potential barriers to participation.
- **Plan each session thoroughly. Be prepared and take advantage of CI lead's expertise where available.** Researchers who were well prepared and seemed to take the sessions seriously benefited from young people who felt needed, valued and listened to. CI leads have expert knowledge and experience with regards to young people's involvement in research. Researchers who engaged with, and sought the expertise of, CI leads found that the activity was more appropriately structured and felt that more was gained from the experience.
- **Be sure to use appropriate and sufficient methods to facilitate effective participation – and be realistic about what input participants will be able to give based on the methods employed.** For many CI activities (for example, gaining young people's input on PILs), an effective approach involved combining presentations (to systematically explain the issues) with creative or interactive discussion (to facilitate young people's thinking and feedback). However, methods need to be sufficient for the involvement sought. For example, researchers in case study eight, who consulted parents about what data collection mode would be best, found that patients were able to feedback their views regarding their perspective on how participants might experience and react to the methods. However, they reported that the methods used for the CI were *not* sufficient for enabling patients to input based on an understanding of the full range of relevant methodological considerations. Feedback about patients' likely responses to a method may still be helpful in highlighting issues important for researchers to address for effective implementation. However, if researchers wish to maximise the input from patients on an issue involving complex methodological considerations, it is important to fully brief them on the technical issues first.
- **Allocate enough time.** As highlighted above, it is important to allow sufficient time to brief participants about the complexities of the issues on which they are being asked to deliberate. In addition, some researchers found that participants valued the chance to meet with other young people or parents with similar concerns and sought to use the sessions as a 'sharing' forum, discussing issues that were broader than

those intended for the CI activity. Where this is likely to be the case (e.g. where CI participants have been recruited based on common medical conditions), it is important to allow sufficient time for this interaction, as well as for the planned CI activities themselves.

- **Keep to the ethos of the group.** Researchers tended to have positive interactions with groups of young people when they approached the group from a 'familiar' standpoint. For example, groups that were used to meeting informally worked well when having informal discussions and debate, whereas the more formal groups preferred presentations and reports.
- **There can be benefit in meeting more than once:** Researchers from two studies found it helpful to meet with a group more than once, allowing them to make refinements between meetings, re-test the revised approach, and allow further fine-tuning if necessary.
- **Ensure that feedback is provided.** Young people valued receiving updates on the progress of the study, particularly with regards to their specific input. For ongoing participation, providing regular updates and feedback proved invaluable in ensuring that young people remained engaged and interested in the study. This is particularly important if there is a desire to involve young people on a number of occasions over time.
- **Participants appreciated not having too long a gap between meetings.** In some cases gaps between meetings were considerable (up to six months). However, shorter gaps between meetings are preferred by young people to support momentum, continued engagement and better recall of previous sessions.
- **Ensure group sizes are sufficient, but also effectively managed.** In one case study the number of young people and families involved (four to eight in any one session) was felt to be insufficient to allow conclusions to be drawn confidently. Larger numbers were felt to be desirable. Some YPAG meetings involved up to 18 young people. In these cases, individual participants reported that discussions could be overwhelming and could make it difficult for everyone to speak. Break-out groups of six to eight young people are recommended in this context.
- **Be prepared to make changes.** Researchers stressed the importance of keeping an open mind and being genuinely prepared to make changes to the study. In this context, they would advise others to consult with young people early on in a study, before details have been finalised, but to ensure that any materials that are being considered by the young

people are of a good standard so as not to ask the young people to point out problems which could have been predicted.

- ***It is beneficial for the Chief Investigator to attend in person.*** It was found that this could raise the profile of the project, make young people feel valued, and also allow immediate authoritative feedback to be given regarding what suggestions might be taken forward. All of this can support positive engagement of young people in the participation activities.

4. Parents' experiences of involvement in Clinical Studies Group (CSG) meetings

This Section provides data from 16 feedback forms completed by parents who participated in a CSG meeting during the period October 2012 to March 2014.¹⁶ Data is useful in providing an indicative picture of experiences but it is important to bear in mind that this sample represents a small proportion of parents' experiences and may not be representative.

4.1 Parents' experiences of involvement in CSG meetings

Around two-thirds of parents participated in face-to-face meetings (9), whilst around a third dialed into tele-conference calls (5).¹⁷

As shown in Table 4.1 below, most parents (11/16) said they actively contributed something at the meeting, and among these, the majority felt their contribution had been listened to (9/11) and none reported feeling that their views were disregarded. A quarter of participants said they did not contribute anything, but at least one of these parents felt this was appropriate because it was their first meeting, and they wanted to observe in the first instance.

Table 4.1 Parent report of contribution in meetings

	CI activity		CI activity
Parent report of whether contributed	N	Parent report of whether contributions were listened to	N
Contributed	11	Listened to	9
		Not listened to	0
		Unknown/missing data	2
Did not contribute	4		
Unknown/missing data	1		

Base: All parents who took part in CSG meetings between October 2012 and March 2014 (16)

¹⁶ Whilst the evaluation period covers April 2013 to March 2014, the inclusion dates were expanded to include feedback from early meetings, to maximise the sample size reported on, and because feedback forms have not previously been included in evaluation reporting.

¹⁷ For two parents this was unspecified

4.2 Parents' involvement in reviewing research proposals

Among the 16 parents providing feedback about a meeting, seven said they had reviewed proposals for specific medical research projects since the previous meeting, including three who had reviewed one or two and four who had reviewed four or more and who were therefore contributing quite substantially.

However, eight said they had not participated in this way. It is not clear whether or not there were proposals to view in these cases, but in general it may be helpful to ensure that parents have the encouragement and support they need to review and feedback on proposals.

Among the seven parents who said they reviewed proposals, all but one said they could understand the proposals indicating that they were communicated in a way that was suitable for lay representatives to understand. However one parent said they did not understand the proposals so there may be some room for improvement in how proposals are communicated in at least one CSG area.

All seven parents said they made suggestions for modifications to be made to proposals. Of these, five said their suggestions were taken on board and none said they were not taken on board indicating that parents' contributions have been taken seriously among this small sample.

Only three of seven parents said they had received feedback following their contributions indicating that this may be an area for improvement in some CSGs.

Table 4.2 Parents' experiences of contributing to study proposals

	CI activity
	N
Parent suggested modifications	
Yes	7
No	0
Parents suggestions were taken on board	
Yes	5
No	0
No response/unsure	2
Feedback provided to parents	
Yes	3
No	3
No response/unsure	1

Base: All parents who had reviewed one or more studies between October 2012 and March 2014 (7)

5. Summary and conclusions

In this concluding Section, we highlight key points from the evaluation findings before reflecting on what these might mean for the future of Consumer Involvement (CI) strategy and practice.

Overall impact of the CI strategy

The NIHR CRN: Children Consumer Involvement Strategy has been **successful in delivering and supporting a range of CI work** with children, young people and parents in 2013-2014.

In particular, the national Co-ordinating Centre and four Local Research Networks (LRNs) have supported a significant number of individual research projects with CI. There were a total of 64 supported projects recorded in monitoring data for 2013-2014 and this compares with 144 projects in the portfolio at that time. In over half of these cases (52%), the researchers reported making specific changes to research approaches as result of the CI.

By helping to inform and improve the content, design and/or implementation of a significant number of projects, the CI Strategy is therefore playing an important role in supporting the effective delivery of National Institute for Health Research (NIHR) research projects.

Based on a small number of parent feedback forms, there is evidence that the CI strategy was successful in enabling some parents to contribute at meetings and feel that their contribution was listened to. Around half also said that they had reviewed specific research proposals and made suggestions for modifications to be made to proposals.

Issues for future consideration

Our evaluation findings raise five points concerning the development of strategy and practice around CI:

1. The need to ensure that sufficient dedicated resources are available to enable effective delivery of consumer involvement.

Whilst effective CI work was recorded in monitoring data by four of the six LRNs, in two LRN areas no activities were recorded in monitoring forms. In these areas the lack of recording of activities is likely to reflect the fact that there is not a dedicated staff member for CI (research nurses were assigned the responsibility as an add-on to their jobs) and so staff therefore probably had less time available for both delivering activities and/or recording them.

- 2. The potential benefit of considering how support with CI can be formally offered by CRN: Children *prior* to acceptance on an NIHR portfolio.** In over half of the individual research projects where CI was supported, the CI input took place prior to acceptance onto NIHR portfolios – either during initial design work to inform the funding application (48%) or to inform the ethics application (9%). This indicates a need to involve consumers at the early stages of a research project, in part due to the benefits this provides and also because CI is often assessed as part of funding and ethics applications.
- 3. The use and value of CI in supporting the more strategic aspects of research - and the need to promote this.** CI work to support individual projects covered a wide range of different aspects of research projects but was most commonly focused on informing very specific implementation issues – for example patient information leaflets and respondent consent/assent or engagement approaches. The case study projects demonstrate the value of using CI across all stages of research studies – including the more strategic aspects of research, such as the outcomes to be measured or overall methodological design.
- 4. Learning about implementation of CI from the ten case studies might be usefully shared.** For example, the need to:
 - Time meetings around young people’s schedules
 - Utilise the expertise of CI leads
 - Ensure that the involvement approach matches the aims one is trying to achieve
 - Effectively manage group sizes and participant engagement

It may be helpful to produce a short accessible summary of relevant learning from the evaluation – particularly around implementation of CI – to distribute to those involved in CI work and/or incorporate into any training or guidance materials produced by CRN: Children.

- 5. The need to ensure that monitoring data approaches are fit for purpose.** Our learning around the recording of monitoring data (see Appendix C) and thoughts about future years of evaluation raise a need to build on the approach used to monitor CI activity this year to enable a more streamlined process for local areas to record and report on their CI work in future years. Closely linked to this is the fact that the number of LRNs has recently increased from six to 15, thus emphasising the need to develop effective monitoring systems to enable the gathering of high-quality data and collation of findings across the network.

Appendix A - Summary of case studies

Summary of the case studies and fieldwork conducted

Study	Aspect of research	Region	No. inter-views	Stakeholders spoken to
1. SPACe Study	Improved participant communication materials	South West LRN	1	Researcher
2. TrialNet Study	Improved participant communication materials	South West LRN	2	Research Nurse and Researcher
3. SNAP Study	Helped to inform study outcomes	East Midlands LRN	2	Researcher and young person
4. RAPID Study	Informed implementation approach	West Midlands LRN	2	Researcher and young person
5. Generation R Event	Promoted effective research with young people in general	CRN: Children National Co-ordinating Centre	3	CI Research Lead, Researcher and young person
6. Health Research Authority	Promoted effective research with young people in general	CRN: Children National Co-ordinating Centre	2	CI Research Lead and Researcher
7. Metfizz Study	Informed implementation approach	CRN: Children National Co-ordinating Centre	2	Researchers
8. Increased Tone Study	Improved participant communication materials. Informed study design	East Midlands LRN	1	Researcher
9. Vitamin D Formulations Study	Helped to inform study outcomes	West Midlands LRN	1	Researcher
10. Involving people in research	Helped raised awareness of good practice in involving people in research	MCRN East	1	Researcher
Total			17	

Appendix B - Full case study examples

Case study 1: Supporting Parents with A Child with Arthritis (SPACE) Study

Main aim of the consumer involvement activity

To seek feedback from children and young people on the design and content of draft information leaflets for children with juvenile idiopathic arthritis (JIA).

Background

The Supporting Parents with A Child with arthritis (SPACE) Study is a feasibility study for a Randomised Controlled Trial (RCT) to evaluate a behavioural intervention for parents early in the diagnosis of JIA. The study design reflects families' advice on the study, and their continued involvement. As part of this work, the South West LRN Young Person's Advisory Group (YPAG) hosted a focus group, led by the Chief Investigator, to seek feedback on draft information leaflets for children and young people.

How consumers were involved

Nine members of the YPAG, aged 10 to 17, were asked to review two leaflets; one for younger children and one for older children and young people. They were also shown a further leaflet for parents, but the focus was primarily on gaining feedback on the design and content of those for children and young people.

Reported impact of the involvement

The young people expressed mixed views on which age groups should receive each leaflet, which validated the researchers' decision to avoid labelling them for specific ages, and instead allow scope for discretion based on individual needs and preferences.

For the most part, the young people liked the graphics and content of the leaflets. There were some minor wording changes, and they were keen to have an overview of the content at the beginning. Accordingly, it was decided to provide a fuller, but succinct, bullet-point summary at the start of each one. This ensured potential participants grasped an understanding of the study quickly.

All of the young people's suggestions were acted on. The Chief Investigator led the group discussion, and was able to discuss each point with them, and indicate straight away what would be done as a result. She also returned to the group some time later to show them the final versions of the leaflets and demonstrate the difference their input had made. The changes made were well received by the young people.

Their experience with the group gave the researchers a great deal of confidence that they had pitched the materials at the right level. This meant that, if the study ran into problems, they could be fairly confident that this element of the design was not likely to be a significant factor.

Expectations were also borne out in practice because recruitment was completed effectively with the local site, without any further changes being required to the information sheets. The Chief Investigator and the research team felt the information sheets aided recruitment to the study as they were easily understood and helped to facilitate the consent process.

Key learning points

- The Chief Investigator felt that it was very important for her to be present and to run the group discussion. This enabled her to give instant feedback and, had the young people wished changes to be made which were not possible, she would have been able to explain why. As the group's membership changes (as they grow up and move on), it also ensured there was some feedback for those who might not still be in the group by the time the final materials were produced.
- She was familiar with the group and comfortable working with them. Had she been less experienced, she would have sought the advice of those leading the group.
- From her perspective, it was important to make sure that the draft materials brought to the group were of a good standard, rather than asking young people to point out problems which could have been predicted.

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Case study 2: TrialNet

Main aim of the consumer involvement activity

To take children's views into account in redesigning information leaflets and assent forms for children and young people to take part in the TrialNet study.

Background

TrialNet is a group of international studies focusing on people who do not have type 1 diabetes but are at increased risk because they have a family member with the disease. Researchers based in Bristol working on one of these studies were keen to improve the existing child assent forms for participation in the study, which they felt were not very child-friendly, and to anglicise text developed for American participants. They asked the South West LRN Young Person's Advisory Group (YPAG) to help with this process.

How consumers were involved

Initially, a researcher met with six young people from the YPAG, mostly aged eight or nine. They were asked to review two leaflets, one for younger children (aged 7-11) and one for older children and young people (aged 12+), and to provide feedback on their design and content. The researcher returned to the group six months later to further get their input by reviewing a revised draft with them.

Reported impact of the involvement

The young people were critical of various aspects of the wording and formatting of the leaflets, and suggested changes which were taken up. For example, they felt that rather than being presented on an A4 sheet, the information for both groups should be in leaflet format for ease of reading and so as to be more young-person friendly. The children also suggested that the forms – particularly the one for older children – were too 'wordy', with a font which was too small, and they suggested adding more pictures. All such suggestions and comments were taken on board and the leaflets were adapted to reflect these suggestions.

The group disliked several aspects of the way the forms warned children about the risk of pain associated with blood samples. They felt that the wording could cause undue alarm, and some would have preferred that it was not mentioned at all. The researcher explained that, ethically, it was important to inform young people about the fact that the process might hurt, but substantive changes were made to the wording, acknowledging that 'it can be sore' but also saying that, if children wished, they could use cream to numb the skin.

The researcher gave feedback on the young people's recommendations at the time, but also returned to the group six months later with new drafts of the

forms to gather further feedback. At this stage, their comments were more minor – for example, indicating preferences for some pictures over others – but it was also useful to gather views from some older children (aged up to 14) who were present at this point. Once the final versions have been through ethics approval, the researcher will return to the group once more, to show them the final products.

Working with the group was enjoyable for the researcher, as well as productive. The young people were engaged and made critical comments which reinforced the researcher's instincts, confirming some of her concerns about the initial drafts. However, they also provided positive suggestions which she would not necessarily have considered, and which were incorporated into the revised leaflets.

Key learning points

- The researcher, who had not worked with the YPAG before, and was relatively new to research, was well prepared by the LRN nurses. They told her what to bring and what to expect, and made some suggestions about the type of questions the young people would be able to answer, which was very helpful.
- It was noted that it was helpful that the researcher attended the session as the young people appeared to show more interest when communicating with the actual researcher.
- The young people felt needed, valued and listened to by the adults involved. They were pleased that all of their suggestions and comments were taken on board and that the leaflets were adapted to reflect these suggestions.

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Case study 3: Smoking, Nicotine, and Pregnancy (SNAP)

Main aim of the consumer involvement activity

To take children's and parents' views into account when deciding what outcomes to measure in a follow-up study of children, now aged six and seven, who were born to smoking mothers.

Background

Consumer involvement informed the development of a bid for a follow-up study to a randomised trial of nicotine-replacement therapy patches in pregnancy: Smoking, Nicotine, and Pregnancy (SNAP) Trial Team. The follow-up study aimed to examine outcomes among children now aged six to seven years who were born to smoking mothers.

How consumers were involved

After learning about NIHR CRN: Children on the Research Design Service website, the Chief Investigator liaised with the East Midlands Consumer Involvement (CI) lead to set up two focus groups among East Midlands LRN Young Person's Advisory Group (YPAG), and adult members of the CI group.

Approximately ten young people aged between eight and 18 took part in the first group. They were asked to listen to a short presentation on the findings of the original study to provide background. It covered issues such as why nicotine replacement therapies are believed to be safer than smoking during pregnancy and outlined the key findings.

Next, the young people were given ten to 15 minutes to discuss two questions:

- What they thought researchers should be looking for when revisiting children at age six or seven.
- Whether it would be more effective to follow up face-to-face or by administering a questionnaire.

The participants split into two smaller groups (each facilitated by a LRN CI lead) and recorded their thoughts in writing and on audio files which they then shared with the wider group.

A second focus group was held with parents who were involved with NIHR CRN: Children and this followed a similar format.

Reported impact of the involvement

In responding to the Chief Investigator's questions, the young people both helped to verify the researcher's ideas and also provided new suggestions that he had not thought about beforehand.

Feedback on content: in particular, they said that whilst it would be important to measure the children's IQ as a continuous outcome measure, researchers should also focus on children's functionality. Participants reasoned that there was little point in being intelligent if children were unable to function, e.g. able to tie their shoelaces. The group also hypothesised that children born to smoking mothers might find it more difficult to make friends. Children said that friendship was very important to them and their peers, and thought that the researchers should also assess children's sociability.

As a result of the focus groups delivered in partnership with NIHR CRN: Children, additional outcome measures on functionality and ability to make friends were put forward in the research proposal. The study team felt that the CI activity was instrumental in ensuring that the study outcomes were valid, important, and meaningful for young people and parents themselves.

Feedback on method: face-to-face communications were believed to be the most effective method for this research because interviewees would be able to speak for themselves. However, young people's reflections on this question were reported to be less useful than the outcome question because they were not able to weigh up the pros and cons of the different methods. The Chief Investigator believed this was because the question was harder to answer without prior knowledge and experience of research methods. Parents gave similar responses to the questions.

The young people impressed the Chief Investigator with their ability to ask sensible and pertinent questions. Their feedback covered many of the issues that had already been identified by academics, including experts in the field, as well as new ideas. In sum this was a 'very useful experience' which the Chief Investigator would recommend to any researcher in a similar situation, and would consider repeating. Although the bid was unsuccessful, CI was not mentioned in any of the reasons given, and its rejection was due to other factors. The Chief Investigator believed the CI activity provided a good basis for informing the bid and may seek funding from other sources.

Key learning points

- Contact with NIHR CRN: Children facilitated access to established groups who were research conversant during a tight time-frame, which was very helpful for the Chief Investigator, especially being new to CI.

- Prior planning with the LRN CI lead proved to be as helpful as expected, enabling the Chief Investigator to be prepared, deliver his presentation and questioning as simply as possible using animation and graphics, and avoiding using technical language. The young people were pleased with the methods of participation used.
- The young people were pleased to receive feedback shortly after the event stating that their ideas had been incorporated into the study.

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Case study 4: Real-time, Adaptive, Predictive Indicators of Deterioration (RAPID) study

Main aim of the consumer involvement activity

To take children's views into account in the development and implementation of a study of wireless devices for monitoring children and young people's heart beat, breathing and oxygen levels.

Background

The RAPID study is a follow up to the Health Foundation funded Young Lives study. This study collected heart beat and breathing information from children wired to monitors in Intensive Care and enabled the development of smart alarms to detect when they were getting sicker. The RAPID study aims to collect the same information using wireless sensors in a population of children on the cardiac ward.

How consumers were involved

A suggestion that young people should be involved went into the original grant application. A series of meetings with the Young Person's Advisory Group (YPAG) informed the development and implementation of a study of wireless devices for monitoring children and young people's vital signs.

The group of 12 young people, aged 12 to 19, gave feedback at five of the YPAG regular meetings sessions over the course of six months.

Prior to the project being funded, young people were invited to review the funding application.

Once the study had been successful in attracting funding, young people from the YPAG group were approached to review the draft Patient Information Leaflets (PILs) which had been developed with an artist, prior to the ethics submission.

The young people were also asked to help consider the design of the monitors. They were taken into the paediatric intensive care unit and shown examples of both the existing observation monitors, and the new monitors. The benefits and drawbacks to the original monitors were explained (for example, that they weren't mobile). In this context, the young people were asked to feed back about the design of the new monitor. Specifically they were asked about where the monitor should be worn – e.g. on the chest, wrist or ankle, depending on what it is being used to monitor and over what period of time - and the possibility of having adapted designs for different age groups.

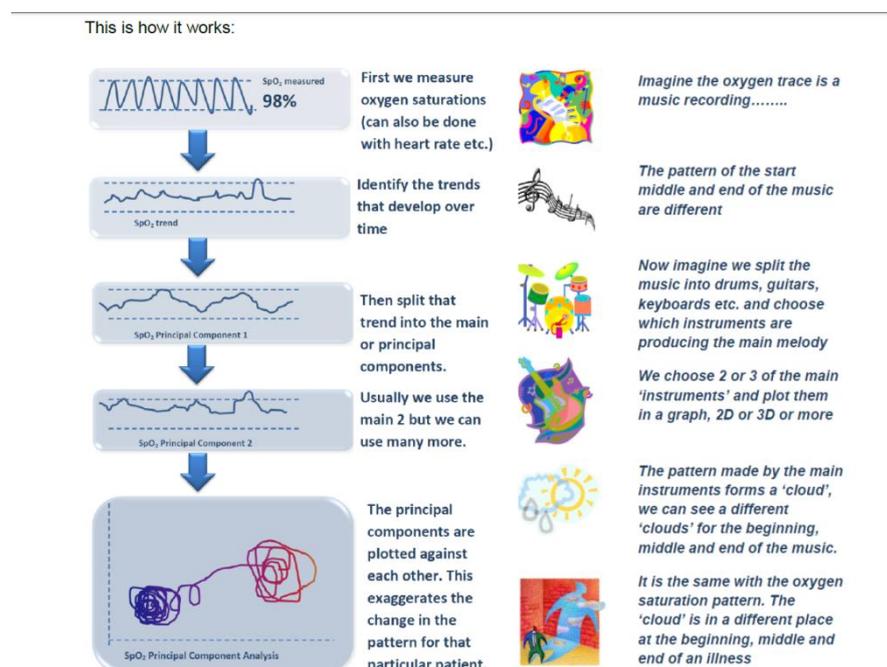
Reported impact of the involvement

The young people were constructively critical of various aspects of the wording and formatting of the PILs, and suggested changes which were taken up. For example, they felt that the leaflet should be more eye-catching and less wordy. They felt that some of the language used in the original draft, including some required or recommended terms within the Integrated Research Application System, was not child-friendly and that too much jargon was used. The young people formulated criteria of 'Do's and Don'ts' which could then be adapted for use when designing future PILs.

The young people said that they would like to see more pictures or cartoons in the leaflet as well as changes to the font, colours, wording, layout and length of paragraphs. This required photographs of the real environment, with children wearing the technology, to be redrawn by an artist to make images realistic but gentler. After seeing the drawings they then added small photographs of the technology back in. These changes were all made and revised versions of the leaflet were brought back to each session for further comment until both parties were completely satisfied. Three versions were developed that were tailored for different ages (young children, children and young people) and finalised with young people's input. A copy of the leaflet for children is provided at the end of this case study.

The young people said that they wanted another optional leaflet, in addition to the PILs, to contain more detailed information on how the monitoring and the mathematical calculations made by the monitor worked. They proposed that communicating this effectively could be achieved by comparing the monitor to music in an orchestra, depicting two main instruments with different melody lines, and a beginning, middle and end to the song. The young people said that this analogy would provide a simple way of explaining how the machine works to other young people, and the suggestion was adopted by the research team, as shown in Figure 1 below.

Figure 1: Excerpt from RAPID study PILS leaflet: How the technology works



Young people's suggestions regarding the design of the sensors were also acted upon and fed into the design of the sensors, helping to ensure they are user-friendly to wear, thus supporting compliance in the study protocols.

Consumer engagement is a prerequisite for ethical approvals and for securing funding. The contribution of the NIHR CRN: Children Young People's Group was regarded as vital by the study team for achieving both of these.

The young people appreciated the ongoing involvement that the researcher had with them and felt that they were being valued and listened to as their proposed changes had been made each time the researcher came back to the group.

The young people prepared a presentation detailing their involvement in the RAPID study and highlighting the impact of their suggestions. They then delivered this presentation at the NIHR CRN: Children AGM.

Key learning points

- The young people appreciated the ongoing involvement over several sessions rather than just once as this enabled them to gain a more in-depth understanding of the topic. However, they felt that in having the five sessions spread over six months, the discussions were spread too widely apart; more closely spaced sessions would have helped with momentum and recall, and maximised effective engagement over time.

- The researcher was well prepared and took the sessions seriously and, as a result, the young people felt needed, valued and listened to by the adults involved. They were pleased that many of their suggestions and comments were taken on board and that the leaflet was adapted to reflect these suggestions.

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Figure 2: RAPID study PILS leaflet for children



Birmingham Children's Hospital **NHS**
NHS Foundation Trust

RAPID: Real-time Adaptive Predictive Indicator of Deterioration [wireless monitoring of vital signs]

Study Information Sheet: for children

- We would like to invite you to take part in a research study.
- Before you decide you need to understand why the research is being done and what it would involve for you.
- Please take time to read the following information and talk to others about the study if you wish.

Why are we doing this study?

We measure your heart beat, breathing and oxygen levels every few hours in hospital to see whether you are getting worse or better.

Sometimes children might become ill so we want to measure your heart beat, breathing and oxygen level *all the time*.

Children and parents have told us they would like heart and breathing monitoring to be wireless. So we are testing new wireless sensors. This hasn't been done before so we are doing this research.



RAPID Participant Information Sheet Children v3 24 02 2013



Birmingham Children's Hospital 
NHS Foundation Trust

Why have I been invited?

We want to be able to use continuous monitoring for all children in hospital but first we are starting with children who are cared for in the cardiac (heart) wards.

Do I have to take part?

It is up to you to decide. We will explain the study and this information, which we will then give to you. If you do not want to participate that's alright. You are also free to withdraw at any time, without giving a reason. If you do want to participate then you and/or your parents need to sign a consent form.

What will happen if I take part?

You will need to wear 2 extra little monitors (plasters) that can collect your heart beat, breathing and oxygen levels all the time.

They are very similar to our usual monitors except they are *wireless* so you can move about more easily without getting tangled.

There are is no danger to taking part in this research but wearing the 2 extra monitors may be a little uncomfortable. Otherwise all your care will be the same.

What will I have to do?

If you and your parents agree to join the study, then the nurses will attach and connect the wireless monitors. We would like you to wear the monitors as long as you are in hospital. If you don't want to join the study then you need do nothing else.

Will the study help me?

We cannot promise the study will help you but we hope it will help other sick children in the future.

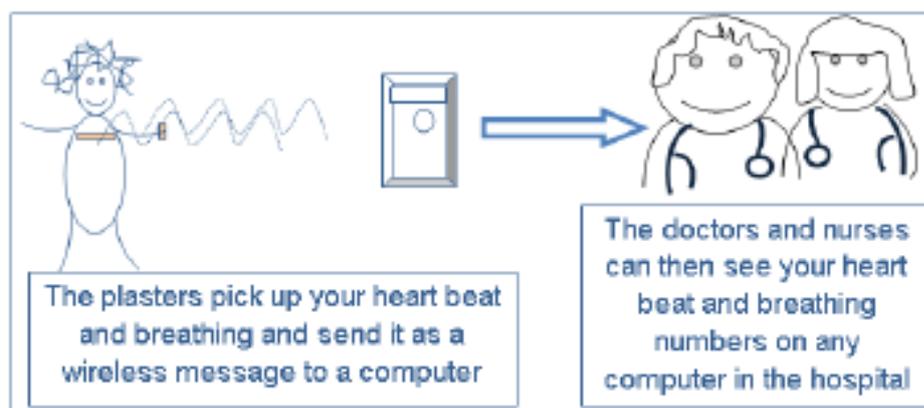
RAPID Participant Information Sheet Children v3 24 02 2013



Birmingham Children's Hospital **NHS**
NHS Foundation Trust

How does it work?

The plasters send your information wirelessly by Wi-Fi. We would like to save information about you on a computer so that we can study it carefully.



We are using the computer program used to monitor racing cars to help us see early signs of children getting sick.

What will happen if I don't want to carry on with the study?

You can withdraw from the study and opt out of the information being stored at any time and all study information related to you will be destroyed.

What if there is a problem?

Any worries about this study can be answered by the research nurses who come to the ward daily.

If you have any questions ask your bedside nurse to contact one of the RAPID Research Team who are available every day or to contact Dr Heather Duncan on 07917 052 953.

Thank you for reading this information!

If you would like some more technical details we have another sheet that explains the details. Just ask the research nurse or your bedside nurse for 'How the RAPID technology works?'

RAPID Participant Information Sheet Children v3 24 02 2013

Case study 5: Generation-R

Main aim of the consumer involvement activity

The Generation-R ('R' for research) event aimed to showcase the value and importance of involving young patients and parents in research.

The event was developed, organised and run by young people and parents and spoke to their belief that the meaningful involvement of children in the design of research would improve its quality, delivery and impact.

Background

In summer 2012, the Consumer Liaison Manager and Director at the national Co-ordinating Centre for NIHR CRN: Children decided to hold a stakeholder event to showcase how young people and parents shape the design of research to improve its quality, delivery and impact. They invited NIHR CRN: Children Young Person's Advisory Group (YPAG) members from each region and parents from the clinical studies group to an initial planning session in October 2012. At this meeting, attendees discussed ideas, drawing on the findings of a survey which the Consumer Liaison Manager had sent to all members to gather views on what type of event they would like.

By the end of the first planning meeting, participants had agreed the main tasks and taken responsibility for different aspects, such as the event format and marketing, to take forward. The planning group came together again in May 2013 in preparation for the Generation-R event, which took place in September 2013.

How consumers were involved

Young people were involved by being empowered and supported to plan the whole event, including both format and content.

Young people were asked to complete an application form explaining why they wanted to take part in organising the event, recording any particular interests they might have so as to help the organisers better allocate tasks. As interest was high, and all applicants were believed to be confident and comfortable communicators, three or four young people from each YPAG were accepted as members of the planning group – an increase from the planned two.

In between the national planning meetings, regional groups met and discussed the event as part of the agenda for the regular YPAG meetings. Each YPAG had a specific task for which they were responsible.

Parents also attended the national planning meetings where they supported young people with ongoing tasks and later were on hand to help on the day.

Aside from the venue choice (the Science Museum, which the young people 'loved' the idea of), the whole event was designed by young people and parents, including design, formats, choice of speakers, topics and sessions, and catering, etc. In the approach that young people and parents took to this, the Consumer Liaison Manager described how young people had very creative and impactful ideas for showcasing Randomised Controlled Trials and networking. Examples of the ideas taken forward by young people included:

- The young people decided on a BBC breakfast format for the first half of the day in preference to a series of regular conference presentations and a theatre room layout. They felt this would make the event different, memorable and impactful. They designed many aspects of the event to fit in with this - from the couches and television screen set up as background, to recording the event as if it was live on television. In preparation for the 'live' screening, some of the young people met with two guest speakers to talk about what they wanted to ask them on the day, finalise the topics and questions, and practice.
- They specified a 'casual' dress code for all delegates, to give a friendly and relaxed feel, and to help ensure that young people and adults (including many high profile figures) could engage with each on a more equal level.
- Young people designed the art work for the event. This helped to emphasise young people's ownership of the event and the 'space' in which the event took place. They chose to design a tube map (as the event was held in London) where each tube line led to a Randomized Controlled Trial related fact or image, such as a portrait of James Lind, one of the first researchers to run a clinical trial. In addition, they linked with Imperial College to recruit a science artist who painted hearts on hands while talking to delegates. Young people also contributed to the art installation in the foyer, supporting an overall sense that it was a youth-led event, with the content and space defined and owned by young people.
- The event was co-chaired by a young person, and the high profile speakers were presented with direct and powerful questioning by young people. The NIHR CRN: Children Joint Interim Director reported that this encouraged speakers' responses to be young-person focused (in content as well as language) in a way that they might not have been if questions had been posed by adults.
- Young people developed films and 'vox pops' to bring key messages to life. For example, they carried out vox pops with members of the public to highlight the public's views of research involving children.

Reported impact of the involvement

From the very first meeting, the young people surprised adult organisers by how passionate they were about promoting research and the involvement of children and young people. This passion gave drive and direction for the Generation-R event as it developed over subsequent months.

The event was reported by case study participants in interviews to have been very successful in achieving what it set out to do in terms of helping to demystify research and to educate the next generation about the benefits of involving children and young people. Key to this, the unique and creative ideas that the young people developed and implemented in taking forward the event were deemed to have made it incredibly memorable, enjoyable and impactful in demonstrating just what can be achieved when young people are involved and empowered.

This was also reflected in feedback from attendees. Young people recorded *vox pops* during the lunch break to record participants' reflections on the impact of consumer involvement and what they would take away from the day. In sum, the high level of input from young people into the event programme made it "one of the most unique experiences ever" (Consumer Liaison Manager) and ensured that the aims of the event were met. Simon Denegri (National Institute for Health Research (NIHR) National Director for Public Participation and Engagement in Research, and Chair of INVOLVE) described it on his blog as "the event of the year".

The event attracted a number of high profile NHS decision-makers and figures in medical research, both in the UK and internationally. Its impact on such attendees was deemed to have been real and immediate, and is expected to have a lasting legacy. For example, Chief Medical Officer, Professor Dame Sally Davies, gave highly vocal endorsements of, and commitments to, children's involvement at the event. A report of the day was subsequently produced by a YPAG member and presented to the Chief Medical Officer, who was also fully supportive of the recommendations made following the event. Reflecting this, the Chief Medical Officer's annual report in October 2013 made a specific recommendation for children and young people's involvement in clinical research¹⁸.

Other feedback provided by attendees, as detailed in the full report of the event¹⁹, included the following:

¹⁸ <https://www.gov.uk/government/publications/chief-medical-officers-annual-report-2012-our-children-deserve-better-prevention-pays>

¹⁹ Medicines for Children Research Network (January 2014) *GenerationR: Young people improving research: 2013 Meeting Report*

- A quote from industry: *"I will encourage my department to involve the YPAG earlier and more often when writing protocols and documents."*
- A quote from a charity funder: *"We will start to ask our grant applicants if they have consulted children in the design of their study."*
- A quote from the Dutch clinical research community: *"The example of involvement in research of young people in the UK is an inspiration for researchers in other countries."*

Key learning points

- The cost and time implications of bringing a national group together when planning a national event must be accounted for but, while it can be challenging, it is worthwhile.
- Regular communication between CI leads was key to ensuring everyone was kept up-to-speed with developments.
- Detailed planning for the day was necessary to its success – including, for example, role descriptions, schedule, timings, and seating plans.
- The success of the event demonstrated the power that a large-scale event can have, and that investing in youth-led activities in this way can pay off.

Further information and a link to a full report of the event can be found online on the NIHR Clinical Research Network website.²⁰

For further information, please contact:
NIHR CRN: Children Co-ordinating Centre
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²⁰ <http://www.crn.nihr.ac.uk/resources/generation-r-report/?h=9>

Case study 6: Health Research Authority (HRA) – public opinion of the research approval process and the role of the HRA

Main aim of the consumer involvement activity

The Health Research Authority (HRA) is looking at the overall research approval process across the NHS and how it might be improved. The HRA worked with young people, as well other patient groups and the general public, to seek their opinions on how to improve the research process and the overall approval system.

The dialogue exercise specifically aimed to seek young people's views on the proposals to streamline and simplify the research approval process to make things easier for researchers, for example, by streamlining consent and assent forms. In addition, the session covered other elements of the role of the HRA, for example, the publication of research findings and patient and public involvement in research.

Background

The HRA is responsible for the running of the National Research Ethics Service and will be taking responsibility for research governance in addition to ethical review. The HRA set up a public dialogue exercise to look at the overall research approval process across the NHS and how it might be improved.

With the support of Sciencewise, a series of workshops have been held with members of the consumer groups across the country. The overall aims have been to seek views on: health research and clinical trials; how patients should be recruited and their valid consent gained; the extent to which they might feel protected by the approval process or at risk; what needs to be in place for them to have trust in the system; and ideas as to how HRA should work with patients and the public in the future.

How consumers were involved

This case study focuses on a two hour workshop held by the HRA with 17 young people from the NIHR CRN: Children Young Person's Advisory Group (YPAG) to seek the opinions of young people regarding the research process and the overall approval system, including the use of participation information sheets.

The dialogue exercise began with a presentation about health research and the role of the HRA and the current system for research approval. Local researchers were then invited to talk about their experiences of seeking research approval. This was followed by facilitated group discussion and more in-depth discussion

in smaller break-out groups. Young people fed back their thoughts and ideas throughout the session.

Reported impact of the involvement

The group of 17 young people made several recommendations for consideration. For example, they suggested that the HRA play a role in promoting Consumer Involvement (CI) in health research; that every research study should involve CI; that the research should be made more accountable to patients and the public, including children and young people, and have CI to prove it; and that, where appropriate, young people, should be involved at every stage of research, including at the early stage of the design of communication materials to, for example, help avoid use of ambiguous wordings.

Young people also recommended that participation information sheet templates produced by the HRA should be amended to include a heading on what patient and public involvement has taken place in the development of the study.

The HRA have reported back the recommendations made by young people to the senior management and steering group so that they can inform the development of the future policy of the approval process. A detailed report has also been produced and can be found at: <http://www.hra.nhs.uk/patients-and-the-public-2/how-the-hra-works-with-patients-and-the-public/what-patients-and-the-public-think-about-health-research/>

The Chief Executive of the HRA and the Chair of the dialogue project Oversight Group gave evidence at the Select Committee on Science and Technology inquiry on clinical trials, in July 2013, and provided [written](#) and [oral](#) evidence drawing directly on the dialogue findings.

The HRA [response](#) to the Committee report (October 2013) also refers to the dialogue and its findings, and explains that the dialogue has informed the HRA's transparency strategy. The project findings fed directly into the wider debate launched by the HRA on the transparency of research through publication of research findings. The HRA published its views in its paper 'Transparent Research', published in May 2013, which refers directly to the dialogue project findings.

The findings of the dialogue also triggered the HRA development of guidance for researchers on 'Information for patients at the end of a study', and informed the development of the '[HRA Strategy for public involvement](#)' - both these initiatives were consulted on in late 2013/early 2014. Dialogue findings are also informing revisions to the standard template Patient Information Sheet that is used by most health researchers.

The results are also being fed into the wider Research Governance Framework, which is being revised in 2014 and, in the longer term, into revision of the [Governance Arrangements for Research Ethics Committees](#).

Key learning points

- It was 'obvious' that the young people had undergone previous training around research, critical analysis and feedback as they could run with the discussion much more than the group of adults from the previous day.
- Linking with researchers well in advance to ensure that materials and presentations were suitable and interesting for the young people was extremely important and worked well.
- Seventeen young people in a group was deemed to be too large a number to facilitate good discussion and allow the effective input of all participants. Smaller sessions or use of break-out groups during larger group sessions were recommended for similar future events.

For further information, please contact:
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Case study 7: Metfizz

Main aim of the consumer involvement activity

The aim of the Consumer Involvement (CI) activity was to work with young women, including those with Poly Cystic Ovary Syndrome (PCOS), to inform the presentation of a new formulation of Metformin for testing among young women with PCOS.

Background

Metfizz is a clinical development project for an effervescent Metformin soluble for the treating of PCOS in adolescent girls. Metfizz receives funding from the Seventh Framework Programme of the European Union and is co-ordinated by EffRx Pharmaceuticals SA, a speciality pharmaceutical company. EffRx will lead the Metfizz product commercialisation.

PCOS is a common disorder affecting 5-10 per cent of women of reproductive age. The common off-label use of Metformin for treating PCOS in children appears to have no greater risk than in adults, but clinical trials are needed to validate the safety and efficacy of this agent in PCOS. This is the first time a pharmaceutical company has formed a partnership with the NIHR CRN: Children consumer liaison work-stream to involve patients from the initial design stage right the way through to completion of the study.

How consumers were involved

The University of Liverpool was approached to take forward Consumer Involvement (CI) in this project. The overall expectation was that young people will be involved throughout, inputting on a range of aspects over time, including the presentation and packaging of medicines, the study protocols, the outcomes to be measured in the study, as well as patient information leaflets.

This case study reports specifically on the CI activity that took place among young people to inform the packaging, flavour and appearance of the medicine for patients in the trial.

Two groups of young people were consulted: (i) a group of 20 members of the NIHR Young Person's Advisory Group (YPAG), aged eight to 18, and (ii) a group of nine young women currently being treated for PCOS, aged 13 to 18.

The YPAG members initially worked together in a group to shortlist possible flavours for the medicine, such as banana, strawberry and orange, and to develop a discussion guide which could be used for consultation and involvement with the PCOS group. The PCOS group were then interviewed individually via one-to-one in-depth interviews to explore their views on the

medicine (flavour, packaging and colour). This group were also given a 'sniff test' of the shortlisted flavours to choose from.

Reported impact of the involvement

The majority of young people consulted recommended that the medicine should be orange flavoured. The research team have therefore opted for this flavour with the expectation that using a flavour that appeals to young people will help support compliance with taking the medicine during the trial. The study is yet to start, but young people's opinions about the new medication will be captured through weekly diaries that young people in the trial will be asked to complete.

When discussing whether the medicine should be coloured or clear, the young people from the YPAG group expressed a preference for it to be coloured, regardless of the additional additives which would need to be included. As it wasn't possible for the PCOS young people to be consulted on this aspect, the CI lead consulted with parents who said that they would prefer the clear medicine for young people as it contained fewer additives. The researchers decided to opt for the clear version based on the assumption that the young people with PCOS would be more likely to be health conscious and aware of the types of additives used in medicines, and thus would be more inclined to opt for a clear medicine which contained fewer additives.

Young people also fed back their views about what the packaging should be like, and many of their suggestions were taken on board.

The research team felt that taking young people's and parents' views into account on the appropriate presentation and packaging of the medicine will have helped to support effective participant engagement in the study, and thereby support its overall success.

The YPAG group were provided with feedback about the progress of the development of the medicine and the impact of their suggestions via regular meetings with the CI lead. At the time of the case study interviews, there were also plans to feed back to the PCOS group about how their suggestions for flavour and packaging were taken on board at their next group meeting.

Key learning points

- The CI lead was grateful for the support of the staff in the clinical research facility and the clinical staff as they were able to provide a physical space for the consultations to take place and offer logistical and practical support.
- Setting up a specialist group for young women with PCOS proved time consuming and challenging and this needs to be borne in mind for any future projects of a similar nature. In this case, this process required the

CI liaising with a key contact who was already working with young people with PCOS and who then contacted all the possible young people asking if they would like to take part. The young people then had to be interviewed and fully briefed before they could be asked for consent to participate in the study. The process of setting up the group took several months.

- Setting dates for meetings with the PCOS group was also challenging on account of the distance that the young people would need to travel and their availability.
- The young people appreciated that their views were being taken into account and were pleased that their choices of flavour and packaging were selected. This highlights the importance of ensuring that young people's input is genuinely taken on board, and the benefit of feeding back to participants.

For further information, please contact:
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Case study 8: Quality of Life with Increased Tone study

Main aim of the consumer involvement activity

Consumer Involvement (CI) for the Quality of Life with Increased Tone study was carried out to help to inform and finalise the trial protocol, including outcomes, and Patient Information Leaflets (PILs) for young people and their parents/carers.

Background

The Quality of Life with Increased Tone study is a randomised controlled trial of oral medication for children with increased tone (such as young people with cerebral palsy). The medicines aim to reduce the tightness and stiffness in their bodies. The study has not started yet, but we involved children with increased tone, and their families, at an early stage in discussing trial outcomes, design, and information sheets.

How consumers were involved

Young people with increased tone and their families met with the group of two or three researchers several times over three years. Between four and eight families took part in each session and sessions lasted approximately two hours. Many of the young people involved had severe learning disabilities so most of the input came from parents/carers although the input of young people with less severe disability was facilitated.

The group discussed three key elements of the study: trial outcomes, trial design protocol, and PILs.

Each session comprised a thirty minute icebreaker followed by a half hour presentation from the researchers about the study and an update on the design. After a short break for participants, the session concluded with a one hour group discussion and a short summary of the session.

All sessions were held after school/work from 5.30pm.

Reported impact of the involvement

Trial Protocol - Outcomes: The group discussed how they often differed in opinion to doctors when prioritising outcomes. For example, doctors seemed to be more focussed on primary clinical outcomes (e.g. the measure of tone) but parents and carers were more concerned with 'secondary' outcomes relating to young people's experiences and quality of life (e.g. pain and participation). These parent- and carer-valued outcomes will be included. The research team

report that this has improved the value of the research because it now addresses the outcomes which are most important to patients themselves.

Trial Protocol - Design: Parents and carers highlighted key areas of concern about the initial study design. For example, the group agreed that they did not support a placebo controlled or a crossover design, for fear of the pain that could ensue from increased tone. They agreed that their preferred method would be a feasibility study of the main current drug versus the new drug. This was in fact the main outcome of the consumer involvement and will form the basis for future trial protocol. The trial has not started yet, so there is no definitive evidence regarding how successful this design will be. However, it is felt that the involvement of patients has resulted in a design that is appropriate to patients' circumstances and that therefore this should help support effective recruitment and retention of patients.

PILs: the most common theme suggested to improve the leaflets was to make them less cumbersome and to have less text. Generally, adults seemed to prefer the leaflets designed for twelve year olds and twelve year olds preferred the ones designed for eight year olds. It was noted that the group was too small to gain a truly balanced view of the PILs, however some themes came through such as the use of colour in fonts and pictures, and having fewer words, if possible, and this feedback has been taken into account. By developing the PILs alongside the consumers, the study researchers hope to have improved effectiveness in engagement with the patients and their parents/carers, aided recruitment, and made consent/assent processes easier.

Consumers were kept informed with regular reports which were sent to them after each meeting. At the time of the case study interviews, there were plans to keep young people informed of the study's progress after it has moved on to the next stage.

Key learning points

- The researchers noted that a group size of larger than four to eight families for each session may have been helpful in providing a more balanced picture of children and families' views.
- Parents and carers tended to use the sessions as a 'sharing' forum, discussing other issues that were unrelated to this specific study. Although this did use up some of the allocated time, it provided an insight into other topics and concerns which, in turn, led to interesting discussions and debates. It could be worth factoring time for this in session plans for future projects.
- Consumers said that they would have preferred to have had sessions spread over a shorter time period and to not have had to wait so long between each one. If the speed of progress of the study precludes a

more streamlined timetable, it may be helpful for researchers to consider ways to keep in touch with participants in between sessions.

- Consumers appreciated having the sessions on week days (for example, avoiding encroachment on weekends), and also that they were run after school/work to make attendance possible.
- Consumer evaluation of the involvement showed that parents and carers valued the chance to give their opinions and to have their queries “answered in a way that I can understand”. They liked having an informal, yet informative, structure to the sessions and said that they would be happy to attend similar sessions if their input was sought.

For further information, please contact:

Local research network: East Midlands LRN

Kirsty Widdowson

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Case study 9: Formulations Research

Main aim of the consumer involvement activity

Young people were consulted as a means of informing a planned study to compare new and existing treatments for children with low levels of vitamin D.

Background

The planned study will identify children whose levels of vitamin D are low and compare the existing treatment, which is daily drops of vitamin D (ten drops every day) for up to eight weeks, to a one-off very large dose of vitamin D (up to 12.5mL = 2.5 teaspoons). Two blood samples will also be required from children that participate in the study.

How consumers were involved

Focus groups were held with young people; these included research-naïve young people (n=30) as well as an experienced NIHR young persons' group of 12 young people aged 11-19.

The discussions focused on exploring young people's perceptions of the two forms of medication and what would be involved for young people in participating in each arm of the study. The aims were to understand how young people viewed the two therapeutic regimes, and identify potential barriers to compliance and how compliance could best be supported in this context. In particular, two specific issues had been identified as potential hurdles within this study and were discussed in detail, including the need for two additional blood samples and ensuring compliance with the therapy for the daily dosing in particular.

Following consultation with young people, the research team consulted with parents regarding any further ideas for how the issues raised by young people could be addressed to help ensure effective delivery of the study. Parents were invited to input via an informal chat after their clinic visits or to feedback via a written form.

Reported impact of the involvement

The young people provided a range of rich feedback regarding their perceptions of the alternative forms of medication.

For example, the young people said that they would prefer to have a one-off dose of medication, as they may forget to take the daily dose, especially if they are feeling well. They also suggested ways that children could be reminded to take the medication if it was to be taken daily, such as via text reminders, sticker charts or rewards.

The young people also raised that compliance with the two extra blood test may be a challenge for some young people but that this was not necessarily insuperable. In particular, they said careful consideration should be made with regards to the timing and location of the blood tests to help ensure accessibility. The group suggested offering blood tests at home, or at convenient locations such as walk-in surgeries instead.

Parent's comments were well aligned to those of the children and young people.

The lead researcher was pleased with the outcomes of the participation activity and said that, although the study would have been possible even without the young people's involvement, their input proved to be invaluable in shaping and improving implementation approaches, because many of their suggestions, such as having text reminders or sticker charts, were innovative and had not been previously considered.

As a result of the CI activity, the study team have been reviewing their protocol to incorporate the views of young people, specifically regarding collection of additional blood samples and the inclusion of age-appropriate tools (e.g. sticker charts or text reminders) to aid in compliance for the daily dosing arm. Revised proposals also include costs to allow for home visits for blood sampling to minimise the impact on participants in response to comments made by the children, young people and parents.

The young people have been contacted since the activity with individual letters from the researcher thanking them for their involvement. At the time of the interviews, there were plans for a poster of the key findings of the study to be shared with the young people, once finalised.

This work has been presented at National and International conferences. As a result of this project, two members of the YPAG also attended formulations work experience at the University of Birmingham and undertook a formulations project.

Key learning points

- The ethos of the Young Person's Advisory Group (YPAG) facilitated effective involvement. In particular, the informal, supportive atmosphere allowed young people to encourage each other to speak and voice their individual opinions.
- For future studies, a more senior researcher or consultant would be approached to speak to the young people in addition to the more junior research, as it is felt that this could give the activity more gravitas and raise the profile of the work amongst the young people.

- The researcher recommended keeping an open mind and being prepared to make genuine modifications to the study accordingly based on feedback. In this context, they would advise others to consult with young people early on in a study, before details have been finalised.
- The researcher stressed the importance of talking through the plan for the day with the YPAG adult leaders in advance of the discussion session with young people, as they had valuable insights about how to make this work best, and were accustomed to working with the young people on similar studies.

For further information, please contact:

Local Research Network: West Midlands LRN

Claire Callens

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Case study 10: Involving People in Research

Main aim of the consumer involvement activity

To gain young people's views about involving people in research.

Background

Following discussions about recent changes in local research networks and how more people could be involved in research, the local healthcare trust, the lead researcher of the NIHR Clinical Research Network and a mental health advocate decided that young people should be consulted to provide their views on the matter.

How consumers were involved

The Young Person's Advisory Group (YPAG) was asked to contribute to a piece of work exploring how to involve more people in research. Eight young people aged five to 16 from the YPAG made a 'research collage', using pictures, phrases and lettering from a range of materials to depict the title 'how to get more people involved in research'.

To create the collage, the group met on a Saturday morning at the time usually allocated to a YPAG meeting. They began the session by deciding upon the top ten messages that they wanted to convey and then working together to find images and words to convey these messages.

Reported impact of the involvement

The collage has been shared widely and is often used at local and national presentations to highlight the key areas that young people consider to be important when involving people in research.

The young people thought the nature of the activity – discussing, cutting and pasting – was fun and allowed for free association of the mind. They noticed that whilst printed words can sometimes have different meanings (e.g. 'collaboration' could mean 'work together' or 'cooperate') – images tended to more clearly depict what they were trying to say (e.g. a hand-shake).

The lead researcher said that the involvement of young people had led to different aspects of the research process being considered. For example, one of the top tips that young people agreed on was for researchers to smile more. They said that the more researchers smile at people and talk about research opportunities in a friendly way, the more people will want to get involved. The researcher agreed that this was a valid point and one that had not been considered previously.

The final collage and top-tips can be viewed here -
<http://research4eastmidlands.blogspot.co.uk/>

Key learning points

- The relatively young age and dynamic of the YPAG group provided an excellent opportunity to work creatively, in that they were an existing group who met regularly and were used to working on similar projects. This method of discussion and collage making was deemed highly successful and a potential method to adopt when working with a range of groups, including adults, as it allowed for group discussion, interaction and creative thinking.
- Running the session during an existing meeting worked well as the young people did not need to allow any additional time for the work.
- The task produced a tangible output and the collage has since served as a visual 'product' which is accessible to lots of people whilst the accompanying 'top-ten' list provides more detail.
- The lead researcher recommended that the session with the young people focus on where *they* are at with the project rather than the stage which the project is at. For example, the young people were unaware of previous discussions, they were simply asked to consider: 'how should we involve people in research?'

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Appendix C – Evaluation methodology

The evaluation is based on three areas of data collection activity:

- a. Collection and analysis of monitoring data for Consumer Involvement (CI) activities.
- b. Qualitative case studies of ten CI activities identified as effective practice.
- c. Collation of data from feedback forms for parents involved in Clinical Studies Groups (CSGs).

a. Monitoring data collection and analysis

The scope of data collection

In 2013-2014, CI activity monitoring focused the Co-ordinating Centre's and the LRNs' CI work with *children and young people*, for *specific individual research studies*. The intention was to pilot data collection on these specific types of activities, before rolling out to monitor data on the other CI activities undertaken within the network.

Monitoring was designed to provide an overall picture of CI activities across the network in terms of: number, types, outputs and reported outcomes. In addition, the evaluation aimed to profile the range of studies supported with CI work, by region, type of research project and stage of project.

Sample

The intention was for monitoring data to be completed by each of the CI leads across the network and the Co-ordinating Centre, for relevant CI activities, as and when they took place.

In practice, only the Co-ordinating Centre, and the four CI leads who had a Young Person's Advisory Group (YPAG) completed the spreadsheet. The manager of the Co-ordinating Centre felt that this reflected the fact that the other areas do not have a dedicated staff member devoted to CI work, and therefore have limited time to conduct and report on CI work.

As such, it needs to be borne in mind that the data does not reflect the activities of two regions; though it is also likely that the level of activity was lower in these areas.

Data collection method

The Consumer Involvement Steering Group supported by the NCB research team developed a monitoring spreadsheet. Many of the fields were "open text box" fields, and data required coding into categories for the purpose of reporting.

It was intended that the spreadsheet should be completed as an online form, as and when activities took place, and an online version was set up. However, due to technological issues, and lack of password access for some CI leads, this was not possible. CI leads were subsequently asked to enter details into an Excel file.

As mentioned, the evaluation sought to profile the range of research studies supported with CI work, by region, type of research project, and stage of project. To do this, data from relevant fields in the CRN: Children project portfolio database was matched into the monitoring spreadsheet. In practice there were a number of challenges in using and interpreting this data. Some manual checks and recoding was necessary. This reflects that the database has not been designed for this type of analytical purpose.

b. CI activity case studies of good practice

The scope and purpose of the case studies

Ten specific CI activities, identified as innovative or effective CI, were explored through qualitative case study work. The purpose of the case studies was to illustrate the range and nature of effective CI work taking place, explore stakeholder's experiences of the CI work, and provide learning regarding how CI can be effectively delivered to make a positive difference to the quality of research study outcomes.

The NIHR CRN: Children Co-ordinating Centre, and six regional Local Research Networks (LRNs) were asked to nominate examples of innovative or effective CI activities.

Case study sampling

Twelve examples were nominated by the Co-ordinating Centre, South West LRN, East Midlands LRN and the West Midlands LRN. We then selected case studies to provide a regional spread across England in terms of the activities represented and a total of ten are reported on here.

All case studies selected involved CI work with children, but a small number also involved parents. In addition, whilst most case studies examined CI work relating to specific individual research studies, two of them involved work relating to approaches to research with children and young people in general.

For each case study the NCB research team aimed to conduct telephone interviews with the study's Chief Investigator, the researcher who led on the CI activity and/or a participant. Between December 2013 and August 2014, ten case studies were completed involving a total of 17 stakeholder interviews. Appendix A provides a full list of the case studies, and the range of stakeholder feedback obtained for each one.

c. Collation of data from feedback forms sent to parents involved in Clinical Studies Groups (CSGs).

The final aspect of data collection was feedback forms from parents who participated in CSGs. Every time a parent/carer/patient representative attends a CSG meeting they are invited to complete a feedback form about their experiences of involvement in the meeting itself, and also regarding any involvement they have had in reviewing individual research proposals since the previous meeting they attended.

For this evaluation report, data was collected from the 14 feedback forms completed by parents who participated in a meeting during the period October 2012 and March 2014.²¹

Whilst this data is based on a small proportion of parents' experiences, it is useful in providing an indicative picture of experiences. However, responses may not be representative, for example, parents who have been most effectively engaged within the CSG may also be those more likely to respond.

d. Collection of data in future years

Drawing on the learning from the evaluation this year, we highlight four activities that we feel would support successful data collection in future years:

- Collectively agree pre-coded categories of CI activity and research types to avoid the need for back coding.
- Review the viability of an online system for recording monitoring data, and consider whether or not it is more user-friendly and efficient than an Excel spreadsheet.
- Exploration of whether some profile data fields should be added to the monitoring data form to avoid the need for matching in and cleaning profile data from the portfolio database.
- Consideration of how to maximise response rates to feedback forms in order to help improve the representativeness of data, including via consultation with parents about this. For example, it may be possible to increase response rates by reducing the burden on parents to completing just one feedback form per year, rather than one every session.

²¹ Whilst the evaluation period covers April 2013 to March 2014, the inclusion dates were expanded to include feedback from early meetings to maximise the sample size reported on, and because feedback forms have not previously been included in evaluation reporting.