



Patient and Public Involvement (PPI) Impact Case Studies 2020-21



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1. ChromaDose

Advancing a bedside blood-testing tool to support personalisation of cancer treatment in children

A co-production initiative between researchers, GenerationR Alliance groups and GOSH Young People's Forum (YPF)

About the researchers and their research

ChromaDose is a project led by Dr Stefan Guldin (UCL Chemical Engineering) which brings together a multidisciplinary team of experts – UK patients, doctors and researchers for 30-months, to develop a bedside drug monitoring technology, enabling optimal dosing (the right amount of medicine) in childhood cancer. Their vision is for all children receiving anthracycline anti-cancer medicines to benefit from the safety and effectiveness of personalised treatment.

How does a doctor choose the right amount of medicine for you?

Until now, the best way has been to use each patient's height and weight as a guide. The problem with this method is, that medicines can move around the bodies of two people (with the same height and weight) very differently.

What is Medicine "exposure"?

It's the concentration of medicine in our blood and how long it stays there. Even if we are all given the same amount of medicine, our individual "exposures" will vary, because medicines are digested and move around each person's body differently. This influences how well medication works and the unwanted side effects patients may experience.

What is the problem?

Anthracyclines are anti-cancer medicines given to more than 10,000 children with cancer in the UK. Unfortunately, these medicines can cause heart problems for two-thirds of children; these side effects are linked to unnecessarily high medicine "exposure".

What is the project aim?

It is impossible to accurately predict patient medicine "exposure" without doing a blood test. During this project, researchers will develop a new tool called ChromaDose to help nurses do these tests at each patient's bedside.





Where in the Research Project Lifecycle did PPI take place?

Patients and the public have been involved in developing the proposal and will be throughout the research lifecycle. The ChromaDose team wish to adopt a co-production model to their Patient and Public Involvement.

The aims are clear and from my perspective the plans are appropriate and realistic - specifically the PPI plans which I think are excellent. The plans to dissemination and impact are clear and I specifically positively note that there are plans to keep patients and public up to date with the research (using appropriate pathways - both in terms of method and also age appropriate) throughout the research process (and not 'just' at the end).

Funding application reviewer

The PPI plans are directly and frequently referred to within and throughout the work plan - both in regards to having input into the research, as well as having a role within the governance/strategic oversight of the research process. From my perspective I don't think they could be improved further.

Funding application reviewer

How would ChromaDose work?

- The technology will assist a nurse in taking a few drops of blood at different times.
- These samples are inserted into the ChromaDose bedside device using the innovative test cassette.
- The machine will automatically measure the amount of drug within each blood drop taking a fluorescent photo (higher amounts of medicine will produce a brighter image).
- With this information, ChromaDose can calculate the patient's drug 'exposure' quickly, easily and reliably.

How does the research benefit patients?

- Drug exposure shows how each patient is processing their treatment, allowing clinicians to predict if the patient will experience unwanted side effects and how successful the drug will be.
- Medicine "exposure" information (provided by ChromaDose whilst the patient is in the room) would help doctors select the right amount of medicine for each patient. This personalisation could improve the chance of the medicine working and reduce unwanted side effects.
- Such a personalised approach has the potential to improve the health outcomes and experiences of patients, elevating the standard of care for children with cancer.

This research has the real potential to offer patient benefit both in terms of optimising/ personalising the amount of treatment a child receives and also reducing the changes of unwanted side effects. Both possible outcomes are equally important in my opinion.

Funding application reviewer.

Who are involved?

The ChromaDose team are working with a diverse group of stakeholders including children, parents, nurses, doctors, educators, designers, scientists and engineers. The Young Persons Advisory Groups (YPAGs) at Great Ormond Street Hospital and North England will remain important collaborators throughout the project. Additionally, parents and wider families of children who have experienced cancer will contribute through the Paediatric Oncology Reference Team (PORT).

- GOSH Young Persons' Advisory Group (YPAG) for research
- YPAGne Young Persons' Advisory Group Newcastle (introduced to the project by GOSH PPIE Lead for research)
- GOSH Young People's Forum
- Representatives from Southampton Young Persons' Advisory Group (YPAG)
- Chelsea Community Hospital School

I positively note another co-applicant is the Patient and Public Involvement Lead for research at Great Ormond Street Hospital BRC who will facilitate the team's engagement with the Young Persons Advisory Group for research at GOSH (YPAG).

Funding application reviewer

Round 1 of Involvement

62 young people completed an online pre-award questionnaire (with embedded videos), this took around 45mins to complete. The team wanted to get their feedback in order to help shape the research from the on-set:

- personal experience with blood tests: **Starter questions**
- need for therapeutic drug monitoring, personalised medicine: **Background**
- how will ChromaDose work: **Technology**
- information giving – age groups, formats: **Patient Information Materials**

Round 2 of Involvement

- GOSH and YPAGne Patient and Public Involvement Leads for research attend Chromadose Kick-off Meeting – January 2021
- The ChromaDose team attend their first YPAG meeting with YPAGne on 11 March 2021 (16 young people attend)
- The ChromaDose team attend their first YPAG meeting with GOSH YPAG on 27 March 2021 (23 young people attend)

The aim of these sessions was for the team to meet the YPAG members, re-introduce the project and consult with the group by:

- showing them the raw data of the pre-award questionnaire
- consultation for interpretation of the results
- asking them to respond to follow-up questions for selected topics centred around (i) blood sampling, (ii) confidence in technology and (iii) modes of interaction, using Jamboard and Google Forms questionnaire in breakout rooms.

ACTIVITY 1: BLOOD SAMPLING

convince you to participate in a clinical study for therapeutic drug monitoring?



ACTIVITY 1: BLOOD SAMPLING

convince you to participate in a clinical study for therapeutic drug monitoring?



What Impact has PPI had on the project so far?

Feedback for the project is overall positive but many questions have already been raised by the YPAG's in terms of how ChromaDose will be developed and how patients will be supported. These thoughtful questions from Round 1 of involvement will help to start shaping the Patient Information Materials for the project and are an example of how impact has already been made at early stages in the research:

- So, does a longer medicine exposure mean the patient is more likely to get side effects?
- If someone has cancer will they only need to do the test once or every time they get prescribed the medicine, e.g. is it like a repeat prescription?
- How much training will nurses need to use this? (cost + time)
- How will you make sure this is available to everyone, e.g. not just private healthcare?
- I forgot to mention this, how often apart are the blood samples taken? If it takes too long, it will be difficult and off putting for the patient. It will also be inconvenient for nurses
- I have a phobia of needles and therefore really struggle to give blood so would never do it if it wasn't really needed. Have you considered if your project would accommodate people who have this phobia?

Young people have also made some recommendations for research protocol following Round 1 of involvement through the online questionnaire:

- Is there any way that you could experiment with a small dosage and calculate how quickly they digest the medication and use that info to help with larger doses?

This is a very good suggestion, which we will follow up in the project.

ChromaDose team member



What are the outcomes so far and what's happening in the future?

The ChromaDose project was successful in its application for funding by an NIHR i4i Product Development Award, which provides £980,000 for a nationwide multi-disciplinary team to conduct intensive research and development over 30 months. (July 2020).

Some of the hypothesis being explored are e.g. the discrepancy between sibling and patient motivation for Therapeutic Drug Monitoring (TDM) and the trust in the automated technology.

A parallel consultation is currently being conducted with the parent group PORT (Paediatric Oncology Reference Team).

Four things need to happen for ChromaDose to become widely used in hospitals:

1. Refine the blood testing method.
2. Create patient information resources and improve the technology design guided by patient and public involvement workshops.
3. Ensure ChromaDose is easy to use by working in close partnership with nurses and doctors.
4. Improve and document ChromaDose's performance to gain official approval as being "safe-to-use".

Patient and Public Involvement and Engagement is a core element of the project and will now provide the team with access to:

- the GOSH YPAG September 2021 meeting
- a follow up YPAGne 2021 meeting

Aims are now for both YPAG's to help with feedback and advice on:

- Product development
- Sampling protocols
- Patient Information Materials

The team will also be updating us with their analysis of pre-award and Round 2 once completed and GOSH YPAG members are currently writing a Blogpost for the ChromaDose and GenerationR websites.

There are plans to engage with patients/families and the public throughout the research process i.e. quarterly newsletter, website and social media updates for all stakeholders, and not 'just' at the end of research. Moreover, specific thought has been given to the engagement needs of children for example, child-friendly information materials.

Funding application reviewer



2. FRACTURE Study

Fast Reporting using Artificial Intelligence (AI) for Children's Traumatic Radiology Examinations

About the researcher and their research

The researcher is a paediatric radiologist with a background in imaging, artificial intelligence (AI) and diagnostic accuracy trials. Due to workforce shortages across the NHS, there is a desperate need for doctors with expertise in imaging children which in some cases leads to mistakes being made. One of these common mistakes is missing fractures on X-ray studies, leading to the wrong treatment decisions for children and a negative impact on long-term recovery.

What the researcher would like to do is to prevent fractures being missed on children's X-rays – getting it right first time (GIRFT), by using a super computer to recognize fractures and thereby making this expert opinion available to everyone.

The research will include several mini-projects:

Step 1. Do we want it?

The researcher will ask a large group of patients and parents what they think of using this type of super computer technology and if they would find this acceptable for use in daily care.

Step 2. Can it be done?

A super computer will be trained to recognise fractures on children's X-rays.

Step 3. Does it work?

It is then important to evaluate how well the super computer can perform compared to an imaging expert (i.e. radiologist).

Step 4. Will it help?

Finally, if the super computer works well and is accurate we will simulate how it may help patients in real life and investigate how to go about implementing something like this into everyday practice.

How does the research benefit patients

By the end of the project, the researcher expects to have developed the FRACTURE algorithm (a working solution) for accurate and automated children's fracture detection, ready to apply for the next level of regulatory approvals for nationwide usage.

This will mean that hopefully fewer fractures will be missed, children will have the correct treatment first time and avoid repeated visits to hospital and time off school.

Given the growing interest in artificial intelligence in imaging, the researcher will develop into a leading expert in this area and be in a position to guide and help other researchers who are trying to develop similar tools to benefit patient care in a more streamlined and efficient manner.





Where in the Research Project Lifecycle did PPI take place?

PPI took place at the very early stages of project planning prior to grant application, and PPI will be intrinsic throughout this project at every step going forwards.

Who were involved?

Two exploratory virtual meetings were conducted in the early project planning stages in July 2020 explaining the current problems with fracture diagnosis on X-rays:

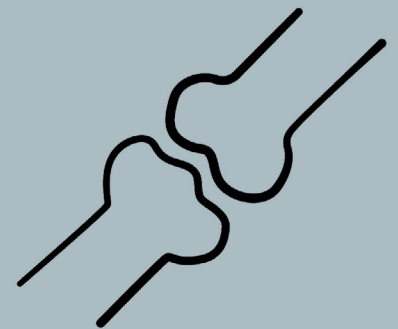
- GOSH Parent and Carer Advisory Group for research
3 parent representatives attended
- GOSH Young Persons' Advisory Group (YPAG) for research
24 children and young people attended, aged between 11-21 years

The PPI research advisory groups were asked how they felt about hospitals using new technology (i.e. super computers) to diagnose medical conditions. Feedback and opinions from these meetings helped to shape the study application and research questions in the project.

A third virtual meeting was held in October 2020 with:

- GOSH Parent and Carer Advisory Group for research & GOSH YPAG
Three parent carers and six YPAG representatives attended

This meeting was conducted to address where potential adaptations to the study design were needed given ongoing COVID restrictions. The meeting was funded through successful application to the NIHR Enabling Involvement Fund.



What Impact has PPI had on the study?

Feedback for the study proposal was overall positive, particularly given the strong emphasis on patient safety and potential in reducing medical errors. Our PPI research advisory groups made the following **recommendations** which have been taken up by the researcher:

1. Adaption of a key study outcome: that any future AI algorithm would support and enhance clinician diagnoses, rather than replace doctors

A strong preference for a 'human in the loop' working with AI was voiced. Mistakes by an AI were also less tolerated than for a human.

2. A new addition to study design: Step 4

A high priority was placed on **examining the impact of AI algorithms on patient care**, such as how it might affect treatment decisions 'in real life' by emergency physicians.

3. Changes to the study design as a result of COVID restrictions

A short **online patient survey for Step 1** (with an explanatory video) via a '**FRACTURE study**' website, disseminated with appointment letters, was now deemed more appropriate than paper questionnaires in hospital waiting rooms. The PPI groups advised that the website should provide study updates, a blog and information relating to AI in medical research for the public.

4. Recommendation to ensure patient views are kept centre stage

Setting up a 'FRACTURE study' steering committee (GOSH YPAG and GOSH Parent and Carer Advisory Group representatives) who will attend biannual meetings throughout the project to discuss updates and opportunities to **influence the direction of the study**, specifically:

- Advice on study protocols and appropriateness of outcome measures
- Development of strategies for troubleshooting issues with data collection/ analysis
- Development of educational tools explaining AI to children, radiologists and NHS managers
- Writing of academic papers, reviewing and revising drafts (including lay summaries)

5. Refining the Plain English and Scientific Summary

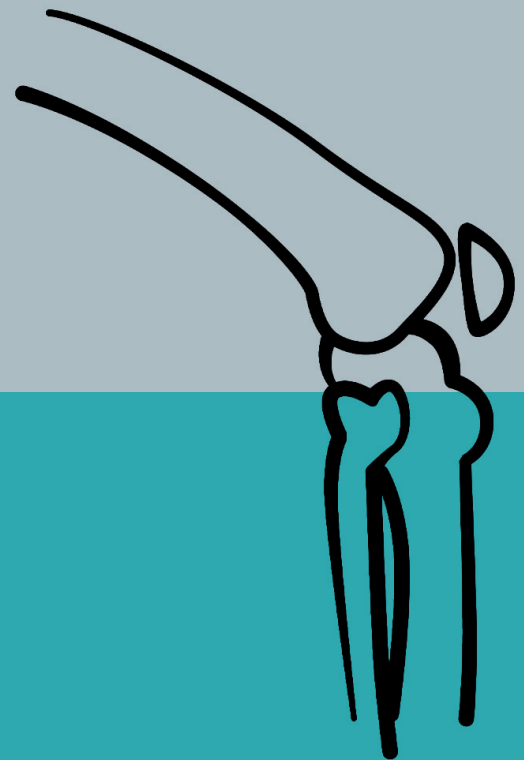
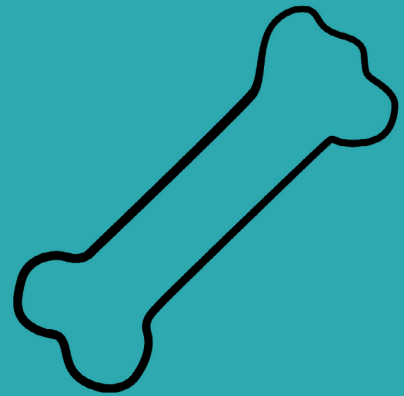
Input from GOSH YPAG members and NIHR RDS lay members have supported the researcher to apply for an NIHR Clinical Doctoral Research Fellowship Grant application.

What are the outcomes so far and what's happening in the future?

The researcher was successful in securing an NIHR Advanced Fellowship Application for this project.

- Three GOSH YPAG and three GOSH Parent and Carer Advisory Group members will now form the PPI FRACTURE Steering Committee.
- Bespoke PPI training for steering committee members will be organised at the start of the award via the NIHR GOSH BRC, with dedicated sessions presented by the advanced fellow on basic principles of machine learning.
- Adult steering committee members will also be offered additional training through the online NIHR Public Reviewers; Raising Research Quality course (<https://www.invo.org.uk/>)
- A FRACTURE study website to inform other researchers and parents/patients about the progress of the study will be created, with help from the steering committee in creating lay summaries for ease of understanding study outcomes.

At the end of the study, a dissemination meeting will be arranged for all GOSH YPAG, Parent and Carer Advisory Group members and affiliated healthcare professionals. The meeting will draw together main findings from the research, thank participants and discuss avenues for dissemination and future research directions. It is intended that one or more presentations will be given by GOSH YPAG members, explaining results in a way that other children and young people can understand.



3. Review of Patient Information Sheets

A study of children and young people with homonymous hemianopia

About the researcher and their research

The researcher holds an MSc in Clinical Ophthalmology at the UCL Institute of Ophthalmology. She has dual registration with the HCPC as both an Orthoptist and a Clinical Scientist, which she utilises in both her clinical practice at GOSH and her research.

The researcher was awarded an NIHR Clinical Doctoral Research Fellowship to pursue her research in Homonymous Hemianopia (damage to one side of the brain causing loss of the opposite side of your vision) in Childhood and the resulting effects on a child's visual function and vision-related quality of life.

The research is split in to two parts or phases:

Phase 1 – A one-off visit to the hospital

Participants would do lots of clinical tests which tells the researcher more about their condition. A subgroup would then be invited to take part in Part 2.

Phase 2 – A pilot trial of wearing two pairs of prism glasses that help adults with the same condition

Participants would wear each pair of glasses for four weeks and return after each four weeks to tell the researcher what they thought of them.

What Impact has PPI had on the design of 16 years+ Patient Information Sheets for Phase 1 of the trial?

GOSH YPAG members provided their feedback online.

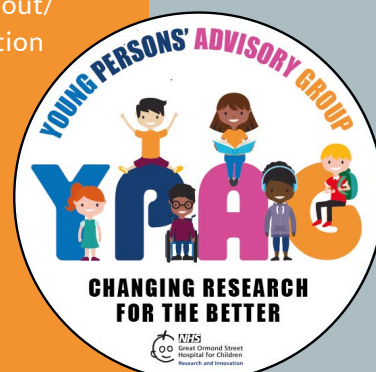
"I am completely blown away by the comments from the YPAG; so insightful and so helpful - please can you pass on my deepest thanks. I've attached updated versions of the 16+ PIS phases 1 and 2"

Researcher

About the trial and burden to patients: What will happen to me if I take part?

Questions raised by GOSH YPAG

- How long will it take? Will I miss school or can it be arranged around holidays or my other hospital appointments?
- Will I get a drink and food?
- Can I have a break if I get tired or need the bathroom?
- The way the information is laid out/ ordered underneath each question needs to be redrafted slightly (this could be done by using bullet points)





Original text:

We will make an appointment for you to come to the hospital for an in-depth eye test. This will involve putting some sensors on your head that measure how well your eyes send messages to your brain. This doesn't hurt and you will get to watch a DVD of your choice on the TV. We will take a photo of your eyes that makes a 3D map of the back of your eyes. We will also ask you to complete some questionnaires that tell us more about your vision.



Changes made on recommendations from GOSH YPAG

We will make an additional appointment for you to come to the hospital for an in-depth eye test. This will involve:

- Putting some sensors on your head that measure how well your eyes send messages to your brain. This doesn't hurt and you will get to watch a DVD of your choice on the TV.
- Taking a photo of your eyes that makes a 3D map of the back of your eyes.
- Completing some questionnaires that tell us more about your vision.

These tests will take approximately 2-3 hours, but as you may have already done some of these tests before your researcher will be able to give you a more individual idea of how long it will take. We will build some breaks in to the testing as suits you.

About the dissemination of results: What will happen to the results of the research trial?

Questions raised by GOSH YPAG

When will the results come out, will I or my parent/carers be notified?

When the study has finished we will present our findings to other doctors, and we will put the results in medical magazines that doctors read. All results will be anonymous, which means that you will not be able to be identified from them.

Changes made on recommendations from YPAG

We will also be sending out a 6 monthly email newsletter to everyone who takes part (if they wish to receive it) to update them on the progress of the research.

About contact details:

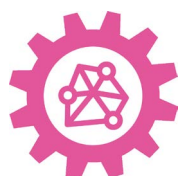
Questions raised by YPAG

Will it take ages for the researcher to respond to queries? Is there a telephone contact number too?

Additional text added to contact email address:

The researcher moves around the hospital a lot and so email is the best way to contact her, if this is not suitable for you/your family or carer please inform us as soon as possible and we will find an alternate solution.

All GOSH YPAG members have been sent a copy of the new Patient Information Sheets to demonstrate the impact they have had.



4. MissionEB

Double blinded placebo control study of Mesenchymal Intravenous Stromal cell infusions in children with recessive dystrophic Epidermolysis Bullosa

About the researchers and their research

This trial is a Great Ormond Street Hospital for Children (GOSH) sponsored trial and is being carried out in collaboration with the Clinical Trials Research Unit at University of Sheffield, Birmingham Children's Hospital NHS Foundation Trust and consultants in paediatric dermatology at GOSH.

Epidermolysis bullosa (EB) is an inherited disease where blistering follows minor injury because of a missing protein in the skin and other organs. Recessive Dystrophic EB (RDEB) is the most severe type of EB and results in widespread disease, causing long-lasting and recurring wounds, scarring, pain and itching.

The study has been funded jointly by NIHR and Cure EB.

How does the research benefit patients?

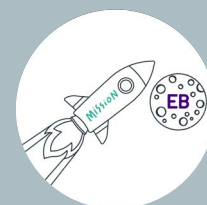
The MissionEB research trial aims to find out if treating recessive dystrophic epidermolysis bullosa (RDEB) with special cells can benefit children with this condition. Mesenchymal stem cells MSC's are found in any organ.

- They help to repair the body and by forming connective tissue can stop immune responses.
- They do this by producing compounds that help other cells to survive and to divide.

We want to find out if MSCs are better than placebo

We want to find out if repeated infusions of these cells are safe

We want to find out if repeated infusions of MSCs help children with severe RDEB



Where in the Research Project Lifecycle did PPI take place?

Patients and the public have been involved in the original study design and throughout the project lifecycle.

Who are involved?

So far the research team have attended two GOSH YPAG meetings and have consulted with the group online to help with development of their Patient Information Sheets.

Meeting 1. January 2020

The research team asked GOSH YPAG: What do you think of the study design and is there anything you would like to change? The group also made recommendations for the Patient Information Sheets online after the meeting.

Meeting 2. November 2020 via Zoom

The research team wanted to come back to the group to update them on changes made as a result of their feedback and ask for more input into information materials for patients



“Amazing work. I’ve really seen the difference and outcome of YPAG as I was reviewing Mission EB PIS”

GOSH Research Governance team

What Impact did PPI have on the design of the research trial and the Patient Information Sheets?

You said/We did

GOSH YPAG said about the Patient Information Sheets:

- Breakdown study information into different age groups

Research team designed:

- Patient Information sheets for younger children (age 6-11) and older children (age 12 – 16)

GOSH YPAG said about the trial:

- Have fewer hospital visits

Research team:

- Removed some of the blood tests and assessments to make the visits easier, possibility of remote or home visits if necessary

GOSH YPAG asked about the trial

- What support is available?

Research team:

- Included in the leaflets information on who the children can contact
- Included pictures of the doctors who will be involved in the trial

Follow up questions to the group:

- Do the leaflets for patients explain the study and are they appropriate for the age group they are aimed at?
- Is there anything you would like to change?
- How would you like to be involved going forward? Annual meetings?

Using whiteboards in Zoom breakout rooms GOSH YPAG gave detailed and meaningful feedback on further development of Patient Information Sheets and how they would like to be involved as the study progresses

Images need to be more consistent in style, graphics too varied

A link to the placebo video in the leaflet would be good

Make clear that everyone will get the real medicine in the end

As a patient you are involved in a lot of medical terms so it’s good to start using it, especially the skin cells

Annual meetings with presentations would be good, we already get a lot of emails so it would be too much to get another email

Just to say I think some of the best feedback that we were able to implement is the advice from the group that actually they do know a lot of the medical language so don't leave this language out. Also they advised us to put in a link to the placebo video which we did by adding a QR code and it works really well, it was a great idea. We changed some of the images based on their feedback as some of the images were a little young.

Mission EB Study Manager

people may worry taking time of school. it is bring going so tying them up together where possible would be good. I would find it interesting but if it works I would want to have the real one not the placebo.
Make clearer that everyone will get the real medicine by the end.
Include in the leaflet that at the end of the study they can know what they were given (medicine or placebo) and when.
Annual meetings with presentations would be good. We already get a lot of emails so it would be too much to get another email.
When will the results be ready? This should be included in the leaflet.
Regular updates (emails and letters with graphics) to patients enrolled in the study would be good, to let patients and parents know what's happening and how they have helped the study.
Would be good to have a website about the study, with a chat so that people involved in the study can contact one another. Maybe a blog where everyone can share their experiences.
if there is a support group that could be included for patients, both on leaflet and website.

Some leaflets have "what if something goes wrong?" - this is good to have a bit on it and mention PALS or something
Language generally is fine; I liked the language. If you are younger your parents can tell you. If you are 9,10,11 you wouldn't want it basic.
Could maybe use the term that cells are the building blocks of life? almost like lego? For cells, use images. As a patient you are involved with a lot of medical terms so it is good to start using it, especially the skin cells
Explain placebo better - why do I have to go to the hospital to get fake medicine?
I still feel like some 6 year olds may not understand the explanation at the start about cells and stuff
6-11 yrs old age group too big; things might be to simple for older kids. Could the age group be further split up? example 6-9 and 9-11 yrs or 5-7 and 8-11.
Only have box for visit 1 - and then explain the doctor will explain what's happening at each visit; however some people did like the visit/boxes as it makes it clearer and so you can see how often you go.
I think a mention that some of your appointments will coincide with your normal hospital appointments too would be good.
If it was my first study I'd be concerned about the use of placebo; it would be good to have the doctors explaining it and reassuring the patient.

Mission EB - 6-11yrs
Images too young for both leaflets
Mission EB logo really clear and effective
Nice font, clear and well spaced
Images need to be more consistent in style, graphics are too varied
Use more technical terms and simplify in brackets
Like the presentation with the dry stone wall image relating to the skin
Would like to know what side effects you might have and how severe they will be
I like how certain words are in bold to bring more attention to them; also like the flipping coin metaphor
Link to the placebo video in the leaflet would be good
Yellow splotches need to be clearer - what do they mean? But they are a good visual effect within the text
Explain why you have to do placebos, as they might be confused
"Question and Answer" style of the leaflet is very clear
Explaining every visit on the leaflet makes it very repetitive; would be good to have the doctors explain what's going to happen in the next visit.
Good to have all the contact info at the end of the leaflet
Like the image about "you can tell someone if you want"
I like the multi answers for the questions. It gives more confidence to the person reading and

Whiteboard feedback which the team took away to make changes to their Patient Information Sheets



5. The C-POS Study

What matters to children and young people facing serious illness

About the researchers and their research

The researchers are a unique multidisciplinary collaboration ; including Great Ormond Street Hospital and the main researcher that we are working with is a palliative care nurse and PhD student from the Royal Marsden Hospital.

The C-POS study is an exciting children's research study aiming to develop the first person-centred outcome measure. An outcome measure is a questionnaire that can be used in routine practice by children, young people and families affected by life-limiting and life-threatening conditions (LLLTC) which addresses the symptoms and concerns that matter most to them.

A recent systematic review has highlighted that no measures suitable for use in this population currently exist. In addition, development of such a measure has been highlighted as an international research priority. The researchers seek to engage children within the research process, rather than relying on proxy data.

So far the researchers have conducted interviews with:

- ill children
- their parents and brothers/sisters
- grown ups whose job is to look after them in hospital or at home

How does the research benefit patients?

The C-POS study addresses a current gap in both methods and evidence: repeated reviews and policies have called for scientific advancement to develop, validate and implement Person-Centred Outcome Measures (PCOMs) for Children and Young People and their families facing LLLTC.

The team will develop a person-centred outcome measure that can be used by children and young people and their families affected by LLLTC, and to test its psychometric properties. They will also be developing implementation guidance once the measure is finalised.

Where in the Research Project Lifecycle did PPI take place?

PPI took place at the very early stages of questionnaire design and again at a second meeting to shape it further. PPI will be intrinsic throughout this project at every step going forwards.



Who were involved?

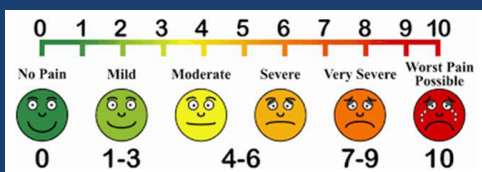
- GOSH Young Persons' Advisory Group (YPAG) for research and representatives from Southampton YPAG (at meeting 2)

Meeting 1:

July 2020 (25 young people attended)

Researchers consulted with the group on 3 things:

1. How they give children the questionnaire
2. How children should answer the questions
3. How far back you think children will be able to remember



I felt like it was both fun and important to consider how this questionnaire would be received by young and older children. YPAG had to think about how children would answer the questions and how far back the children could remember.

GOSH YPAG member Sandra

Meeting 2:

March 2021 (22 Young people attended)

Researchers consulted with the group on 2 things:

1. How should we label the versions (e.g., Version A, Version B, etc.) – children with serious illness have different levels of understanding so we don't want to use age to label the versions
2. What would be your top 10 questions from the list on the next slide?

What Impact has PPI had on the study?

The research team have already incorporated changes and chosen different ways of answering the questions based on your help from last time.

Example of YPAG feedback:

Do you prefer descriptors + numbers or the smiley faces?

- I think smiley faces is good but there is not enough options (3 is limited and not enough)
- Faces with more info would be better
- Faces is less confusing, the other one is more confusing, and I would struggle to choose one
- I think 5 faces are needed
- 😊 for no pain, 😞/😞 or 😞 for worst possible pain

Changes made:

For younger children 5-7 years

3) How much have you been able to do the things that are fun yesterday or today?

Not at all	Sometimes	All of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
😞	😞	😊

For older children

1) How much have you been affected/bothered by pain:

- yesterday or today
- over the past week?

Not at all	Occasion-ally	Sometimes	Most of the time	All of the time/A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
😊	😊	😊	😊	😞

Not at all	Sometimes	A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
😊	😊	😞

Feedback from Meeting 2

Label version ideas: could name after animals (panda, wolf, monkey, dogs – different types, polar bear, penguin, cats, tiger, lynx, dolphin, peacock, raven, hedgehog and bunny) or colours (warm colours for compete, gold, red, blue, yellow, pink, green, purple, sunset colours, orange blue in different shades).

Could also name after mystical creatures or Disney characters (merida) or cartoon characters (peppa pig) or star wars or marvel or movie characters (lion king, black panther, spiderman, the minions), different areas (rainforests, oceans, deserts, Antarctica) or hobbies (football, arts), movie series (harry potter, star wars) or seasons or emojis.

Have to be careful that different animals aren't associated with certain personalities because it might upset some children.

Green is a difficult colour as can be associated with sickness. Olive green could work. Blue is quite a calming colour.

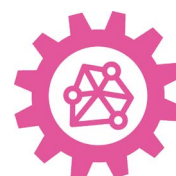
What are the outcomes so far and what's happening in the future?

GOSH YPAG have featured in the C-POS Newsletter

GOSH YPAG representative has written blogpost for GenerationR website

GOSH YPAG representative will be prepared to attend an Ethics Committee Meeting with the team:

We will have another phase of the study going to ethics later this year/early next year and would love for one of the group to join us for that
C-POS research team member



6. Revising a Research Objective as a result of PPI

About the researcher and their research

The researcher is a Research Fellow in the NIHR Children and Families Policy Research Unit at UCL Great Ormond Street Institute of Child Health. Her research focuses on use of administrative health records (e.g.: primary and secondary care records, birth and death certificates) to study health outcomes of children with complex health needs (with focus on learning disabilities and autism) and their families.



How does the research benefit patients?

Children with learning disabilities or autism may have multiple physical and mental health needs and require more frequent contacts with healthcare care than other children. Transition from paediatric to adult health care services can disrupt the continuity of care and have a negative impact on the health of young people. This research looked at changes in healthcare use (such as the number of planned and emergency admissions, length of stay and reasons for admission) before, during and after transition to adult care to determine how improvements to health care services for children with learning disabilities or autism can lead to better health outcomes.

The study captured over 60,000 young people with LD and 58,000 with ASD. Healthcare use changed during transition from paediatric to adult care – there were more emergency admissions after transition especially for mental health problems, and fewer and shorter planned admissions after transition. These findings could partially reflect unmet health needs due to higher thresholds for planned hospitalisation or accessing support from adult mental health or social care services, or loss of support from school. The findings will be of importance to the NHS Long Term Plan, which sets an ambition to improve care of young people with LD/ASD especially around transition.

Where in the Research Project Lifecycle did PPI take place?

PPI took place at the very early stages of the research study – the initial research topic.

Researchers came to PPI with a broad research question that they wanted to examine. PPI helped to identify a specific research objective to focus on.

Who were involved?

GOSH Parent and Carer Advisory Group for research (PCAG) met with the researcher to discuss an idea for a project looking at indicators of good and poor coordination of NHS care for children with complex health needs and learning disabilities, and their relationship to emergency admission rates.

What Impact has PPI had on the study?

Original research topic:

Looking at indicators of good and poor coordination of NHS care for children with complex health needs and learning disabilities and how they are associated with emergency admissions (as measure of unmet health needs).

The group suggested that coordination of care often fails during transition from paediatric to adult care: adult care is more fragmented, care is often provided across multiple hospitals, patient information is not always shared between institutions.

We discussed previous CPRU research, which showed that emergency admission rates for young people in England increased after transition to adult care, likely reflecting unmet physical or mental health needs of young people.

New research topic:

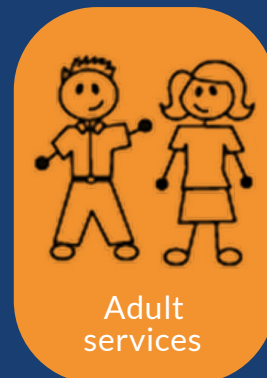
'comparing healthcare use before and after transition for children with complex health needs and learning disabilities or autism'

Transition from paediatric to adult care:

Often specialist, holistic, hospital-based



Aged 16-18

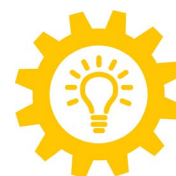


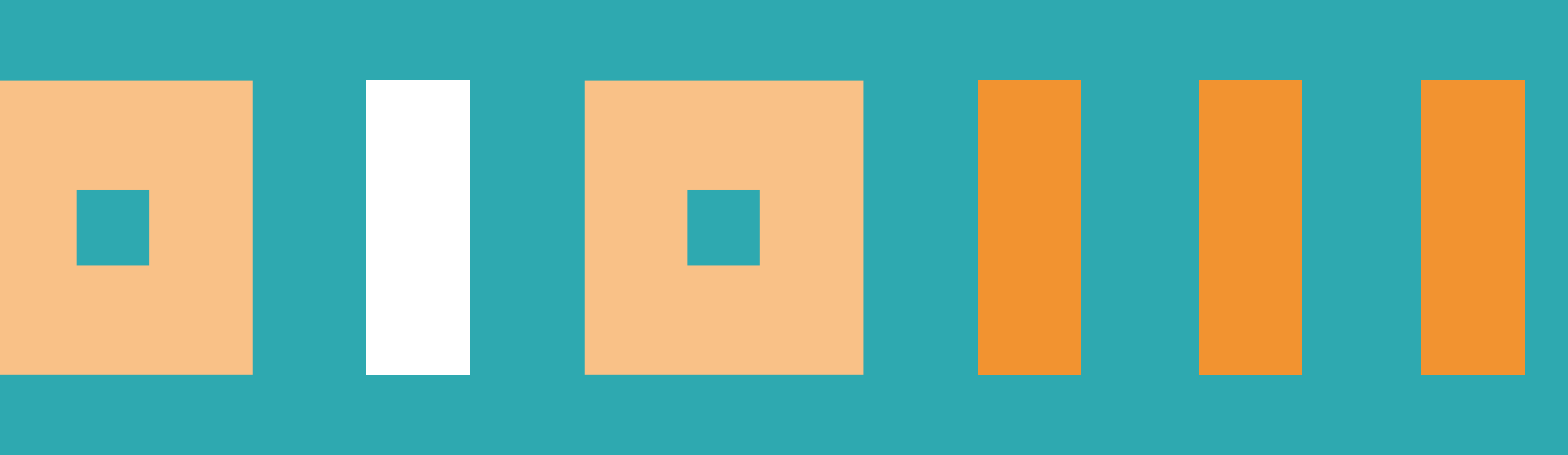
- More fragmented care
- Higher thresholds for hospital admission
- Longer waiting times
- Source of stress

What are the outcomes so far and what's happening in the future?

The research team have prepared a paper intended for submission to Lancet Adolescent and Child Health. They met with the Parent and Carer Advisory Group to discuss the findings from the paper and one parent has joined the research team and will **co-author** the paper as "expert through experience". They are hoping to present the findings at the Royal College of Paediatrics and Child Health (virtual) annual conference.

The researcher will be applying for future funding to work with PCAG to **co-create** an infographic summarising the findings. This will be used to disseminate findings to stake holders and policy makers.



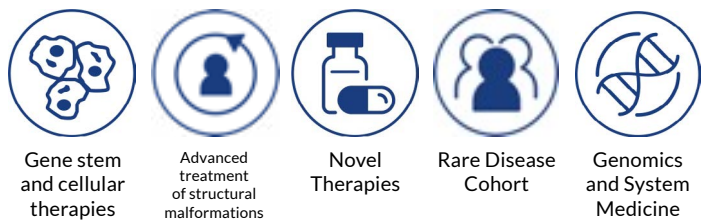




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BRC Themes



GOSH Directorates

