

**Patient and Public Involvement & Engagement (PPIE) in
Experimental Medicine and Early Phase Studies in Children & Young
People**

**NIHR ALDER HEY CLINICAL RESEARCH FACILITY (AHCRF) PPIE
STRATEGY 2022-2027**

Written by Jenny Preston

Table of Contents

Glossary	3
Who are we?	4
Our Vision	5
Definitions	5
Lundy’s Model of Participation.....	6
Principles of Participation	8
Patient and Public Engagement.....	9
Strategic Objectives	9
Partnerships and Collaborations.....	9
Leadership and Governance	10
Resources.....	10
Communication and Dissemination	10

Glossary

AH: Alder Hey Children's NHS Foundation Trust

AHCRF: NIHR Alder Hey Clinical Research Facility

CRF: Clinical Research Facility

Collaboration: Work together in partnership with people affected by health conditions to make decisions about the research.

Consultation: Asking people affected by health conditions their views and advice on aspects of the research to help shape it better.

CYP: Children and Young People

EM: Experimental Medicine

EP: Early Phase

eYPAGnet: European Young Person's Advisory Group Network

NIHR: National Institute for Health and Care Research

PPIE: Patient and Public Involvement and Engagement

REAP: Research, Education, Awareness Programme

UNCRC: United Nations Convention on the Rights of the Child

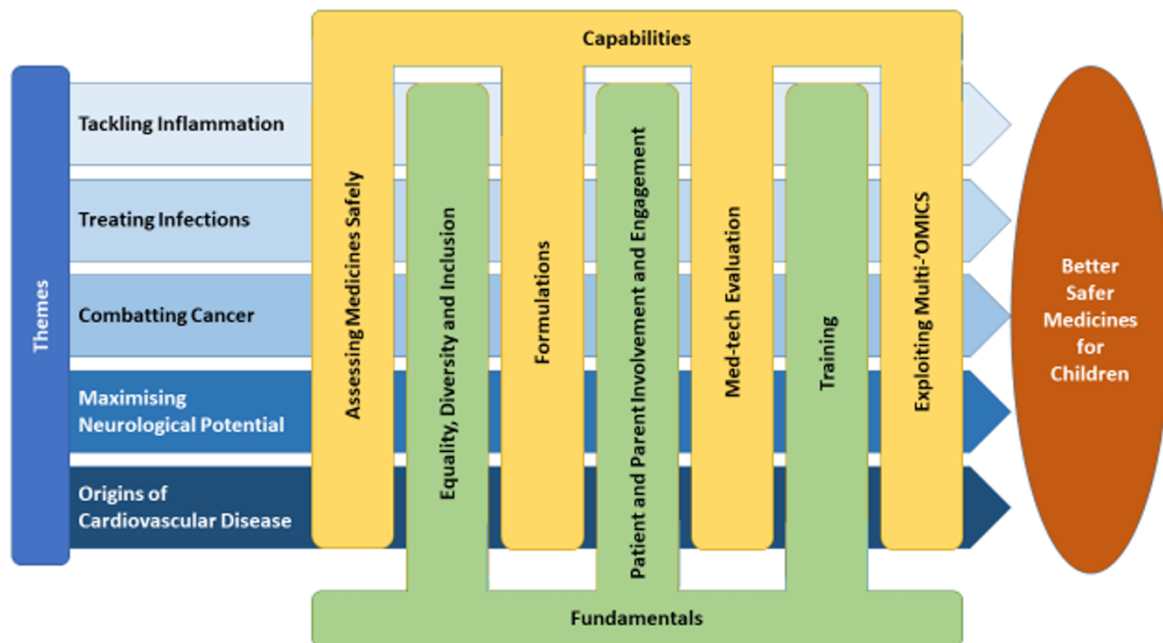
YPAG: Young Person's Advisory Group

Who are we?

Alder Hey Children’s NHS Foundation Trust (AH) is one of Europe’s largest children’s hospitals, providing secondary care for Liverpool’s local population and provides care for complex diseases across Northwest England and North Wales. Within AH, the National Institute for Health and Social Care (NIHR) Alder Hey CRF (AHCRCF) was established (since 2012) as an internationally leading facility for experimental medicine (EM) and early phase (EP) research for children and young people (CYP). We pride ourselves on being child-centred and on delivering tailored, high-quality, complex/high intensity paediatric EP/EM research in areas of unmet clinical need.

Patient and public involvement and engagement (PPIE) is a central element to the work of the AHCRCF alongside Equality, Diversity and Inclusion, and training (see Figure 1). This summary document sets out our approach to PPIE, the vision, background, and key objectives. The full version can be accessed upon request.

Figure 1: Research Themes, Capabilities and Fundamentals through which the AHCRCF will deliver its strategy.



This strategy is aligned to national NIHR strategies (Going the Extra Mile¹; UK Clinical Research Facility Network PPIE Theme²) and continues to work with leaders in the field to ensure our program of work complies with the UK Standards for Public Involvement.³ More crucially, our work with CYP

¹ NIHR [Going the Extra Mile](#)

² [UKCRF Network PPIE Theme](#)

³ [UK Standards for Public Involvement](#)

aligns to a child-centred, rights-based approach⁴ that ensures the right for CYP to express their views, and the right for their views to be given due weight.

PPIE in EM and EP studies in children and young people (CYP) has underpinned every aspect of the AHCRF to date. Since 2012 extensive PPIE activities had been carried out informed by CYP and families. This was achieved through national leadership and expertise, driving forward in partnership with the NIHR GenerationR Alliance (coordinated by the PPIE team within the AHCRF), working co-creatively with organisations such as, the James Lind Initiative; One NIHR (Going the Extra Mile); European Medicines Agency Network of Paediatric Research Networks (EnprEMA); International collaborations (e.g. international Children's Advisory Network (iCAN) and the European Young Person's Advisory Group Network (eYPAGnet, Conect4Children); regulators (such as the Health Research Authority, and the Medicines and Healthcare products Regulatory Agency); and industry partners.

Our Vision

The NIHR AHCRF will improve the health and well-being of children by providing a world-class centre of expertise that is internationally competitive in driving the development of better, safer medicines and other therapies for babies, children and young people.

PPIE is an integral part of the AHCRF strategy. We want to build on the extensive PPIE work already undertaken by the AHCRF team. Over the last decade, we have involved CYP and families as equal and valued stakeholders and nurtured a productive and empowering working relationships. We are world renowned for creating the first ever Young Person's Advisory Group (YPAG) known as GenerationR, (<https://generationr.org.uk>) which was set up in 2006 to support the design and conduct of paediatric clinical trials. This model is now emulated across the UK (via GenerationR Alliance), and across the globe through international networks such as, the International Children's Advisory Network (iCAN), and the European Young Person's Advisory Network (eYPAGnet) that was co-founded by the AHCRF Senior PPIE Lead (JP). AHCRF also have a Parent and Carer's Research Forum that compliments the work of GenerationR Liverpool YPAG, and we intend to grow this forum to extend our reach to wider groups of parents and families with experience of looking after a child/ren with chronic conditions.

Over the next few years we will extend meaningful PPIE with CYP and families, across the AHCRF activities, structures and networks through active consultation, collaboration, and co-production in individual research projects relating to AHCRF's research themes.

We will use transparent processes for working with CYP, families and members of the public, thus ensuring that EM and EP study development at the AHCRF can flourish in an informed and inclusive environment.

Definitions

We use the following definitions from the [NIHR](#) for 'involvement', 'engagement', and 'participation'. For CYP's participation in decision-making we adopt a child-centred, rights-based approach informed by the United Nations Convention on the Rights of the Child (UNCRC).

⁴ A rights-based approach is the application of human rights standards in practice. The right to participation is one of the underpinning principles of a rights-based approach and it also recognises the interdependence of all human rights, meaning the realisation of one right may depend on the realisation of others.

Involvement: research being carried out ‘with’ or ‘by’ patients or members of the public rather than ‘to’, ‘about’ or ‘for’ them. It is an active partnership between patients, families, and members of the public with researchers that influences and shapes research.

Engagement: where information and knowledge about research is provided and disseminated.

Participation: taking part in a research study, for example being recruited to take part in a clinical trial or another kind of research study, joining in a focus group or completing a questionnaire.

CYP’s participation in decision-making: we define this as *“the process by which CYP have active involvement and real influence in decision-making on matters affecting their lives, both directly and indirectly”*. This definition is consistent with Article 12 of the UN Convention on the Rights of the Child (UNCRC), which underlies this strategy (see Table 1).

Lundy’s Model of Participation ^[1] is grounded in the UNCRC and focused on a rights-based approach to involving CYP in both individual and collective decision-making.

Table 1: Article 12 of the UNCRC

<p>Article 12 of the UNCRC (often referred to as the Participation Article) states:</p> <ol style="list-style-type: none">1. State Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.2. For this purpose, the child shall in particular be provided the opportunity to be heard in any judicial and administrative proceedings affecting the child, either directly, or through a representative or an appropriate body, in a manner consistent with the procedural rules of national law. <p>*For the purpose of this strategy we align our approach to point 1.</p>

Lundy’s Model of Participation

There are a range of models of participation. The best-known models include Hart’s ladder of Participation, first developed by Sherry Arnstein in 1969; Treseder’s Degrees of Participation; Shier’s Pathways to Participation; Kirby et al’s Model of Participation; and Lundy’s Model of Participation. This strategy is underpinned by Lundy’s Model of Participation^[1] as the most appropriate to achieving its objectives. The model provides a way of conceptualising Article 12 which is intended to focus health research decision-makers on the distinct, albeit interrelated, elements of the provision. The four elements have a rational chronological order (see Figure 2) and accompanying checklist that explores whether we are meeting the various components of the model (see Figure 3):

SPACE: Children and young people must be given safe, inclusive opportunities to form and express their view

VOICE: Children must be facilitated to express their view

AUDIENCE: The view must be listened to

INFLUENCE: The view must be acted upon, as appropriate

Figure 2: Lundy's Model of Participation

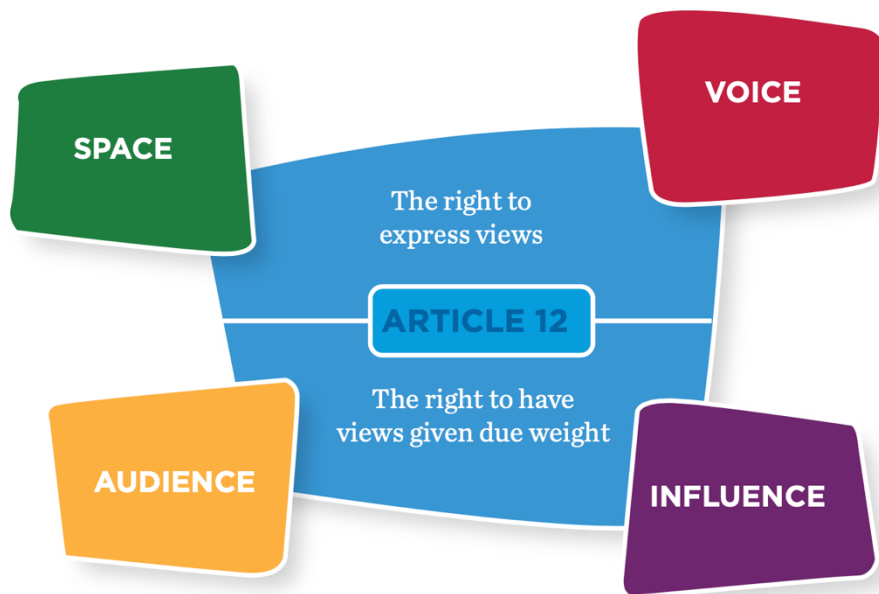
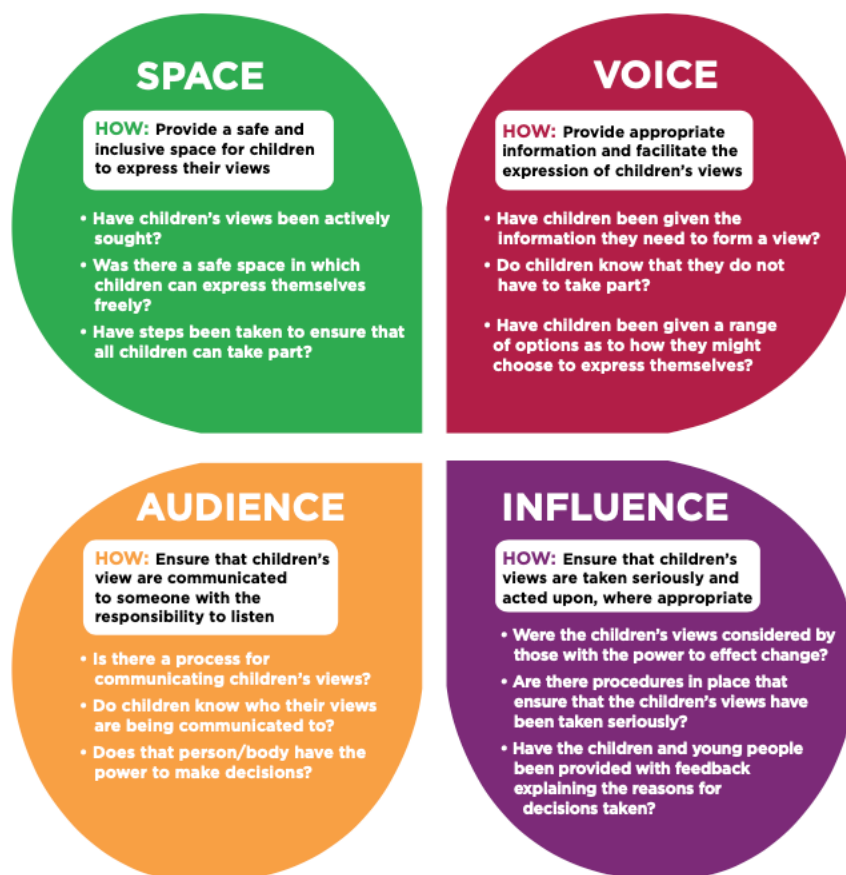


Figure 3: Lundy Model Checklist



Principles of Participation

The present PPIE strategy follows the nine basic requirements for meaningful and ethical children and family participation as laid out in General Comment on Article 12 of the UNCRC (see Table 3). The requirements refer to both the context for participation and the process of participation in all AHCRC PPIE activities.

Table 3: Nine basic requirements for meaningful and ethical participation

Nine basic requirements for effective and ethical participation
Requirement 1: Participation is transparent and informative
Requirement 2: Participation is voluntary
Requirement 3: Participation is respectful
Requirement 4: Participation is relevant
Requirement 5: Participation is child-friendly (or family friendly)
Requirement 6: Participation is inclusive
Requirement 7: Participation is supported by training for adults
Requirement 8: Participation is safe and sensitive to risk
Requirement 9: Participation is accountable

Patient and Public Engagement

Patient and Public Engagement (PPE) is a precursor to involvement and thus is a central pillar of the PPIE strategy. The purpose of our PPE is to engender greater understanding and awareness of medical research amongst CYP, their families and members of the public. This is to achieve higher levels of participation (both in the design of research and as participants of the actual research) and participant retention in trials, greater receptivity to innovation, increased willingness to self-management and better medication (or other) compliance.

Our key **PPE Strategic Aim** is to engage, inform, educate, and stimulate thinking about the work of the AHCRF among the citizens of today and tomorrow in Liverpool, nationally and internationally. We will do this across all the AHCRF's environments through our targeted, tested methods to penetrate hard-to-reach communities as well as the better represented, receptive ones. This will be achieved through our Research, Education, Awareness, Program (REAP).

The objectives of REAP are: (1) to consult actively and meaningfully (i.e., through two-way dialogue); (2) to raise awareness of biomedical and medical technology research amongst CYP, families and members of the public; and (3) to create a unique, sustainable cohort of children and families who are available to participate in and contribute to the design and conduct of paediatric research. Implementation of REAP is embedded in the delivery plan below.

Strategic Objectives

We will build on the successes of our previous 2017-2022 PPIE strategy and focus on four priorities:

Strategic objective 1: Increasing sustainable capacity and capability for involvement and engagement across AHCRF activities.

Strategic objective 2: Broadening the diversity of CYP and family involvement and engagement

Strategic objective 3: Continuously improving AHCRF services through patient experience and public awareness.

Strategic objective 4: Embedding standards, reporting and a culture of feedback and evaluation to demonstrate the impact of CYP and family involvement activities.

A detailed operational plan is available upon request, email jennifer.preston@liverpool.ac.uk

Partnerships and Collaborations

We will continue to partner with key stakeholders (regulators; industry, charities, academia) to co-develop innovative projects that empowers CYP and their families to participate in EM and EP research. We will also continue to work with relevant PPIE activities in other NIHR Infrastructure programmes, such as the Great Ormond Street Hospital (GOSH) Biomedical Research Centre (BRC), UKCRF Network, One NIHR, etc, as well as build on our partnerships across Europe and internationally (Conect4Children, European Medicines Agency, European Network of Research Ethics Committees (EUREC), Multi-Regional Clinical Trials: The MRCT Center of Brigham and Women's Hospital and Harvard, and STARCHILD Health (Toronto)). This will ensure that the AHCRF is in a prime position to benefit from ongoing activity and maximise resources for new involvement/engagement activities.

Leadership and Governance

Leadership is provided by the AHCRF PPIE Senior Manager and supported by the Youth and Family Participation Officer. The CRF governance structures are centred around a monthly operational group (examining studies) and monthly senior group (assessing our compliance with NIHR objectives, and integration with the Alder Hey Clinical Research Division [CRD]). Parents and young people's voices and views are integral to the way we run our CRF, and the broader CRD. We are particularly keen that the voices of parents, who have caring as well as potentially work responsibilities, and young people in full time education are heard. We have therefore co-developed this PPIE strategy to enable their voices to be heard at these routine business meetings. To achieve this, we collate the patient and parent feedback from CRF, and formally report to the CRF operational group. Our PPIE team who sit on both the operational and senior groups feed in information from our highly committed PPIE community, while taking back specific concerns or queries as well. Their input to these meetings is a standing item on the minutes and has been for many years.

We believe this ensures that parents and young people with busy lives, who have already committed to helping in research, can provide input via the meeting(s) they have already agreed to attend, which are centred around them, rather than attend a business meeting where PPIE is a sub-set of the agenda, maximising the value of their time. Meetings with parents and young people are organised at six-monthly intervals to review progress with the strategy, which is fed back to the senior's team, and incorporated into the NIHR AHCRF annual report to the NIHR.

We have a designated a considerable amount of resource to PPIE including staff time, a consumable budget to deliver PPIE activities which includes a payments policy that avoids patients and families not being out of pocket from taking part and to thank them for their contributions.

All PPIE activities comply with ethical, safeguarding and GDPR principles.

Resources

PPIE Senior Manager: Jenny Preston

Youth Participation and Family Support Officer: Sammy Ainsworth.

Budget allocated for PPIE activities awarded in 2022.

Communication and Dissemination

The AH communications team will incorporate all PPIE activities, opportunities for involvement and engagement; sharing best practices of how PPI shaped/changed research studies to accommodate the needs of young patients and their families within its communication plan. This will be supported by CYP and families.

A co-produced social media strategy and implementation plan will 'reach-out' to as many stakeholders as possible about the work undertaken by AHCRF and PPIE activities. The strategy will include the continuation and support of annual national awareness raising campaigns such as the NIHR's 'IAmResearch' event, and international awareness campaigns such as, International Clinical Trials Day, and World Young Rheumatic Disease Day (WORD DAY) (co-founded by SA, and colleagues at AH) to raise awareness and educate families across the globe about rheumatic diseases in children; educating CYP about medical research through the media, and via public engagement events to share cutting edge research with the public, for example 'Meet the Scientist' – a series of family- friendly weekend events, in partnership with the World Museum.

The PPIE team will continue to publish and co-author with CYP and families to share best practice.

REFERENCES

1. Lundy, L., *'Voice' is not enough: conceptualising Article 12 of the United Nations Convention on the Rights of the Child*. *British Educational Research Journal*, 2007. **33**(6): p. 927-942.