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Ethics and Patient and Public Involvement with Children and Young People

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Abstract

Patient and Public Involvement (PPI) is important both in research and in quality improvement activities related to healthcare services more widely. While PPI activities do not require formal ethical approval, they can raise a number of ethical concerns, through the introduction of complex technical medical concepts, challenging language or sensitive subject areas. There is very little published literature to guide ethical practice in this area.

We have been conducting PPI with children and young people throughout a research study in paediatric palliative care. PPI started during the application process, and continued to guide and shape the research as it progressed.

Ethical issues can arise at any time in PPI work. Although many can be predicted and planned for, the nature of PPI means that researchers can be presented with ideas and concepts they had not previously considered, requiring reflexivity and a reactive approach.

This paper describes how we considered and addressed the potential ethical issues of PPI within our research. The approach that emerged provides a framework that can be adapted to a range of contexts and will be of immediate relevance to researchers and clinicians who are conducting PPI to inform their work.

Background

Patient and Public Involvement (PPI) is the active involvement of patients and members of the public in the design and process of research. It aims to ensure that research is relevant to the intended audience and that their views are taken into account (1). The importance of the active participation of children and young people in research that concerns their care is increasingly recognised (2-4), and is a specific focus of INVOLVE, the national advisory group for the advancement and promotion of public involvement (5, 6). PPI can take place at any stage of the research process, from creating the initial research questions to specific aspects of study design, data analysis and dissemination, and is required for many research grant applications. PPI is also an important element of service design projects in healthcare (7, 8).

Researchers, clinicians and healthcare managers have a responsibility to ensure that PPI is not tokenistic (9, 10). Those who conduct PPI for research, service design or quality improvement must be willing to listen to, and act upon ideas and suggestions from children and young people, including any that challenge their own ideas or those that they have not considered before.

In the UK, there is no requirement for ethical approval when undertaking PPI work. Guidance for the conduct of PPI includes the Royal College of Paediatrics and Child Health (RCPCH) research charter and resources from INVOLVE (11-13). There are also PPI reporting frameworks such as the GRIPP checklist (14), and the PiiAF framework (15), a tool to assess the impact of PPI. A range of guidance on ethical research with children is available (5, 16, 17), but little specifically relates to the ethics of PPI with children and young people, and the need for an ethical code of conduct for PPI has been raised (18).

Objective

The purpose of this paper is to describe an ethical framework to guide PPI that was developed during a paediatric palliative care research project.

All photographs are included with the consent of the young people who are pictured.

An introduction to the PPI groups

Our PPI has been with existing groups of children and young people at a children's hospital (Birmingham Children's Hospital Young Person's Advisory Group and the NIHR Clinical Research Network Young Person's Advisory Group) and a children's hospice (Acorns Children's Hospice, West Midlands) (Figure 1). Group members range in age from 12 to 20 years. Accessing existing groups

from a range of organisations had several benefits; members have a wide range of experiences and ideas, and have already received training in elements of research, policy and communication. Some have previous experience in both research and service design projects. The groups are supported by research nurses and support workers, and our PPI work has been be incorporated into an established timetable for group meetings that is convenient for young people.

From these groups we have recruited smaller groups for specific activities, including conference presentations, writing papers (19) and the development of further research.

Figure 1: PPI groups

Ethical PPI in paediatric palliative care research: A practical example and a framework

Research in paediatric palliative care is a sensitive subject area. This paper describes our approach to PPI with children and young people for a paediatric palliative care project. This provided a context for constructing a framework for an ethical approach to PPI with wider relevance to other research or quality improvement projects (Table 1). An ethically sound approach will add quality to all PPI activity, whether that is in research, service design, or quality improvement.

Table 1: An ethical approach to PPI: key principles

Step	Ethical approach
1	Prioritise PPI with children and young people
2	Agree language and work towards a shared understanding of tasks
3	Gain consent for PPI
4	Maximise the benefits for PPI group members
5	Minimise the risk of harm
6	Ensure equity of access to PPI
7	Provide training for the researcher
8	Offer training for the PPI group
9	Provide funding and recognition

1. Prioritise PPI with Children and Young People

Article 12 of the United Nations Convention on the Rights of the Child (UNCRC) states that all children and young people who are capable of forming their own views, have a right to express those views freely in all matters affecting them, with the views of the child being given due weight in accordance with their age and maturity (5). However there is wide debate amongst academics regarding the autonomy of children and young people. Some argue that children and young people are competent and able to make their own decisions. Others are more cautious, arguing that competence is difficult to assess in children as their level of maturity and experience varies significantly depending on the context (20).

Children and young people want their contribution to have impact (1, 21, 22). Before starting PPI, adult researchers must be clear about how they will accommodate suggestions that are made. This can be challenging (4), particularly as the perspectives of children may differ from their own. There are inevitable power dynamics between the adult researcher and PPI group members during each interaction, which arise through factors related to both the researcher and the children and young people. The adult researcher comes with qualifications and professional status (23). Children and young people bring their own knowledge and experience of the world, and can challenge clinicians who are used to assuming responsibility for the management and co-ordination of teams (24).

In order to build an appropriate rapport with the group and to fulfil the objectives of the PPI, the researcher requires insight into the power dynamics, good communication skills, self-awareness and a reflexive approach, moving between different roles; teacher, colleague, mentor and group facilitator, depending on the task. Understanding the experience and knowledge, ambition, qualifications and status of PPI group members in relation to each other also helps, and can develop naturally over a number of sessions with the same group.

In our PPI, children and young people have challenged the researcher with their knowledge of technology and social media. Some bring the experience of illness as a sibling or as a patient. They have strong views about aspects of the research project including the language used, and the design of study resources and interviews, and they are passionate about dissemination and impact. The established groups we have been working with already have an identity and autonomy as a group, and high expectations of how their views are valued. This may have been different if the group had been made up of volunteers selected more generally.

In order to assure group members that their contributions have resulted in changes, we provide regular feedback at subsequent meetings, through sharing documents such as participant

information resources and through a project Twitter account (@journeythrucare), set up at the group's request (Figure 2).

Figure 2: Feedback

2. Agree language and work towards shared understanding of tasks

A crucial aspect of communication in PPI is ensuring shared understanding for each particular task. Anticipating this challenge and planning PPI group sessions with clear, focussed questions and tasks is beneficial, and there are suggestions to guide this process in the RCPCH&Us Recipes for Engagement resource (25). Clear explanations of how each task relates to the research, and regularly checking back with group members to ensure there is shared understanding of every PPI task, are helpful strategies.

Group members question medical jargon and terms that are unfamiliar to them. An example from our work relates to the term "palliative care". During our initial PPI activity, group members including young people who had been patients at the local children's hospice, raised concerns about the term "palliative care". They had not heard of it, and they perceived it negatively. They associated the term with death and dying, and did not want to relate it to themselves or to other children and young people. Similar concerns have been identified in previous research (26-28). The young people suggested changing the study title to "The Journey through Care", designed a logo for the study (figure 3), and participant information leaflets were edited to refer to "life-limiting" and "life-threatening" conditions or "conditions which may or may not get better", but not specifically to "palliative care". This has had positive implications for the research and has led us to design further research into language in palliative care.

Figure 3: Project logo

3. Gain informed consent

Ethical approval and the use of consent or agreement forms for children, young people or their parents are not necessary for PPI. However, the principles of informed consent should still be carefully considered particularly if the subject of the research is potentially sensitive, when PPI groups include members who may have mixed personal experiences and where group members are under the age of 16 years.

At each stage of our PPI work we have asked participants for verbal agreement in relation to each activity. Our approach and learning points are as follows:

1. To find out about the size of the group and age range, and whether anyone has personal experiences that may be difficult for them before the meeting.
2. To carefully prepare each session in advance, with specific information, tasks and questions for the group in clear, accessible plain English.
3. To allow time for introductions and discussions about any experiences related to palliative care early on in the meeting.
4. Making clear to group members that they are under no obligation to take part in any element of the PPI work for this project, and can leave the session at any time.
5. Asking for verbal agreement from group members at each meeting, reminding them about the subject area and confirming that they are all feeling okay to talk about the research.
6. Providing written information to take away, including details of the study and the contact details of the researcher.
7. Encouraging group members, particularly members under the age of 16 years, to discuss their involvement with their parents.
8. Reassuring group members that their contribution can remain anonymous if that is their wish.

4. Maximise the benefits for PPI group members

The benefits of PPI for those who take part are often listed as contributing to an original piece of research, gaining new skills and knowledge, working with others and having the opportunity to take an active role in dissemination. We have actively sought to provide opportunities for PPI group members to engage in activities that they consider to be beneficial to themselves, as well as of benefit to the study. This has included conference presentations and co-authorship of papers (Figure 4)(19).

Figure 4: PPI group members at the Royal College of Paediatrics and Child Health (RCPCH) conference 2017.

5. Minimise the risk of harm

There is a potential for harm to people who take part in PPI related to the discussion of sensitive subject areas. Anticipating and planning this is helpful for both the researcher and group members, providing the security of a clear framework with which to approach problems if they arise.

Given the potential risk of harm to PPI group members through conversations about palliative care, our approach to PPI included a brief risk assessment as follows:

Table 2: PPI risk assessment

Stage of PPI	Potential Risks	Plan to mitigate risks
Approaching groups of young people	Young people who live with life-limiting or life-threatening conditions are at constant risk of a deterioration in their health. These are situations that other young people may not be familiar with and which they therefore might find difficult.	Groups of young people, some of whom have life-limiting conditions and others who do not, were approached separately and through two different organisations (the hospital and hospice). PPI work with each group is carried out concurrently but not at the same group sessions.
Support for PPI group members	Discussion of experiences of life-limiting conditions can cause distress for children and young people.	Should any children or young people who require support either during and following the meeting, this can be provided by the researcher or by the group facilitators. Whilst PPI work can result in open and honest conversations about difficult topics, this is not the same as professional emotional support. If necessary, group members can be provided with information about whether to access further support.
Using research findings to develop recommendations	There are ethical considerations for the research study participants in terms of ensuring their anonymity and to avoid misinterpretation of qualitative data.	The researcher will be responsible for conducting the data analysis before this is shared with PPI group members, and for ensuring that findings remain in context. No identifiable or raw data will be shared.

We used a method based on "Tell Me…" from the RCPCH & Us Recipes for Engagement (25) to gather confidential feedback from PPI group members about their personal experiences of being involved in this research. Although we had planned for potential risks and possible distress, this has not been a problem in our study and feedback to date has been very positive.

6. Ensure equity of access to PPI

There is more that could be done to ensure equitable access to involvement opportunities for all children and young people. This is the focus of national campaigns In the UK including "OK to ask" (29) and "I Am Research" (30). Social media is a powerful tool through which opportunities could be advertised, or through which PPI could be conducted.

Through working with groups from both the hospital and the hospice, we have had PPI input from children and young people with a diverse range of family and illness experiences and cultural backgrounds. The groups are advertised widely and CYP apply to join. Within the PPI we are also aware of the need for equity of access to opportunities such as attendance at conferences and co-authoring papers. The young people involved in our study have suggested approaching schools and youth groups to present work to a wider audience and to improve awareness and understanding of both research and PPI, through educational sessions and assemblies.

7. Design training for the researcher

Currently there is no consistent or standardised training in the conduct of PPI for researchers (31). Individual researchers need to address their own training needs. This includes the practical skills necessary for effective PPI (such as facilitation of workshops with CYP of different ages), and consideration of the more subtle, complex issues that can arise in PPI including planning for potential ethical concerns. There is work in progress to develop standards for PPI; training resources would support their implementation (32).

8. Design training for the group

CYP may require access to training that is relevant to the proposed PPI activities. The relevant approach will depend on the activity that PPI group members are being asked to carry out (33). Researchers are often in a position to provide such training. For example, Coad and her team provided specific training to young people so that they were in a position to take an active role in qualitative data analysis (33). Other researchers have recruited and trained PPI co-researchers, but describe significant challenges regarding governance and administration processes (34).

PPI can create the opportunity for children and young people to design and carry out their own research which should also be supported with adequate training. Young person to young person research may enable valuable insights that might not emerge in adult to young person research (35, 36).

9. Provide funding and recognition

PPI work involves time and other costs which should be covered by the cost of research. Detailed guidance exists for this (37). The contribution of PPI group members can also be recognised individually and collectively, through thank you certificates, vouchers and events that can be designed in partnership with the PPI group.

Conclusion

The importance of incorporating PPI with children and young people in research, service design and quality improvement activities is well-recognised. However, there has been little guidance about how best to conduct such activity. As described in this paper, a systematic approach to recognising and addressing ethical issues relevant to the planned PPI work informed the design and implementation of the approach taken. The framework that emerged is likely to be relevant in numerous contexts and could be used to support ethical review of proposed PPI work. In this way, it could be used to identify and address ethical concerns pre-emptively, and so minimise the risk of harm to children and young people while maximising the value of their contribution.

Word count: 2394

Authorship Statement

SM, A-M S, JC and JD conceptualised the article. SM led on writing of the manuscript. SN, EH and DK reviewed the manuscript for relevance and context. JC, A-M S and JD reviewed the manuscript for intellectual content. All authors edited the final manuscript.

Competing interests:
The authors declare no competing interests.

Funding statement

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