Positioning Children’s Voice in Clinical Trials Research: A New Model for Planning, Collaboration, and Reflection

How to cite:


For guidance on citations see FAQs.

© 2017 The Authors

Version: Version of Record

Link(s) to article on publisher’s website:
http://dx.doi.org/doi:10.1177/1049732317726760

Copyright and Moral Rights for the articles on this site are retained by the individual authors and/or other copyright owners. For more information on Open Research Online’s data policy on reuse of materials please consult the policies page.
Positioning Children’s Voice in Clinical Trials Research: A New Model for Planning, Collaboration, and Reflection

Amanda Lees1, Jane Payler2, Claire Ballinger3, Penny Lawrence4, Saul N. Faust3, and Geoffrey Meads1

Abstract
Following the United Nations Convention on the Rights of the Child, there has been considerable growth in research with children about health and services that affect them. Creative methods to engage with children have also been developed. One area where progress has been slower is the inclusion of children’s perspectives in qualitative research in the context of clinical trials or feasibility studies. Addressing this gap, this article discusses experiences of, and reflections on, the process of researching children’s views as part of a clinical feasibility study. The article considers what worked well and highlights remaining dilemmas. A new continuum of children’s engagement in research is presented, designed to assist researchers to make explicit the contingent demands on their research, and to suggest a range of techniques from within the broader fields of health, childhood studies, and education research that could be used to forward qualitative research in clinical contexts.

Keywords
children; illness and disease; lived experience; methodology; research design; qualitative; semi-structured interviews; United Kingdom

Background and Introduction
Within the academic fields of early years, sociology of childhood, childhood studies, and childhood education, there has been a long tradition of research with children. Guided by the United Nations Convention on the Rights of the Child (UNCRC; United Nations, 1989), researchers from the domains of sociology of childhood (Prout & James, 1997), early years, and inclusive education have developed approaches to prioritize children’s voice from a children’s rights perspective. In particular, Article 12 of UNCRC sets out that children have the right to have their views respected once they are capable of forming them. In response to this, research methods have prioritized building interactive relationships with children (Nind & Hewett, 2006), consultation (Aubery & Dahl, 2006; Porter et al., 2008; Porter et al., 2010), finding ways beyond talk to seek children’s views (Alderson, Hawthorne, & Killen, 2005; Bae, 2010; Clark & Moss, 2011), and engaging children in setting research agendas, as well as directing the methods (Bradbury-Jones & Taylor, 2015; Kellett, 2010, 2011) while attempting to avoid “othering” children in the research relationship (Lahman, 2008).

Within the field of health care research, however, progress has been slower. Fears relating to the ability of children to understand and communicate complex issues has traditionally led to the seeking of “proxy” adult perspectives (especially parents) in qualitative research, instead of direct engagement with children themselves (Huang, O’Connor, Ke, & Lee, 2016). This may have been exacerbated by a traditional preference within health research for the use of quantitative clinical studies, such as randomized controlled trials (RCTs). Important for rigorously testing the efficacy of treatments and procedures, such approaches are used to identify causal relations and are characterized by the strict control of variables and confounding factors, through the use of standard operating procedures and protocols (Lewin, Glenton, & Oxman, 2009). Within this paradigm, the more emergent, flexible, and nuanced approach of qualitative research—particularly that with children and young
people—may be viewed as beset with pitfalls (Cooper et al., 2014).

Nevertheless, in the decades since the UNCRC, the picture has gradually changed. There is a growing body of qualitative health research with children and young people, in which researchers have sought perspectives and personal experiences of illness and treatment (e.g., Horstman, Aldiss, Richardson, & Gibson, 2008), views on broader concepts related to health and well-being (e.g., Irwin & Johnson, 2005), and input into the design and delivery of services via Patient and Public Involvement (PPI) initiatives such as youth councils (e.g., Coad et al., 2008). In the United Kingdom, this has been reinforced by an increased policy focus on the importance of incorporating children’s interests and views into the design of health and care services that affect them (for a discussion, see Weil, Lemer, Webb, & Hargreaves, 2015), with engagement with children and young people now seen as the “gold standard.” Although a recent report (Office of the Children’s Commissioner, 2013) suggests that children’s participation is not yet embedded in health decision making, there has been undeniable progress in research with children and the development of creative methods with which to engage them.

A remaining shortfall for the inclusion of the views of children and young people, however, relates to qualitative research that is carried out alongside clinical trials including pilot, full trials, or feasibility studies (feasibility studies are “pre-studies” that, through a variety of different strands of data collection, assess the feasibility of carrying out a future full clinical trial). The value of using qualitative research with adults within, or alongside, RCTs is becoming more widely accepted (Cooper et al., 2014), with researchers such as Donovan et al. (2002) illustrating the transformative effects that can result when qualitative understandings are sought from patients and professionals to assist the design, conduct and analysis of trials. Qualitative research can be incorporated before, during, or after clinical trials, with a range of aims, shown in the list (taken from Lewin et al., 2009) below. It is important to state that while we use the term qualitative research in this article, we do not see this as one single paradigm that is in opposition to quantitative research. Rather we see qualitative research as encompassing a range of methods, approaches, and paradigms (Field, 2017), as is discussed more fully later (see, for example, Table 1). We nevertheless find Lewin et al.’s categorization, in List 1, useful and would accept that research that seeks participants’ views, opinions, and understandings (i.e., that is broadly “qualitative”) can enhance the design, conduct and interpretation of clinical trials research.

The policy precedent for involvement of children and young people set out above also holds true for research within and about RCTs. Children’s views and understandings should be taken into account when they are being asked to become involved in a trial which may involve nonstandard treatments with, as yet, unknown effects. Generally, however, they are not. The need to gather protocol-specific data, worries about children’s capacity to understand complex concepts and make competent decisions, as well as uncertainty about the resources required are all possible deterring factors (Coad et al., 2008; John, Hope, Savulescu, Stein, & Pollard, 2008; Weil et al., 2015). Lewin et al. (2009) carried out a systematic sample of 100 trials published in English from the register of the Cochrane Effective Practice and Organization of Care Review Group between the years of 2001 and 2003. Of those, 30 included a qualitative element. Of that 30, only one study engaged with young people (teen mothers), and none with younger children, below the age of 12. Since that date, few studies have been published that have attempted to include the views of children or young people in qualitative research, within (Lloyd & Wyatt, 2014) or about RCTs (Shilling et al., 2011).

Speaking to the identified gap, this article focuses on the means of engaging children’s perspectives in clinical trials research. We report on methodology at two interwoven levels in this article. On one level, we report on the approach involved in interviewing children (and their families), as a subsection of a wider feasibility study (duration of intravenous antibiotic therapy for children with acute osteomyelitis [OM] or septic arthritis [SA]: a feasibility study, HTA no: 10/046/01: DINOSAUR study). At another level, we report on our method of planning, collaboration, and reflection between the qualitative health researchers originally working on the clinical trials study and colleagues with expertise in the fields of

<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before a trial</strong></td>
</tr>
<tr>
<td>• To explore issues related to the health care question of interest or context of the research</td>
</tr>
<tr>
<td>• To generate hypotheses for examination in the randomized controlled trial</td>
</tr>
<tr>
<td>• To develop and refine the intervention</td>
</tr>
<tr>
<td>• To develop or select appropriate outcome measures</td>
</tr>
<tr>
<td><strong>During a trial</strong></td>
</tr>
<tr>
<td>• To examine whether the intervention was delivered as intended, including describing the intervention as delivered</td>
</tr>
<tr>
<td>• To “unpack” processes of implementation and change</td>
</tr>
<tr>
<td>• To explore deliverers’ and recipients’ responses to the intervention</td>
</tr>
<tr>
<td><strong>After a trial</strong></td>
</tr>
<tr>
<td>• To explore reasons for the findings of the trial</td>
</tr>
<tr>
<td>• To explain variations in effectiveness within the sample</td>
</tr>
<tr>
<td>• To examine the appropriateness of the underlying theory</td>
</tr>
<tr>
<td>• To generate further questions or hypotheses</td>
</tr>
</tbody>
</table>
### Table 1. Continuum of Children's Engagement With Research and Locus of Decision Making (Payler, 2016).

<table>
<thead>
<tr>
<th>Approach</th>
<th>Children as Researchers</th>
<th>Children as Coresearchers With Adults</th>
<th>Children as Participants in &quot;Open-Ended Research&quot; by Adults</th>
<th>Children as Expert Reference Groups to Adults-Led Research</th>
<th>Children as Participants in &quot;Closed-Purpose Research&quot; by Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outline</td>
<td>Children are usually trained in research methods by adults; Children set own research agendas (within parameters of adult guidance, depending on age/size of children); Children use own research processes to conduct own research studies; Children report on own research findings; Adults as facilitators for child researchers.</td>
<td>Children coconstruct research agendas and questions with adults; Children contribute to determining research methods; Children are key researchers and research participants, seeking and contributing to data; Children may contribute to presentation of findings; Alternatively, children may be involved in selected stages of the research process; Adult-child research facilitated throughout by adult coresearchers.</td>
<td>Exploratory research by adults with aim of eliciting matters of importance to children within broad themes and children's perspectives on them; Adults use children's perspectives to further shape research questions; Adults seek ways to give &quot;voice&quot; to children's experiences through multiple methods; Adult researchers seeking to research children's experiences sensitively.</td>
<td>Child reference groups are consulted to influence adult research agendas; Children comment on appropriateness of methods, findings, and reporting procedures; Adult researchers seek guidance, training, and legitimation for their research from children.</td>
<td>Adult sets research agenda, questions and approach; Children's views or experiences are sought as data on closely defined topics or questions within tightly controlled inclusion/exclusion parameters; Adult researchers seek reliable and valid data from children where children are the source of data rather than the generators of data.</td>
</tr>
<tr>
<td>Epistemological and ontological underpinning</td>
<td>Reality is socially constructed in that it is multi-voiced and multi-perspectival. Children as experts in their own lives (but not in other children's lives).</td>
<td>Reality is socially constructed in that it is multi-voiced and multi-perspectival; knowledge is coconstructed in dialogic manner between adults and children.</td>
<td>Reality exists and can be uncovered. Children's experiences can add to knowledge of that reality if and when their participation is considered reliable and trustworthy.</td>
<td>Reality exists and can be uncovered. Data from children's experiences can add to knowledge of that reality if and when their participation is considered reliable and trustworthy.</td>
<td>Reality exists and can be uncovered. Data from children's experiences can add to knowledge of that reality if and when their participation is considered reliable and trustworthy.</td>
</tr>
<tr>
<td>Potential strengths of the approach</td>
<td>Children determine what is important to research, which could be different from adults' views; Children carry out the research in ways that are meaningful for them; Full engagement in the research process could empower children's participation; Children may feel full ownership of the project and its findings.</td>
<td>Keeps close to children's experiences, but partially shaped by adult facilitation, so can mesh adult and child concerns; Adult researchers incorporate children's perspectives into the entire research, but adult coresearchers are more likely to contribute to maintaining the rigour of the research project.</td>
<td>Keeps close to children's experiences; Approach can be more inclusive of perspectives of very young children or those with less capacity for independent communication and action; Approach is not reliant on verbal articulation or children's capability to carry out research themselves, Adult coresearchers incorporate children's perspectives, but maintain the rigour of the research project.</td>
<td>Gives scope for children to influence some aspects of research design or methods within limitations, potentially offering previously unthought-of perspectives.</td>
<td>Uses predetermined protocols to study specific research question(s) from predetermined approach; Allows control to be retained over features deemed important to research aims; Adult control maintains rigour of the research project.</td>
</tr>
<tr>
<td>Potential weaknesses of the approach</td>
<td>Could exclude children who have less capacity for independent communication and action; Topics for research could be constrained by those topics children feel sufficiently comfortable and skilled to research, further limited by adult facilitation of what is considered &quot;suitable and safe&quot; for children to research; Research training might lead to children being supported to conduct research in ways that adults construct for them, leading to socialisation rather than empowerment.</td>
<td>Could exclude children who have less capacity for independent communication and action, although this will be facilitated by adults; Topics for research could be constrained by those topics adults consider &quot;suitable and safe&quot; for children to research in collaboration with adults.</td>
<td>Open-ended nature of research could mean that specific findings considered to be of use to policy or practice are not arrived at or are not taken up.</td>
<td>Reliant on selected children &quot;representing&quot; other children's views, which could be questionable. Could exclude children with less capacity for independent communication and action, including very young children.</td>
<td>Could exclude previously unthought-of perspectives, questions, and agendas; Prioritizes adult perspectives over children's experiences; Could adopt a deficit view of young children's capacity for contributing meaningfully to research, thereby restricting access to meaningful data through limited methods; Reliability through adult control could be at the expense of validity where genuine access to children's authentic perspectives and experiences is not obtained, depending on researcher skill and exact methods adopted.</td>
</tr>
</tbody>
</table>

Note. Approaches outlined are indicative points along the continuum, but do not comprise its entirety. "Children as researchers" alone encompasses many variations, see, for example, Kim (2015).
early childhood and education research that has led us to a new understanding of the possibilities for researching children’s voice in clinical trials. The collaborative method undertaken has resonance with Wickson, Carew, and Russell’s (2006) review of the challenges and principles in transdisciplinary research. It acknowledges the value of (a) collaboration between research communities, “What becomes important then is the ability of the individual to fuse knowledge from a number of different disciplines and engage with stakeholders in the process of generating knowledge” (Wickson et al., 2006, p. 1052); (b) reflection, “... using different bodies of knowledge and their methodological approaches to critically reflect on one another in a transformative process” (Wickson et al., 2006, p. 1054). The steps undertaken in the two levels of methodology are discussed and followed by a critical review of the challenges and implications of engaging with children’s perspectives in such studies.

This qualitative study, involving interviewing children and their families, could be located at points 1, 3, and 4 of Lewin et al.’s categorization above (List 1) in that it set out to explore issues related to the health care question of interest or context of the research, to develop and refine the intervention, and to develop appropriate outcome measures. Although this study was carried out in the context of clinical trials research, we believe it also holds relevance for health research more broadly, and research with children within other academic fields.

The qualitative research team was made up of two health researchers with extensive experience of qualitative methods (qualitative lead: C.B.), experience of conducting qualitative research in pediatric settings and family homes (research fellow: A.L.), but without experience of engaging children directly as research participants. The team was enhanced by the involvement of an early childhood researcher (co-author: P.L.), with experience of using a variety of research methods to engage young children. Although P.L. was less involved in data collection than A.L., she was instrumental in helping us to develop interview guides and prompt material for different ages of children and in recommending the use of toys and puppets with younger participants (see Clark, 2005 for a review of such methods). Once data collection and analysis were completed, we undertook a process of reflection on the approach used, engaging the expertise of J.P.

As a professor of education (Early Years), J.P. has firsthand experience of conducting research with young children. For example, she has used digital ethnographic case study methodology in early years’ settings and in homes, incorporating video, digital audio recording of children’s naturalistic interactions and of situated discussions with children, and video-prompted informal interviews with practitioners, to foreground children’s experiences and perspectives (Georgeson & Payler, 2015; Payler, 2007, 2009; Payler, Georgeson, & Wong, 2015). Through a series of discussions, we reflected on what we felt had worked well with our approach to interviewing children and families, as well as areas of remaining difficulty or dilemma. Some of these had been immediately apparent; others emerged with hindsight. J.P.’s role in these discussions was to highlight approaches and learning from research in education, early years, and childhood studies that we might usefully use when seeking to address these dilemmas in any future work. These discussions enabled us to surface and reflect on the differing ontological and epistemological assumptions underpinning research within different disciplines, which in turn, inform and shape methodological approaches, each with strengths and limitations. These reflections are presented below, with reference to study data. We go on to suggest a theoretically informed continuum of children’s engagement in research, designed to help researchers consider the contextual and theoretical constraints of individual projects, and within that, the range of techniques that may be available to them.

**Background to the Study**

This qualitative study was conducted as part of a larger, mixed-methods study to investigate the feasibility of a future RCT to determine optimum duration of intravenous antibiotic therapy for children with acute OM or SA.

In exploring the feasibility of a future RCT to identify optimum point of switch from intravenous to oral antibiotics in the treatment of OM or SA, it was critical that the views of affected children and their parents were included in the data used to inform decision making. The overall purpose of the interviews was to explore children’s and parents’ views, understanding and experiences of both bone and joint infections and treatment, and willingness to participate in a future RCT. Our aims were as follows:

1. To explore the experiences of children, and their parents, treated with intravenous and/or oral antibi-otic therapy for bone and joint infection about their condition and understanding about treatment.
2. To identify which clinical outcomes are most important to young people, and their parents, with bone and joint infections, to contribute to the wider stakeholder Delphi and stakeholder consultation process.
3. To explore the views of children, and their par-ents, admitted to hospital with bone and joint infections about participating in a RCT, in particular focusing on:
   a. information required to provide informed consent
b. views about and acceptability of potential interventions

c. willingness to be randomized to either arm (i.e., treatment or control)

d. influences on the above factors.

**Approach**

A purposive sample of children aged birth to 16 years was identified from four of the seven centers in the South of England, who had participated in the main Dinosaur service evaluation and microbiology substudy. The purposive sampling strategy addressed variation with regard to age, gender, and ethnicity.

The Inclusion criteria for interviews identified were as follows:

- Parents and children from 3 months to 16 years old, treated for OM and/or SA;
- Children who had been treated for bone and joint infections at one of the seven sites participating in main service evaluation and microbiology substudy;
- Parents/children who had taken part in the main Dinosaur study and consented to take part in this qualitative study.

Twenty-six families were recruited to the study. The age distribution of children represented was as follows: birth to 3 years = 10 children, 4 to 7 years = 5 children, 8 to 12 years = 4 children, and 13+ years = 7 children. Children under the age of 4 were excluded from participating in interviews directly (although they were usually present whilst interviews were being conducted) due to their age. Eight children took part in research interviews, of which three were aged 8 to 12 and five were aged 13+.

What Worked Well

**Adapting Interview to Child’s Age and “Expressional Style”**

Children do not represent a homogeneous group. Children’s capacity to understand and express themselves develops with age and experience. This was a particular issue in this study, as the children treated for bone and joint infections ranged in age from new-born babies through to young adults.

As health researchers dealing primarily with adults, A.L. and C.B. did not possess expert understanding of child development (although this can of course be found in the academic literature, for example, J. E. Gibson, 2012). We did, however, have our own personal experience of interacting with children of various ages in our roles of parent (A.L.) and aunt (C.B.), which Garbarino and Stott (1992) have identified as valuable in conducting research with children. To supplement this, we enlisted the help of a number of colleagues within the broader faculty, in particular working within Education and Early Years. A group of colleagues met together before data collection to discuss the proposed research approach and interview guides; in particular P.L. provided detailed guidance about the appropriate use of language register, attention span and ability to grapple with complex ideas according to the various ages of children we were hoping to approach. As a result of this, we developed three interview guides, with associated prompt material. Prompt material involved a process diagram of the proposed RCT and a list of potential benefits and risks associated with each of the trial arms.

- Young children up to the age of 7: This interview guide consisted of simple questions about children’s experiences and understandings, involving the use of a doctor glove puppet and a dinosaur toy (Clark, 2005). Because of the complex issues involved, this interview guide did not include a section on the proposed RCT. As discussed below, however, no children in this age group took part in interviews. This was primarily because parents did not wish to involve younger children in talking about an event that had often been upsetting and traumatic for them—an issue which is discussed further later.
- Children aged 8 to 12 years: This interview guide involved simplified language, but did cover all the
same topics as the adult guide, including seeking
views about the proposed trial (“test”).
• Young people aged 13+ and adult: The same guide
was used for both young people and adults.

As well as tailoring data collection tools, we also
sought to match the “expressional style” of the child
(Irwin & Johnson, 2005, p. 826). This involved follow-
ing children’s preferences around whether they would
rather be interviewed along with or separate from their
parents, tailoring questioning to help children express
themselves (e.g., using closed questions where neces-
sary, going “off topic”), and recognizing and responding
to varying attention spans. At the beginning of each
interview, A.L. (or P.L.) asked children whether they
would like to be interviewed with, or separately from
their parents, and, if they would like to be interviewed
separately, whether they would like to go first or second
(reflections on this—and the process of “assent” are
included in the discussion). All but one of the children
opted to be interviewed with their parents in the room.
At times, this worked as two separate interviews (with
various “chipping in” from the other parties) and some-
times it evolved into one interview—with the researcher
addressing different questions to the different parties
present (in these cases, it felt more like a focus group
than a research interview). Flexibility was certainly key
in this regard. Children also sometimes opted to leave
the interview for a time (perhaps leaving the room, or
engaging in a different activity in the room such as
drawing or playing on a phone), rejoining to answer fur-
ther questions at a later stage. This combined with the
presence of family pets, babies, toddlers, phone calls,
doorbells, requests for food, and so on, all made for
interesting research settings. At times, A.L. (more used
to interviewing adults, who at least tend to sit still), felt
anxious that the interviews would not be yielding the
information required. Nevertheless, although seemingly
somewhat chaotic, the adoption of these techniques
yielded useful and insightful research data. We were
impressed at the ability of the children (including
younger respondents) to recall and describe their experi-
nences of becoming unwell, being treated, and their
recovery from bone and joint infection, as illustrated by
Tessy’s (aged 9) recollections recounted below (pseu-
donyms have been used for all of the child respondents):

Interviewer: . . . Can you remember how long you were on
the medicine for when you got home?

Tessy: . . . I had to have one week off school but then I think
I might have had the medicine for two weeks or something
. . . I had it at six o’clock at night and eight o’clock in the
morning.

Mum: You had it three times a day, I remember going up to
the school to give it to you at lunchtimes. So yes.

Interviewer: Thank you, and can you remember what the
doctors told you about what had been making you poorly
Tessy?

Tessy: I think they said from my ear infection the bugs might
have got into my blood and went down to my knee.

Children also exhibited thoughtfulness and compre-
hension of some of the more complicated ideas concern-
ing the trial and randomization. Some expressed ideas
that resonated by those given with adult respondents in
other interviews. In the quote below, Rebecca (aged 10) is
expressing her distrust of the concept of randomization.
Her view was shared (although expressed in different
terms) by a number of adult respondents who feared that
involvement in a trial, and the process of randomization,
may threaten children’s access to tailored treatment that
best suited their individual needs. Her response also made
us reflect on how we could in future, also include an
explanation of “equipoise” in our description of the trial
process.

Interviewer: Would you have liked to have taken part in this
test? It doesn’t matter, you can tell me honestly.

Rebecca (age 10): Not really.

Interviewer: Why do you say that?

Rebecca: Just the thought of a computer that doesn’t know
any of your details choosing what treatment you have,
because it should be a computer, or a person, who knows all
your details and if you’ve had stuff in the past what treatment
you get. It’s a bit different.

. . . . . . . I just think it’s a bit risky.

Gaining Assent and Building Rapport

A number of authors have highlighted difficulties experi-
enced in gaining trust from children, which may make
them reticent to share their experiences with researchers
(e.g., Irwin & Johnson, 2005). In this study, we did not
feel that children were reticent to engage with us—chil-
dren appeared happy to share their experiences and often
tried hard to read and process prompt information.

To ensure children were comfortable with the inter-
view process, we sought their “assent” to participate
(equivalent to “consent” in the case of adult respondents).
This involved them writing their name on a simplified set
of statements about the research once the researchers had
given a description about the project. The process of
Respect that it was alright to give critical comments (e.g., “I

private respondents (parents in particular) from the burden

and P.L. themselves were not doctors or nurses, (and

activities to pediatric vaccine trials. Although association with known

of providing answers that would be “acceptable” with

professionals more closely involved with their child’s

imperative that they understood, and were able to ask

questions about the proposed study. To help with this, we
gave a simple explanation on arrival and provided a child
information sheet ahead of the appointment (and again at
the appointment if required), which they could read if
they wished. We also explained that their participation
was voluntary, that they could withdraw from the research
at any point, without giving a reason, and that the answers
they provide would be confidential and not attributable to
them personally.

As discussed above, we also followed children’s stated
preference about whether to be interviewed with, or separately from parents, which we discuss further below. Although this appeared to work well in the main, in a couple of cases where adults appeared to “take over” the interviews, it may have been more fruitful to interview separately.

We suggest there were a number of reasons for the
case we experienced in this respect of gaining assent and
building rapport. Although we had not met with these
families before, this was not the first contact families and
children had had with researchers from the Dinosaur
project. Their first involvement had been while in hospi-
tal, when a research nurse had explained the broader
study to them and asked whether they would be willing
to have some extra samples taken to contribute to the
microbiology part of the study. In addition, families were
asked whether they would be willing to be recontacted at
a later date about taking part in a research interview.

Only those families who had agreed to be recontacted
were approached about participating in this study. Families
tended to have had some contact with the hospital and
the medical team who had treated the child, and to whom
they were (generally) grateful. In fact, on several occasions,
the researcher had to explain that she herself was
not a nurse or doctor, but rather a qualitative researcher,
working with medics for this study. This suggests that
association with known and trusted professionals can help
build trust with children and their families and facilitate the interview process. Chantler et al. (2007) made a
similar suggestion when considering recruitment to pedi-
atriatroutcome and studies—characterized by shorter sections, punctuated with talk from

the researcher and asides. This was certainly our experience,

as the researcher’s voice. Interviews with children do not tend to result in these “solid blocks of text” (Irwin
& Johnson, 2005; Wilson & Powell, 2001), and are characterized by shorter sections, punctuated with talk from
the researcher and asides. This was certainly our experience,
and yielded an issue for the reporting and analysis of data, which we only noted with hindsight.

Transcribed passages of uninterrupted talk offer rich pickings for those illustrative quotes that can bring qualitative data alive. The absence of these from the children’s transcripts made the finding of pithy illustrative quotes (such as are used in traditional adult-focused reporting techniques) harder in the transcripts of the children’s interviews. Because of this, the quotes used in the presentation and report originated mainly from adult respondents.

This was pointed out to us by the 17-year-old PPI rep-
resentative at the end of a presentation made at the study
stakeholder day. She suggested that, as the quotes came

Reporting Conventions and “Quote-Able” Data

It has been acknowledged by previous researchers of
children’s views that data originating from interviews
with children does not mirror that of adults, whose talk
tends to include longer sections of narrative, uninter-
rupted by the researcher’s voice. Interviews with children
do not tend to result in these “solid blocks of text” (Irwin

and Johnson, 2005; Wilson & Powell, 2001), and are characterized by shorter sections, punctuated with talk from
the researcher and asides. This was certainly our experience,
and yielded an issue for the reporting and analysis of data, which we only noted with hindsight.

Transcribed passages of uninterrupted talk offer rich pickings for those illustrative quotes that can bring qualitative data alive. The absence of these from the children’s transcripts made the finding of pithy illustrative quotes (such as are used in traditional adult-focused reporting techniques) harder in the transcripts of the children’s interviews. Because of this, the quotes used in the presentation and report originated mainly from adult respondents.

This was pointed out to us by the 17-year-old PPI repre-
sentative at the end of a presentation made at the study
stakeholder day. She suggested that, as the quotes came

remaining Dilemmas

remain Dilemmas

remaining Dilemmas

Reporting Conventions and “Quote-Able” Data

It has been acknowledged by previous researchers of
children’s views that data originating from interviews
with children does not mirror that of adults, whose talk
tends to include longer sections of narrative, uninter-
rupted by the researcher’s voice. Interviews with children
do not tend to result in these “solid blocks of text” (Irwin

and Johnson, 2005; Wilson & Powell, 2001), and are characterized by shorter sections, punctuated with talk from
the researcher and asides. This was certainly our experience,
and yielded an issue for the reporting and analysis of data, which we only noted with hindsight.

Transcribed passages of uninterrupted talk offer rich pickings for those illustrative quotes that can bring qualitative data alive. The absence of these from the children’s transcripts made the finding of pithy illustrative quotes (such as are used in traditional adult-focused reporting techniques) harder in the transcripts of the children’s interviews. Because of this, the quotes used in the presentation and report originated mainly from adult respondents.

This was pointed out to us by the 17-year-old PPI rep-
resentative at the end of a presentation made at the study
stakeholder day. She suggested that, as the quotes came

remaining Dilemmas

Reporting Conventions and “Quote-Able” Data

It has been acknowledged by previous researchers of
children’s views that data originating from interviews
with children does not mirror that of adults, whose talk
tends to include longer sections of narrative, uninter-
rupted by the researcher’s voice. Interviews with children
do not tend to result in these “solid blocks of text” (Irwin

and Johnson, 2005; Wilson & Powell, 2001), and are characterized by shorter sections, punctuated with talk from
the researcher and asides. This was certainly our experience,
and yielded an issue for the reporting and analysis of data, which we only noted with hindsight.

Transcribed passages of uninterrupted talk offer rich pickings for those illustrative quotes that can bring qualitative data alive. The absence of these from the children’s transcripts made the finding of pithy illustrative quotes (such as are used in traditional adult-focused reporting techniques) harder in the transcripts of the children’s interviews. Because of this, the quotes used in the presentation and report originated mainly from adult respondents.

This was pointed out to us by the 17-year-old PPI repre-
sentative at the end of a presentation made at the study
stakeholder day. She suggested that, as the quotes came
mainly from the parents, the child voice was being less represented. This was a useful and valuable point. Contrary to the approach taken with data collection, we had been seeking to insert qualitative data from the children into the adult reporting paradigm. There is work to do in considering how such data can be best presented and reported more creatively by health researchers, and it is important to consult PPI reps, and participants themselves, about how this might be done. Equally, it calls into question the appropriateness of relying solely on interview data when trying to examine and represent children’s views on their health, illnesses, and treatments. This is an area where qualitative health research can learn from other disciplines, and is discussed further below.

**Differing Perspectives of Children and Adults**

Another unanticipated issue arose in instances where children and adults expressed different perceptions, or gave differing emphasis, when reporting the same events. Although able to acknowledge the painful aspects of their illness and treatment, we noticed that on a number of occasions, children appeared to downplay the impact of events on them, or to focus on different issues to their parents, whose accounts tended to emphasize the high levels of distress they and their child experienced. Some examples are shown below; as explained above, these extracts are somewhat extended, due to the nature of the data we gathered:

Researcher: So, I just wanted to ask you what it was like for you when you were having your antibiotics like this, through the line? (Referring to a picture of an IV line)

Toby: It kind of stung sometimes, but then sometimes it didn’t even hurt at all and I just forgot about it.

Researcher: . . . did you think there was anything good about having the antibiotics like this? (Referring to picture of line).

Toby: Yes, they kind of made me feel better over like the few days.

Researcher: Was there anything that wasn’t very nice about having them like this?

Toby: Sometimes when it went through the tube it kind of stung a bit along the vein.

Dad, interjecting: The first time they put it in, he was in agony and they had to stop it and take it out and redo it, because we weren’t quite sure whether it was in a wrong vein or something. They tried different sites on the same arm . . . in the end they tried another site on the same arm and it was horrendous. He was . . .

Toby: Screaming.

Dad: He was like . . . “Rip it out” [dramatic voice] . . . That’s why (when) Toby was going “it stung a little bit,” I thought, hang on this is the boy that was sitting there going ‘Rip it out!’” [dramatic voice].

In Toby’s account, he has presented receiving the IV antibiotics as stinging a bit, whereas his dad has described it as agonizing. In another instance, of apparent “downplaying,” Tessy (9), talking about her admission to hospital, stresses her experiences of using a wheelchair (a theme she returned to several times during the interview), above the discomfort described in her mum’s narrative.

Mum: And so then we went up to the children’s hospital . . .

Tessy: I got my first wheelchair with the big wheels, and I kept bumping into walls [chuckles].

Researcher: Did they send you pretty much straight on then?

Mum: Yes, they did start explaining about the septicemia, but obviously they need to run tests. They couldn’t do anything at the (local hospital), it’s just like an outpatients—it’s not like an A&E place.

Tessy: They told me to go to the (main hospital).

Mum: They did, didn’t they? And I couldn’t, and by that time, by the time I got into (location) she was saying she couldn’t walk and I had to carry her. Which was why we got the wheelchair in the first place.

Tessy: But when we went to the first one, I remember I had to wait on a wooden bench for a wheelchair . . . That was my first wheelchair. With tiny wheels.

Mum: Yes, that one was because your leg was sore and you were tired. But yes, by the time we got to the children’s hospital she was finding it really painful to even stand, like put any weight at all on her legs.

In another instance, Charlotte (13) talked about receiving a general anesthetic—the extract highlights the difference in experience of child and parent.

Researcher: So you had to have a general anesthetic?

Charlotte: I think so.

Mum: Yes.

Researcher: What was that like mum?

Mum: That’s not nice is it?
Charlotte: I was fine.

Mum: She’s all right, anything.

Researcher: I was thinking about mum—I bet she was more worried than you?

Mum: It’s worse for the parents watching . . .

Charlotte: Why? Dad cried, I was like, “What are you doing?”

In the third extract from Charlotte, it is clear that she was less distressed by the incident than her parents were. In the previous two extracts, children present more pragmatic accounts of events, with parents tending to focus most on the level of distress they perceived in their child. Wilson and Powell (2001) showed us that children may focus on different issues as an event takes place (illustrated by Tessy’s fascination by the wheelchair), and that this affects how they store and present their memories. In hindsight, we reflect that as adult researchers, our analysis afforded greater weight to the descriptions given by parents about events and that we tended to see children to be “downplaying” the seriousness of events for the sake of the interview. Thus, we took from Toby’s extract that his initial experience of having the IV cannula inserted was highly unpleasant, even though this is not how he initially describes it. We understood from Tessy’s mum that the child was poorly and in a lot of discomfort, even though Tessy herself focuses more on experiences with various wheelchairs. Despite these interpretations, it is possible that parents’ heightened levels of anxiety during the time of their child’s illness may have led them to overstate the discomfort and risk associated with their child’s condition (thus making children’s accounts in fact more “accurate”). The recognition of these differing perspectives, and how we may take them more fully in to account, is revisited later.

Gatekeepers and a Risk of Paternalism?

Linked to this was the issue of protective feelings that arise in adults when considering talking to children about events that they may have found upsetting and unpleasant. As described above, parents of children up to seven were reticent to involve them in interviews about their experiences of being ill. As a parent herself, this felt completely understandable to A.L., who did not at any stage question this decision on the part of parents. Similarly, during the interview process, there were a number of points when AL felt uncomfortable at asking children (and indeed parents) to go over events in cases where children had been particularly unwell or upset. In one interview, a teenage girl and her mum described their frustration and sadness at the failure of treatment, such that the child’s infection had become a chronic, persistent, and debilitating problem. In this interview, AL did not feel she could show the prompt materials relating to antibiotic therapy—feeling that she did not want to introduce any more potential worries by highlighting a list of potential risks of prolonged antibiotic therapy. In some ways, this resonates with the findings of Donovan, Paramasivan, de Salis, and Toerien (2014) who found that in recruiting to clinical trials, medics may exclude inviting particular patients for a variety of protective reasons.

Of course, issues of empathy, and attending to the feelings of respondents are paramount in qualitative research. However, the role of these protective feelings was questioned by our insightful PPI representative, who suggested that while adults may feel that children will not want to talk about something, or that a particular set of information may trouble them, we do not really know this to be the case until we ask them. This was food for thought, particularly in light of the findings discussed above in relation to the differing interpretations of children and adults about events. It was further illustrated by an exchange between a mum and her 15-year-old whose condition had made him critically ill.

Mum: You’ve moved on better than I have.

Sebastien: Yes, it happens, can’t do anything about it now, that’s my way of looking at it.

Mum: That’s a very good way. That’s a very healthy way.

Although certainly not seeking to downplay the need to conduct research in an ethical and considerate way, this suggests that sometimes our own feelings as researchers may limit the data we collect from children, who may be more resilient than we think. Here again, we suggest that involving children as PPI representatives during the design phase of the study would help us to get a better understanding of when we are being rightly cautious and when we may be becoming “overprotective,” thus limiting the potential for children to be heard. It would also be worth considering here the issue of whether it may be preferable for children to be interviewed on their own (separately from their parents) if they are old enough (although what constitutes “old enough” and who decides is also contestable). In this study, the presence of the parents with the child did influence the course of discussions, with interactions happening between children and parents in the context of the interview. In this way, interviews became at points more like a focus group, which can have strengths as a method of data collection with children (F. Gibson, 2007; Horner, 2000; Morgan, Gibbs,
maxwell, & britten, 2002). although this may have stimulated new and different ways of thinking, it is possible that children may have felt freer to present their accounts in their own voices, outside of the presence of their parents. this must be weighed against confidence of children to talk to researchers independently of their parents’ support.

discussion

key methodological issues and dilemmas were surfaced during the joint critical reflection between the authors. these have been flagged for attention throughout the article and include

- ethical considerations (assent, the role of gatekeepers) and links to the quality of research data
- methods beyond interviewing for collecting data and tools for reporting/analysis that allow space for children’s views to be heard.
- the quality of researchers’ interview skills, drawing on their interpersonal qualities, and the implications for training.

each of these will be considered shortly and contribute to our suggested interdisciplinary framework for moving the field of health and illness research with children forwards. however, before this, we suggest that there are fundamental deliberations necessary with regard to where health research positions itself in relation to children’s perspectives because something more than developing or appropriating research tools is required to enable the field to avoid token voices. such deliberations contribute to weil et al. ’s (2015) call for further progress in children’s voices being listened to, their needs understood, and rights respected.

children’s engagement in research more broadly to date might usefully be conceptualized as a continuum ranging from children being empowered and trained to undertake research of their own choosing to children’s views or responses being sought in relation to strictly adult-defined questions by means of adult-oriented methods (see table 1: continuum of children’s engagement with research, payler, 2016).

different locations along the continuum imply different underpinning epistemologies and conceptions of children and are often associated with different research paradigms (some of the epistemological and ontological debates are discussed in kim, 2016) as well as methods. different locations along the continuum are also implied by the nature of the research questions under investigation as well as by who determines the research questions or indeed the research agendas. we suggest that by surfacing these different approaches to children’s engagement in research and the associated implications for agenda, methodologies, and design, new possibilities for qualitative health research with children may be considered. clinical research historically operates from a paradigm in which carefully defined and bounded research protocols are determined by professionals according to scientific principles to answer specific questions necessary to further knowledge and treatment. thus, it appears to fit more closely to the right-hand end of the continuum. this end of the continuum can be associated with the realist approaches, where “reality” is seen as having an external existence of its own—however ambiguously represented—that can be uncovered through the research process and intellect of the researcher (hollway & jefferson, 2000). in such approaches, children’s perspectives may be sidelined in favor of the more factually “accurate” impressions of adults, or at least sought according to tightly defined criteria.

other positions along the continuum might offer further openings to enhancing health and medical research. at the left-hand end of the continuum, the freedom and empowerment accorded to child researchers has the potential to open the way for their views, perspectives, and priorities to be valued equally to those of their adult counterparts, although this claim is not without critique (see, for example, kim, 2015). we can draw a parallel here to constructivism’s (guba & lincoln, 1989) recognition of the value of differing perceptions of “reality.” as woodgate (2001) wrote,

when children are viewed from an alternative perspective, the major principles of the qualitative paradigm may actually serve as facilitators to apprehending their thoughts and feelings. the following key principles of the qualitative research paradigm are . . . (a) realities are constructed by human beings who are viewed as active agents making sense out of the realities they encounter; (b) realities are multiple and must be perceived holistically and from various vantage points; and (c) realities are shared and mutually shaped by the researcher and research participants. (p. 149)

it is important to note, however, that positions at the far left of the continuum are likely to be most accessible to children whose learning, experiences, development, or culture facilitate receptiveness to research training and competence to carry it out, such that it could exclude very young children or those with communication or learning difficulties or disabilities. in this case, children as “open-ended research participants” may be the more liberating and inclusive approach.

although children are already part of influencing aspects of practice through the ppi movement (e.g., nihr medicines for children research network, 2011, 2013), the left-hand side of the continuum might still
Ethical Considerations (Assent/Gatekeepers) and the Quality of Research Data

Ethical issues were raised during the conduct of the research reflection with regard to how to conduct research with children that allowed for and facilitated their willing and informed participation, and how and when to seek their assent. Such issues have an impact on the quality and authenticity of data obtained. What are the implications of asking children if they would like to be interviewed alone or for their parents to be present when their parents are present while that question is asked? Some children will feel that it implies they have something to hide if they state they do not want parents to be present; some will feel more relaxed with parents present; others may want parents present but temper what they then say during the interview to save parents’ feelings or to save face themselves. Decisions about access, privacy, and assent impact on the quality of the data subsequently generated. Christensen and Prout (2002, p. 490) set out a summary of key questions to address when considering ethical symmetry in research with children which could be used to ensure ethically appropriate qualitative health research with children.

Methods Beyond Interviewing: Research Design and Tools for Collection and Analysis

Some of the difficulties encountered in eliciting children’s perspectives and experiences of health, illness, and treatments, particularly but not exclusively those of the youngest children, pertain to the limitations of one-off, time-limited interviews conducted by a researcher with prompts largely based on verbal articulation or written material. Such methods have distinct limitations and it would be worth considering other methods, some of which are discussed by Clark & Moss, 2011:

1. Prompts using audio-recorded chat-and-walk tours of the facilities linked to the episodes of illness and treatment (Clark & Moss, 2011, pp. 28–29) (could be virtual using a video recording of the facilities, using loose photographs or comic-strip style).
2. Discussions based around reviewing sets of photographs.
3. Giving children cameras to take photographs of their experiences and then tell their story/discuss them (Clark & Moss, 2011, pp. 23–27).
4. Engaging views over time, for example, by sending back an audio podcast of the researcher telling the “story” of what the child told the researcher and inviting the child to add extra comments as they think of them to a digital voice recorder or video blog.
5. Giving children [and parents] questions and prompts in advance so that they have time and opportunity to think about their responses and add to them over time, preferably digitally.
6. Video-recording of informal interviews, [virtual tours] and discussions to enable deeper and more sensitive analysis of the child’s responses, particularly the nonverbal features of communication.

Similarly, creative approaches to the development of prompt materials for younger children are required. It is important to also give thought to how the findings from these and more traditional methods will be analyzed and presented to ensure that children’s views are accurately interpreted and heard (Punch, 2002). We suggest that consideration as to the outputs of the research are included at the design stage, with due consideration made to the requirements of the each research study. Ethically, it may be important to think about how children might understand and accept the role their views will have—for example, where children are involved in service redesign, it may be reasonable for them to see direct implementation of their suggestions, while in other instances, this is less likely. This sits alongside broader debates about the
role and purpose of qualitative research alongside clinical trials (Cooper et al., 2014).

It may be assumed that once data are collected, the task of analysis is likely to be beyond the participation of children, particularly younger children. However, Lundy, McCvoy, and Byrne (2011) provided a useful example of how preparing for children’s involvement with children prior to data collection and involving children during analysis can enhance the quality of the research and its findings. For example, framing their research within a children’s rights perspective, Lundy et al. (2011) explained how they used workshops with visual and kinaesthetic methods in advance of the data collection phase of their research with 4- and 5-year-olds to introduce the children to “the broader concepts in which the research study was situated” (p. 721) so that the children could engage more fully with the purpose of and substantive issues related to the research, thus facilitating their participation as co-researchers and having a direct impact on the validity of the findings. Lundy et al. (2011) also explained how they engaged the 4- and 5-year-olds in the analysis of their coresearched data through finding visual ways to represent the study results meaningfully and then using these to facilitate discussion.

In sum, although the picture survey highlighted what children liked or found difficult, it did not always tell us why this was the case. The [child co-researchers] were able to provide expert perspectives that enabled us to gain insight and understanding into the reasons underlying the responses. (Lundy et al., 2011, p. 727)

Such approaches are indicative of the range of ways in which research with children can be analyzed, enriching findings and interpretations. Insight may also be afforded from narrative techniques for analysis and related, psychodynamically informed work, for example, Hollway and Jefferson (2000), which acknowledge that responses and impressions given by research subjects are likely to be subject to a range of conscious or unconscious influences, such as the need to defend against particularly anxiety provoking or emotionally intense experiences. In these interviews it may have been helpful to consider influencing factors that could have shaped children’s (and adults’) responses to questions about their experiences (e.g., downplaying to make the situation feel more manageable, not wishing to upset parents by showing their own distress at events, etc.).

Quality of Researchers’ Interpersonal/Research Skills

The most elegant and open research tools might be inadvertently operationalized in different ways by the mediation of different researchers; no two interviews are really the same when undertaken by different researchers. There is more at play in gaining and maintaining genuine participation of children than an association with known/trusted doctors or nurses. To engage children in genuine and open participation, with children being willing and able to access, recall, and reveal their feelings and memories about illness and treatments, requires interpersonal skills that are sensitive and responsive to the child as an individual and to his or her context. There are clearly implications for selection, training, and personal development of researchers for such tasks as well as for developing appropriate research tools.

Conclusion

In this article, through critical reflection on the two interwoven levels of methodology—researching children’s perspectives on clinical trials and collaborative engagement with researchers from disciplines beyond health—we have presented a new model for planning, collaboration, and reflection to advance the field of qualitative health research in relation to children’s voice in clinical trials. We described how the context within which a study was carried out set parameters around the methods chosen to collect and report our data and, as a result, raised some issues as to how accurately children’s perspectives were heard and reported. For researchers operating within the health field, there is great value in explicitly acknowledging and defining the constraints of context and of ontological and epistemological positioning. Such an exercise would provide a starting place on the presented continuum of engagement. However, rather than adopting a fixed point, by considering approaches and perspectives of childhood researchers from disciplines with a broader range of approaches, and by engaging wholeheartedly with children and young people’s PPI representatives, a wider array of methods for collection and analysis become available, with the potential to take heed more closely of children’s views and perspectives. Such potential could open up clinical research to more authentic findings about what matters to children and why.

Authors’ Note

This report includes data from independent research commissioned by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, Medical Research Council (MRC), Central Commissioning Facility (CCF), The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), the NIHR Health Technology Assessment Programme or the Department of Health.
Declaration of Conflicting Interests
The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding
The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (Wessex) at University Hospital Southampton NHS Foundation Trust and the University of Southampton; and the NIHR Health Technology Assessment Programme (Project No. HTA 10-146-01).

References
Field, J. (2017). Losing the so-called paradigm war: Does our confusion, disarray and retreat contribute to the advance? Journal of Applied Hermeneutics, Article 5. doi: 10515/ sy5fg9ap2
Horstman, M., Aldiss, S., Richardson, A., & Gibson, F. (2008). Methodological issues when using the draw and write


**Author Biographies**

**Amanda Lees**, is a senior researcher in the Health and Wellbeing Research Group at the University of Winchester, Winchester, UK.

**Jane Payler**, is a professor of education (Early Years), within the School of Education, Childhood and Youth in the Faculty of Wellbeing, Education and Language Studies, The Open University, Stuart Hall Building, Walton Hall, Milton Keynes, UK.

**Claire Ballinger**, is the strategic lead for the Wessex Public Involvement Network (PIN) at the University of Southampton, Southampton General Hospital, Tremona Road, Southampton, UK.

**Penny Lawrence**, is a senior lecturer in early childhood studies, at the School of Education, University of Roehampton, London, UK.

**Saul N. Faust**, is professor of paediatric immunology and infectious diseases, Faculty of Medicine and Director of the NIHR Wellcome Trust Clinical Research Facility, University of Southampton and University Hospital Southampton NHS Foundation Trust, Southampton, UK.

**Geoffrey Meads**, is professor of health sciences research, Health and Wellbeing Research Group, University of Winchester, Winchester, UK.