Ethical challenges in research with orphans and vulnerable children: a qualitative study of researcher experiences

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Background: Orphans and vulnerable children (OVCs) represent a significant population worldwide, enduring poor health and living conditions. Evidence-based interventions are needed. However, without parents, ethical concerns about including OVCs in research persist. The aim of our study was to better understand the ethical challenges facing researchers who work with OVCs.

Methods: We conducted semi-structured interviews with 12 international pediatric researchers working with OVCs in seven countries. We used descriptive content analysis to characterize the ethical rationale for inclusion and associated challenges.

Results: Researchers believed research was justified as a necessary means for informing evidence-based interventions to benefit OVCs directly or as a population. Ethical challenges included difficulty identifying OVCs given variation among children living without parents; difficulty identifying guardians among a range of caregivers; concerns about meaningfulness of guardian consent; difficulty assessing risk; and responding to children’s many needs.

Conclusions: A range of caregivers bear responsibility to protect OVC’s interests in place of parents in research but are often not prepared to do so. This places greater burden on researchers to assess risks and respond to children’s needs. Findings suggest that we should improve support and rethink the roles of guardians, researchers and older children in research participation and protection.

Keywords: Assent, Consent, International research ethics, Orphans, Vulnerable children, Vulnerable populations

Background

Orphaned, homeless and other unaccompanied children and young people—often referred to internationally as orphans and vulnerable children, or OVCs—represent a significant but poorly represented global population. UNICEF estimates that there are approximately 153 million orphans worldwide.1,2 Sub-Saharan Africa and Southeast Asia continue to have the highest number of orphaned children due to parental loss from HIV/AIDS, with 17.9 million children estimated to have lost one or both parents to the disease.1,2 In high-income countries, the numbers of unaccompanied children living without parents are still significant relative to available resources and child welfare institutions. For example, the US government estimates that approximately 380 000 children are living without families—that is, living in transient residence, on the street, or in transitional institutions.3 Thousands of unaccompanied children and young people in Europe have lost or been separated from parents following war and political conflicts in Afghanistan, Iraq and Syria.2 That we see such varied estimates of unaccompanied children and young people reflects the challenges of mapping and reaching a still largely invisible and transient population.

The health and social impact of living on one’s own as a child or teen is significant. These children endure dangerous living conditions, sexual exploitation, violence and exposure to the elements. Equally devastating is the under-reported impact of undiagnosed and untreated childhood illnesses: high rates of preventable infections, lack of access to vaccinations and dental care, treatment and prevention of sexually transmitted diseases, malnutrition, and the long-term psychological impact of stress.4–6 Innovative, effective solutions to address the social, economic and health conditions in which these children live and struggle are needed. There are many well-meaning humanitarian and governmental organizations, large and small, offering aid to vulnerable children; however, the
programs and interventions are varied and often not sufficiently evidence-based. While research can improve the evidence-base, without parents to advocate for their protection and best interests these children are highly vulnerable to exploitation and harm, raising ethical concerns about their inclusion in research.3–12

For this reason research including OVCs as a target population remains relatively limited when compared to research with general pediatric populations. Whereas inclusion of OVCs in clinical pediatric research with prospects of direct therapeutic benefit to the child is increasingly permitted with the presence of a legal guardian to consent on behalf of the child. Ethical guidance varies between two approaches. The most common approach is to apply the same ethical criteria for the inclusion of all children in research, with no child permitted in research who does not have a parent or guardian to consent on his or her behalf; in this case OVCs might be ruled out for lacking a guardian or in case-by-base, context-specific judgments about the risk-benefit balance for especially vulnerable children.13–19 This reflects the longstanding view that research protections ought to assume that all children are vulnerable by virtue of their social dependence on parents or guardians and their underdeveloped capacity to understand and appreciate harms and risks.20,21 An emerging approach, taken by countries such as South Africa and the United States, names the population of OVCs as a special vulnerable population and includes additional protections—such as the use of study advocates—that extend beyond general protections designed to safeguard all children.13,14 These tailored protections arose partly in response to concerns about unjustly excluding OVCs from potentially beneficial research in settings with a very high burden of childhood diseases, while recognizing the practical and ethical challenges of inclusion without parents to protect the child’s interests in research.

One concern with the inclusive approach to protection for all children is that it places significant ethical weight on the role of parents, caregivers and guardians to protect a child’s interests through the consent process and during ongoing participation in a study. For children living in institutions, temporary foster homes, or other transient social settings, guardians are expected to act in place of parents to ensure that the interests of the child are protected, concerns about participation in the study are expressed, symptoms are reported and so on. In addition, taking the approach that all children are vulnerable and developing ethical guidance and regulation accordingly might potentially overlook special, context-dependent vulnerabilities or ethical challenges that only arise for some children. Other studies on research including OVCs have revealed a number of culturally specific challenges related to assent/consent, the need for allowing direct consent of unaccompanied but independent adolescents, and varying understandings of what constitutes an orphan, guardian or family.12–16

Given the substantial pediatric research supported by US funding agencies but conducted with populations of vulnerable children internationally, we designed a qualitative interview study with a purposive sample of US, European and South African pediatric researchers who have conducted research with children living as wards of the state or OVCs in compliance with the US Federal Regulations that govern research with this vulnerable group. The objective was to identify and characterize the ethical challenges arising following Ethics Review Board approval and to identify gaps in guidance and regulation, particularly for US investigators working internationally. Our group of experts included pediatric researchers engaged in medical, public health or social science research with children living as wards of the state, orphans, and homeless children and adolescents in seven countries (Table 1). Our aims were to gain a contextual understanding of the ethical issues that researchers encounter in practice and to better appreciate the ethical rationale for including OVCs in research from the perspective of those investigating the health and social challenges facing unaccompanied children.

### Methods

#### Study design and sampling

We conducted semi-structured qualitative interviews with a purposive sampling of pediatric investigators who have conducted

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<th>Table 1. Participant and study demographics</th>
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<td><strong>Researchers’ nationality</strong></td>
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<td>US (8), Tanzania (1), South Africa (1).</td>
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<td>Other: longitudinal surveys, ethnographic study, cross sectional study evaluating health</td>
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*Several investigators enrolled different ages of children in their studies.*
research that enrolled orphans or wards of the state. We relied on literature reviews to characterize the types of studies involving OVCs and to identify a population of investigators for recruitment. The US is one of a few countries that has special government ethics guidance for including OVCs in research.24 The US is one of a few countries that has special government ethics guidance for including OVCs in research.24

We conducted preliminary interviews with four pediatric institutional review board chairs regarding the experience of reviewing research protocols involving wards of the state and OVCs. This informed our interview guide for researchers, but these data are not included here given that only one had sufficient experience reviewing such studies. The interview guide domains included: beliefs and values regarding the ethical rationale for inclusion/exclusion of OVCs in research; experience with study design/enrollment; experience with assent/consent and decision making with guardians; judgments and values on risk/benefit, ancillary care, and compensation. At the end of each interview participants were given the opportunity to share additional thoughts about any issues not covered.

**Data collection**

We recruited researchers representing a variety of public health, non-profit and academic institutions. We identified pediatric clinical investigators who received US federal funding or were published in the top medical, pediatric and social science journals from 2000–2010. Investigators were identified via the PubMed and RePORT databases (Box 1). A total of 12 investigators were recruited for inclusion in telephone interviews.

**Data analysis**

TB conducted the interviews. All interviews were transcribed and imported to ATLAS.ti qualitative software to facilitate data analysis. TB and MK were responsible for coding the transcripts, which included an iterative process involving several reviews of the transcripts. Analysis began with organizing the data by concept, then by theme, and eventually by constructing theoretic relationships between concepts and themes present in the data.27,28 A codebook was designed based on a review of a subset of the transcripts and revised iteratively. Codes included the a priori ethical concepts that informed our interview guide as well as emergent concepts and themes from the data. Analytic memos were used to create an audit trail and document the evolution of code definitions, including impressions about the themes emerging from the data. A second round of coding identified themes in the narrative text. Themes included ethical concerns, values, perspectives, conflicts or barriers, and processes for addressing conflicts or barriers in conducting research with OVCs. Coded results were then shared with the expert advisory panel (BW, LL, BR, SMH) for in depth discussion about interpretation of findings. The panel discussed impressions of the results from a multidisciplinary perspective, revised themes, and together decided on the most salient themes vis-à-vis understanding researchers’ experience of ethical challenges in research with OVCs.

**Ethical considerations**

Ethics approval for the study was obtained from the Seattle Children’s Research Institute’s IRB. Potential participants were contacted by e-mail with a letter explaining the study and asking
for permission to schedule a telephone interview. Upon agreement, participants were contacted by follow-up e-mail to arrange a time for the interview. Before the interview portion of our study, all participants were given pre-interview demographic questions to complete, and a consent form to be discussed at the time of the interview. Oral consent was obtained at the beginning of each audio-recorded telephone interview. Detailed participant demographics and mention of specific study details have been omitted to protect researcher confidentiality.

Results

Data are organized by the cross-cutting ethical themes that emerged from researchers’ own descriptions of the rationale for including OVCs in research and ethical challenges encountered in the field, following ethics approval.

Ethical rationale for including OVCs in research

Because this was a purposive sample of experts working with OVCs, we were interested in how they articulated the ethical rationale for including OVCs in research and the reasons or circumstances for excluding OVCs from research. Nearly all viewed research as an important tool for better understanding the specific needs of children and teens living as OVCs and raising awareness about those needs.

I firmly believe that it’s important for us to include orphans and other vulnerable children in our research. Otherwise, how else would we know how to conduct interventions that address their circumstances? We need to make sure that they are represented. (Participant 9)

Several spoke passionately about inclusion in potentially beneficial research as matter of fairness and social justice.

Kids who are the most disenfranchised won’t have the opportunity to participate in potentially helpful interventions, and interventions won’t be able to be developed that are tailored to their unique needs. (Participant 2)

If there’s a direct benefit to the child in participating, then I think they should have access to it. [Chemotherapy trials, etc. I mean, if the kid needs treatment and didn’t get something, I think it’s not right to say they shouldn’t get it because they’re orphans. (Participant 10)

At the same time, these researchers were experienced with the daily life and vulnerabilities of children living without parents. To gauge researchers’ attitudes toward acceptable risk thresholds in research, we presented brief descriptions of different types of pediatric research attended with greater levels of risk. All but one participant agreed that research involving greater than minimal risk that does not offer the prospect of a direct benefit to the child or contributing to scientific knowledge that will in turn enable us to improve interventions and programs to help this population of vulnerable children. In this sense, they viewed research as a tool for addressing their physical and psychosocial vulnerabilities.

This group faces, oftentimes, significantly poor outcomes in whatever you might be looking at—education or health—mental and physical health. So, I would argue for inclusion of this group. And, part of that is because I think they are vulnerable on a number of levels, and that excluding them from research would basically prevent us from trying to address these issues, and to support them in a way that is evidence-based. (Participant 8)

The researchers working in low-income countries also believed it was important to include OVCs in research offering prospect of direct benefit if that was the only context in which they could receive the benefit (e.g., a vaccine or preventive care).

The issue for me would be: what’s the level of benefit to the participant in research? And if the research offers the only option, or the potential of direct benefit and there’s no other way to get it, then I think it’s unethical to exclude orphans, just because they’re orphans. Because then they don’t have access to something that other kids would. (Participant 10)

However, when asked how they weigh the background, daily risks and stress in the lives of OVCs, researchers were hesitant to enroll OVCs in research if they thought doing so might cause added stress or trauma. Several researchers felt this should be true for any children in research, particularly when working in low-resource settings.

I think they are a vulnerable population for a lot of reasons, and I think, as you would say for any particularly vulnerable population, it isn’t probably ethical to conduct high risk research on a vulnerable population, if it could be just as well conducted on another population. (Participant 5)

Another participant referenced the history of exploitative experiments with orphans to underscore what he felt to be the central ethical worry, which is that orphans had historically been used as a convenience sample:

I think what people were trying to get away from is the fact that you just use orphans because it’s convenient. And that they’re coerced in some way from doing things they wouldn’t normally do… you wouldn’t want to make the assumption that just because it’s easy to enroll the orphans that you should. (Participant 10)

Researchers all thought minimal risk and slightly greater than minimal risk research with this population is ethically justified, but only if offering benefit to the child or contributing to scientific knowledge that will in turn enable us to improve interventions and programs to help this population of vulnerable children. In this sense, they viewed research as a tool for addressing their physical and psychosocial vulnerabilities.

If you had a child who had, maybe, a serious mental or physical ailment that was not the focus of the study, that the study itself could be harmful to the child, or the information from the child in that study would not really be useful because of the situation of the child, particularly on disability grounds… we would never want to continue trying to recruit a child if there was any harm that could come to the child. (Participant 1)
Several researchers noted personal challenges in navigating ethics approval for research involving vulnerable children and worried that barriers to approval might create a disincentive for including OVCs in potentially beneficial research. 

I think my biggest worry is that people won't do this kind of research because they're fearful and they don't have the knowledge to be able to know what can and can't be done. ... I think doing research [in my case] with homeless kids— you can count the number of people who do intervention research on one hand. That's a big problem! And I think it's because many people are fearful because they don't understand the regulations or know them, or they don't know what protections they have, and the protections for the kids. I think it's systemic. I think the IRB/REC almost doesn't want people to do this research, because it puts the university, at what they consider to be more risk. (Participant 2)

Who is an orphan? Challenges defining the population of vulnerable children

Classification and definitions of research populations are important when it comes to applying the relevant protections for special populations, like pregnant women or prisoners. Researchers noted that a major challenge is accurately describing a population, including OVCs in potentially beneficial research. Variation was especially pronounced in contexts where informal custody arrangements are the norm, and where children who would technically be considered orphans (have lost both parents) are not viewed as orphans as long as they had relatives, neighbors or community members to care for them.

If a child loses their parents, they've still got parents in the form of uncles or the grandparents. Our notion of orphans, in social terms, doesn't really apply in many parts of Africa. (Participant 3)

Investigators conducting research in sub-Saharan Africa noted that many children who are considered orphans and may reside in an orphanage have parents who are alive. They are considered ‘social orphans’ because their parents have given them up due to economic necessity, migration or illness. Similarly, children who have lost one parent but live with the surviving parent might still be considered an orphan, to acknowledge the loss of one parent as significant.

My definition of orphan is different from a child that's fostered. [Orphaned means] either one or both parents are no longer alive. Any orphan could live with a surviving parent; and a non-orphan may not live with either surviving parent, [and be fostered]. So, fostering and orphanhood, at least in, let's say, a setting like South Africa, are very different things. (Participant 1)

In addition, for the researchers working in low-income settings the social and economic situation for most children was one of vulnerability and was attended by complex and fluid social support structures. Therefore, these conditions were not unique to orphans.

Who is a guardian and who is fit to be a guardian?

These difficulties in classifying the children were accompanied by challenges in identifying the responsible caregiver or guardian. In countries where the social and cultural context embraced more fluid definitions of family, based on caring and relationships over strict biological definitions, investigators faced challenges in applying the narrower definition of ‘guardian’. For example, a child might be brought in by an ‘aunty’ who is actually a young woman in the village whose family has taken the child in, but is not biologically related to the child. This concept of informal fostering posed challenges for researchers conducting research under regulations or research ethics committee requirements that they obtain informed consent from a legal guardian, typically defined as ‘an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.’ Because the largest populations of orphaned children are in low-resource settings where parental loss is due to endemic diseases, poverty and/or conflict, these are also regions whose legal infrastructure is undeveloped or compromised. Lacking functioning child welfare institutions or processes for the judicial assignment of child custody, the very idea of a ‘legal guardian’ was often misplaced.

Most fosterage in this area is informal. So one of my challenges was to decide that I didn't need to use that legal definition of fosterage, or needing to have a legal caregiver appointed for a child for informed consent, because it doesn't make sense ethically in this context. That's not the way the system works. It's not the structure of foster care, here. The area where I work there is a huge amount of informal fostering, even of children

Box 2. Who is an ‘OVC’? Variation in terminology

Double orphan:
Having lost both parents before the age of 18.

Single orphan:
Having lost one parent and being estranged from the other.

Ward of State:
Orphaned, in protected custody of the state, or non-orphan, parental rights severed by the courts. This includes many foster children who have not been adopted.

Homeless or street youth:
Living outside a home or institutional setting, typically on the streets, with period stays at halfway houses for homeless youth and/or adults.

Orphans and vulnerable children:
Orphans and vulnerable children, a more inclusive umbrella term used in the global health context to classify both orphans and homeless or street youth.

Social orphan:
One or both parents alive but child has been left at an orphanage or with another family because they cannot take care of the child due to illness, poverty or drug or alcohol addiction.

Unaccompanied children:
Children displaced by war or natural disaster and separated from parents/family.
whose parents are both alive. It’s probably the most common scenario here for children, is that they are living with a relative and their parents are migrant laborers. So, it’s very, very common for children not to be living with a legal guardian, or a parent even when their parents are alive and working and everything, so it definitely took a little bit of thinking and talking through with the ethics board, here. (Participant 5)

Those working in low-income settings also reported that several adult caregivers might be considered responsible for an orphaned child, taking turns bringing a child to the research clinic. Whichever adult presented with a child was typically assumed to be the guardian for that child, and thus responsible and able to consent for the child or oversee the ongoing participation of the child.

There wasn’t an explicit process. I think for all children, regardless of whether they had a parent or guardian present to sign the consent form, these issues are taken into account. We didn’t specifically delineate having different sorts of guardians. (Participant 9)

Despite the fact that investigators cited difficulties in identifying a legal guardian, most felt that adults and guardians who accompanied children to research did their best in difficult circumstances to protect the child’s best interests.

The gatekeepers like the head of the clinic or the head of the shelters I do think that they do a good job, for the most part, of, obviously, knowing the kids and having their best interests at heart. (Participant 12)

However, researchers with experience working with general pediatric populations noted important differences when it came to asking parents versus guardians for permission to enroll a child in research. For several researchers, this recognition of the limits of temporary caregivers or orphanage staff to know a child well, to love a child, or to have time to engage in decisions surrounding research resulted in a sense that the onus of responsibility to protect the child’s interests fell to the researcher.

Asking a parent for permission... That’s different than an orphanage director who’s responsible for 500 kids, who may not have the same level of investment in those kids. So they might just say ‘Sure, it’s fine with me.’ Then, the burden is on us to make sure we’re not taking advantage of the situation. (Participant 6)

Assessing research risk for OVCs

Researchers were asked to reflect on their experience and assessments of risk, comparing OVCs in the research context with children with at least one parent. When asked whether the background risks, or features of the OVCs daily lives factored into the consideration of research risk, researchers offered a few examples of situations where the stress or risk of research ‘added insult to injury’ and would lead them not to recruit a child, or continue with a survey or study intervention. That threshold tended to be increased physical or psychological stress/discomfort without direct benefit to the child. However, the majority of researchers did believe that inclusion in minimal risk research was justified when data would inform programs aimed at improving the health or well-being for this population of children. For example, this participant was responding to a study vignette describing a minimal risk observational study of play behavior in a school or orphanage.

I think it’s a question of study aim. Clearly, I could imagine studies in which asking these kinds of questions about orphans, particularly, would provide us with this research that would be of benefit to orphans and vulnerable children, themselves. In which case I do think it’s ok to enroll them. Especially because I could imagine that play behavior would be something that would potentially be affected by orphan status. That would be something that would deserve study, in the aim of intervention. (Participant 5)

Several of the researchers took the view that all children in research are vulnerable, and not just those children living in low-resource settings. One researcher pointed out the same types of ethical challenges with children who have parents but who have irresponsible parents or parents who are unable to attend to a child’s participation in research. On this line of reasoning he suggested we might need greater research protection for children with divorced parents, working parents, or other parents who for various reasons are not present.

Doing a study directly targeting orphans, or doing a study where you’re just sampling from a general child population, you’re going to have the same sort of challenges, how do you deal with the parents who aren’t present, you know? (Participant 5)

Several investigators working in low-resource settings said they do not perceive significant differences between orphans and non-orphans in this socioeconomic context. In part it is difficult to classify orphans differently since so many children are living away from their birth parents. And in part all children and many adults in low-resource settings were viewed as equally vulnerable to the risk of exploitation or harms in research given such extreme social and economic needs and, at times, lack of adequate social support.

Limitations of assent and guardian consent

When asked about challenges or difficulties that arise in the assent/permission/consent process researchers offered a number of examples that illustrated the inherent limitations on the quality of consent from guardians over parents. As mentioned, foremost was the issue of determining who the rightful guardian of a child without biological or adoptive parents should be.

What happens in the case when the child doesn’t have a clear legal guardian? [I]n the case of a lot of the children that we work with, maybe their guardian is a bit more informal, and maybe, for example, they’ve been placed with their grandmother, after their parent has died. And that hasn’t been legally formalized, so, one ethical issue that we come across is who, as an adult, is allowed to give consent? And that, I think, is quite a grey area in working with this population. (Participant 8)

Researchers reported a lack of fit between the international and many country-level requirements of parental permission or consent and the complex social reality of caretaker or guardian...
structures for OVCs. Particularly for researchers working with children living on the streets, or in regions with high rates of child-headed households, it was often unlikely or difficult to locate an adult caregiver responsible for the child.

It’s important to make sure that the inclusion procedures include, especially informed consent, have sufficient flexibility within them, to make sure that the needs of children who have been orphaned can be recognized. [S]ome of the children may well have had guardians who were able to answer for them and to indicate their consent. Other children, the individual to whom informed consent ought to be directed was not entirely clear. There may not have been an obvious parent or guardian immediately available. The issues around informed consent were very touchy and tricky. (Participant 9)

When asked about what specifically made consent challenging, researchers spoke primarily about assessing an unaccompanied child’s or adolescent’s background risks and capacity to make decisions about research without adequate adult support. Those who worked with adolescents observed that many were making other important decisions and even heading households of younger siblings after parents had died. Despite high levels of independence among some, researchers worried about whether they could give meaningful consent without having an adult to protect their interests.

If they aren’t an orphan, they at least nominally have someone, an adult person who we would hope would have some judgment in the young person’s best interests at heart to help protect them from being exploited with research, and to help to have them understand. […] I always contract myself about [informed consent with homeless youth] because obviously, as researchers, we want to get the research done, and get funding and results, so, it’s stepping back and realizing where that young person is, and making sure that we’re not taking advantage of them. … I mean the reality of the street life is such that there’s a lot of substance use. And there’s also a lot of coexisting mental illness issues, problems with education, reading level … So, it’s trying to figure out ways of assessing that, and whether they are at a place right then that they can understand, even, what they’re consenting to. (Participant 12)

Particularly for those children and adolescents who lacked stable caregivers, researchers described a sense of personal responsibility for judging whether research participation was in the child’s interest, and noted feeling conflicted as researchers, making such assessments in the place of caregivers. Several researchers felt personally responsible for providing extra protection for children without parents in the context of research participation.

I feel like the kids who don’t have a parent; they don’t have the natural protections that kids who have parents or guardians do, and so, I think it’s something that we have to take on. Being the extra protection for those kids. (Participant 2)

### Benefits, ancillary care and compensation

We asked researchers a series of questions about benefits within and beyond the study. Compensation for research participation was usually geared to basic needs, such as medical care, food or school supplies. Researchers did not report concerns about such compensation being coercive as benefits were addressing basic needs and the research was viewed as beneficial. Their concerns with compensation primarily pertained to the broader community, or other children not enrolled in the study. Several researchers mentioned the challenges of offering even basic benefits to children in the study when other children, and other members of the community, were also hungry or in need of basic supplies for the home or school, echoing familiar challenges in offering fair benefits in a resource-poor community. Researchers described how well-meaning attempts to meet those needs can sometimes lead to unintended consequences, as one researcher illustrated.

The interviews were being done at school, after hours, so it was, ‘Well it’s going to take up your time. We’ll arrange to provide food.’ There was a discussion with the children, ‘We’re happy to provide food, what would you like?’ And the kids said they all wanted Kentucky Fried … Now, it’s a nice idea … a form of compensation that’s not really excessive. Except … it’s a poor township, so most of them have never had this. Kentucky Fried’s a real treat. […] There was a point at which other kids came around and saw that these kids were getting Kentucky Fried. There was almost going to be a riot. It was fairly tense. Other kids were wanting it, other teachers were wanting it, demanding it. They handled it by basically barricading themselves in a room and handing Kentucky Fried out the window to avoid being mobbed. […] Look, we made a basic error, I mean, I’m just glad the kids weren’t hurt, that the caterer wasn’t hurt. (Participant 3)

We asked researchers whether they felt they had special obligations to orphans above and beyond the possible benefits of research and protection from harm within the confines of the study. Nearly all shared accounts of responding to basic needs of the children as a matter of course, such as providing food, shelter, school supplies, foster placement, and even considering adoption themselves. The responses were not presented as being unusual or ‘special’ obligations, rather as what anyone in similar situations would do.

I work with homeless kids and these kids need housing. But my project can’t provide housing. What we do is, we try to link up the kids to other housing programs in the city. They won’t go to the runaway shelter because the runaway shelter has requirements that their parents be contacted, or child protection services. So the younger kids won’t go there. So what was happening is that the kids would sleep on our research porch, outside in the summer. And the neighbors would complain, and they would say, ‘You’ve got homeless kids sleeping on your porch. You need to house them.’ (Participant 2)

Most of the researchers had been working in these countries for many years and had well established links to other aid and community organizations. If immediate aid could not be offered by the researcher or study team most of the researchers working with OVCs would connect the children or teens with resources elsewhere in the community, but these were not described as one-off referrals. Many personally accompanied a child or adolescent to make sure they received care and assistance.
I make sure that they’re already tied into resources, and I feel like that’s kind of an ethical obligation. So, that they’re getting the help that I think that they need and that they’re willing to accept. [...] You know, for instance, if we are talking about some pretty deep depression, even if it’s not active suicide ideations, of working with them, getting their consent first, but actually taking them, walking them to somebody who can help with that. (Participant 12)

Researchers reported resourceful ways of responding to children’s basic needs, often at personal expense, but most were done without institutional or sponsor support. Researchers recognized the limits of sustainability in this approach but all wrestled with the emotional pull to respond. As one researcher said, ‘if not me, then who?’

Discussion

Researchers in this study made a strong ethical case for the importance of designing research aimed at improving the lives of orphans and other especially vulnerable children. This idea that better evidence is needed to inform innovative social programs and targeted health interventions was important in thinking about the potential role for research as a tool for helping vulnerable populations of children. There was also a shared sense that in cases where directly beneficial medical interventions could only be obtained through research—as is often the case in low-resource settings with high childhood disease burden—it would be unjust to exclude OVCs by default. Rather, careful consideration should be made to find ways to ensure access to research with prospect of direct benefit. This echoes others who have cautioned against the unjust exclusion of vulnerable populations in research, especially children, pregnant women and pregnant adolescents.29-31

At the same time researchers expressed concern about the risks facing these children in their daily lives and worried about introducing added harm or psychological stress in research. Several researchers raised concerns about adolescents’ psychological capacity to participate meaningfully in consent given the common attendant problems of life on the street, such as substance abuse and high levels of stress. For this reason they were sometimes inclined to exclude younger OVCs from research not offering reasonable prospect of direct benefit. Even in studies with direct benefits, several were inclined to exclude a child who was distressed or had significant attendant sociobehavioral challenges, but the latter seemed to reflect a broader concern for any child who experiences added stress by participating in research. Others have raised concerns about the meaningfulness of direct consent by orphans who may agree to participate in research because they want to show respect to adult caretakers or consent by orphans who may agree to participate in research.

Our findings do raise questions about prioritizing the role of guardians in consent and ongoing support of vulnerable children enrolled in research. Results suggest substantial weight is being placed on the responsibility of guardians without reflecting the limitations and variations of that role. Researchers in our study reported that any adult available is providing consent, and most did not view evaluation of a guardian as practical. While researchers reported many very caring and attentive guardian caregivers, they also raised significant concerns about the real constraints on the head of a busy orphanage, or new foster parent, or temporary caregiver to know a child well and advocate in the way parents do in the clinical and research decision making contexts. In countries devastated by conflict, the HIV/AIDS pandemic or the Ebola crisis, centuries old social nets of kinship-based care for orphans have either unraveled through severe stress or evolved to include institutional support provided by churches and NGOs.33 Because the largest population of OVCs are in low-income, high disease burden regions, the specific vulnerabilities of children in this setting are more complex and exist in a context with absent or limited child protection institutions. Others have called for a more flexible and creative approach to social support coupled with child-centered participatory methods of research that better recognize the complex social reality of children living without parents, acknowledging both their vulnerability and their agency.22-25,34-36 In countries like Zimbabwe where traditional culture views children without parents as the responsibility of the community, we have seen that waiving strict legal guardianship as a condition of enrollment can make a significant difference in improving access for orphaned children to potential benefits of research.

In cases where adult caregivers were not consistently present during research or did not know the child well, researchers felt that much of the onus of protection fell to the research team. All reported difficult situations surrounding ancillary care duties—e.g. how to respond to basic needs for food and shelter, school supplies, other health needs, or reports of neglect or abuse in a foster home. Researchers reported creative ways of responding to children’s needs, often at personal expense, but most were ad hoc and done without institutional support or an eye to what is sustainable in context.37,38 While the need to anticipate and plan for meeting ancillary care obligations and reasonable compensation have become more routine in international research studies in low resource settings these researchers shared many stories about the practical challenges in the field of managing such decisions.38-41 All reported a sense of personal obligation to respond to vulnerable children’s needs and spent considerable time connecting children or teens to resources and care outside the research context. At the same time, many shared examples of well meaning efforts gone awry, with unintended consequences associated with offering food or other benefits in a low-resource context.26 This can be a great deal to expect of researchers, particularly research staff and trainees, and raises genuine concerns about conflicts of interest. Yet the strong sense of personal obligation and involvement resonates with calls to consider the more relational aspects of ethical obligations among researchers, participants and communities.42-44

These researchers also confirmed the persistent challenges of determining fair research benefits and avoiding unintended harms or misunderstanding within the broader community.24,25,38 For this group, the needs of the dependent child clearly took precedence and concerns about sustainability
were secondary to responding to immediate needs. As mentioned, researchers expressed a strong sense of personal responsibility to respond to the children’s basic needs and were aware of potential conflicts of interest but did not discuss clear solutions to the question of balancing these considerations. Nor did they speak to the broader moral expectations of the community for researchers to aid and ‘take in’ orphans, as others have reported.24,25 This finding is consistent with other studies involving fieldworkers’ sense of personal obligation and lack of systematic processes for managing the often overwhelming needs of participants.24–26,37,38

The insights offered by researchers working with OVCs in low-resource settings confirmed that vulnerability is varied, highly contextual, and does not necessarily undermine autonomy and other abilities to engage meaningfully in research decisions, although this group clearly understood additional support was needed during research participation. These researchers confirmed the need for additional empirical work to characterize specific vulnerabilities of unaccompanied children as well as clarify their role as social actors and identify creative strategies for improving social support.24,34,43,45

The results also highlight the limitations of research regulations based on vague definitions of special vulnerable populations, and yet largely inflexible guidelines for procedures, such as consent/assent. In the case of wards of the state or OVCs, researchers described situations where those categories clearly do not fit local social or legal contexts. Researchers described current international definitions of wards, OVCs, and guardians as ‘legalistic’, failing to fit more complex definitions of family, parenting, and fluid networks of social support, including peer support. Although this is not merely a disconnect between international research regulation and country-level regulation. As others have argued, the laws on human subjects protection pertaining to children within countries like Thailand, South Africa and Zimbabwe are often in tension with the social reality in which unaccompanied children and adolescents live.22,23,31,36

Because research ethics guidance often relies on strict legal definitions of unaccompanied children, a wide range of vulnerable children who appear with an adult declared as the child’s caregiver might mean that vulnerable children are being recruited into research without adequate protection and advocacy from a responsible adult. Similarly, adolescents who are independent, self-supporting and making clinical decisions for themselves but responsible adult. Similarly, adolescents who are independent, self-supporting and making clinical decisions for themselves but

research are blurred and the need for trusting adult relationships is so pressing.

**Conclusion**

A range of caregivers bear responsibility to protect OVCs’ interests in research in place of parents but are often not prepared to do so. This places greater burden on researchers to assess risks and respond to children’s needs. Our findings suggest that we improve support and possibly rethink the roles of guardians, researchers, and older children in research participation and protection to ensure that children living without parents have fair access to potentially beneficial research and that research aimed at addressing their health and social needs is encouraged.

**Authors’ contributions:** MK conceived and designed the study, developed draft interview instruments with input from DD, TB and BW, contributed to creation of coding scheme, conducted normative analysis on the findings, co-wrote the first draft of the paper with TB and wrote the second full draft of the paper. TB helped revise interview instruments, conducted interviews, conducted first phase of coding and qualitative analysis, participated in the team discussion of data, and with MK wrote the first paper draft. BW contributed to the study design, team discussion of initial qualitative analysis and final draft of paper. LL, BR and SMH contributed to the team discussion of initial qualitative analysis and final draft of paper. DD contributed to study design, instrument design, team analysis and final draft of paper. All authors read and approved the final version of the paper. MK is the guarantor of the paper.

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