


Refining Interventions Through Formative Research: A Focus on Ethical Considerations in a Family-Based Home-Based Counseling and Testing (FBCT) Intervention in KwaZulu-Natal

Journal of Empirical Research on Human Research Ethics
2020, Vol. 15(3) 153–162
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DOI: 10.1177/1556264619885214
journals.sagepub.com/home/jre



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Abstract

Conducting formative research is a scientific, ethical, and community engagement imperative. This article describes how formative research refined ethical processes for a family-based home-based counseling and testing (FBCT) intervention in KwaZulu-Natal. In-depth interviews were conducted to explore community ($n = 20$) and key stakeholders' ($n = 20$) needs, concerns, and perspectives on the FBCT model, including ethical issues for working with children and families. Data were analyzed thematically using NVivo software. Four key ethical considerations emerged, namely, respect for community norms and cultural practices; confidentiality, privacy, and forced disclosure; identifying potential risks and benefits; and voluntariness and capacity to consent. Data were used to refine the intervention and address participants' concerns by engaging the community, providing ethics training for intervention staff, and incorporating independent consent mechanisms for adolescent HIV testing that supported opportunities for family-based testing and disclosure.

Keywords

family-based counseling and testing, informed consent, HIV counseling and testing, disclosure, risks and benefits

Introduction

South Africa continues to experience a significant burden of HIV, with 18.9% of 15 to 49 year olds infected with HIV in 2016 (Joint United Nations Programme on HIV/AIDS [UNAIDS], 2017). Despite its controversially slow start to antiretroviral treatment (ART) rollout, since 2008 the country has made impressive strides in increasing access to ART to the extent that South Africa has the largest ART program in the world (Mayosi et al., 2012). Despite the implementation of universal test and treat guidelines (South African National Department of Health, 2016), just over half of HIV-positive adults (56%) and children (55%) were initiated on ART in 2016 (UNAIDS, 2017).

HIV counseling and testing (HCT) is an important gateway to HIV prevention and treatment, particularly in resource-constrained contexts. HCT has traditionally been offered through health care facilities (facility-based HCT); but uptake has been notably poor, particularly in sub-Saharan Africa (Cherutich, Bunnell, & Mermin, 2013). As a result, innovative approaches have been developed including HIV self-testing (Lippman et al., 2018; Makusha et al.,

2015) and delivering HCT services to home. Home-based counseling and testing (HBCT) is a highly acceptable, scalable, and cost-effective approach to increase both HIV testing and linkage to care in sub-Saharan Africa (Barnabas et al., 2016; Barnabas et al., 2014; van Rooyen et al., 2013). Previous research has identified several positive benefits of HBCT, and this approach is being increasingly implemented in several countries (Sabapathy, Van den Bergh, Fidler, Hayes, & Ford, 2012). The HBCT model achieved over 90% coverage of HCT of adults in households, identified HIV-infected persons early, and linked 90% of the participants to care by 6 months (Barnabas et al., 2014).

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Built on the success of this earlier HBCT intervention (Barnabas et al., 2014), this research aimed to develop a family-based counseling and testing (FBCT) model to (a) provide HCT to entire households, (b) link households to appropriate care, (c) support all family members with HIV disclosure, (d) foster intergenerational communication about HIV and other sensitive issues, and (e) increase support and health promotion among family members affected by HIV (van Rooyen, Essack et al., 2016). Readers are referred to van Rooyen, Essack et al. (2016) for a detailed discussion of the FBCT intervention development process, theory of change and intervention phases and content.

This article focuses on one aspect of the FBCT intervention development process, the formative research. Conducting formative research is a scientific, ethical, and community engagement imperative. It involves collecting data useful for the development, refinement, and implementation of intervention programs (Scott et al., 2018), as well as for enhancing community engagement and community ownership of research. Furthermore, formative research may usefully inform the geographic and cultural relevance of potential research and interventions (Gittelsohn et al., 2006).

Meaningful stakeholder engagement is a key ethical requirement of research, and necessitates that the community is involved in all phases of the research process (UNAIDS & AIDS Vaccine Advocacy Coalition [AVAC], 2011). Formative research provides one such opportunity for meaningful engagement. Good Participatory Practice Guidelines (UNAIDS & AVAC, 2011, p. 27) describe that “formative research activities enable research teams to gain an informed understanding of the local population, sociocultural norms and practices, local power dynamics, local perceptions, channels of communication and decision-making, and local history of research.” This article describes how the formative research helped ethically refine components of the FBCT intervention content and delivery process, particularly with a focus on informed consent processes, HIV testing, and disclosure.

Method

Semi-structured in-depth interviews were conducted with 20 key informants and 20 community stakeholders from the Vulindlela community in KwaZulu-Natal. Key informants included social workers, home-based counselors and care workers, legal and ethical advisors, and other government or nongovernmental service providers working with children, families, and couples generally, and HIV/AIDS specifically. Community stakeholders included health care providers, traditional and community leadership groups, and caregivers. Key informants consisted of individuals who had extensive knowledge and/or experience of the topic but who were not part of the intervention, whereas community stakeholders included individuals who may be

affected by or affect the intervention through their participation. Interviews explored their perspectives on the FBCT model, potential implementation challenges, possible barriers or facilitators to uptake, potential social harms, and ethical issues when working with children and families. Participants were asked about family norms and cultural practices for dealing with family matters, views on testing children and parents for HIV, parent-child relationships, community responses to HIV/AIDS, disclosure experiences, and community and household stigma. Participants were purposively selected from existing social and community networks in the area, and community stakeholders who previously participated in the HBCT intervention. All participants were adults 18 years and older, both male ($n = 20$) and female ($n = 20$). Focus groups were also conducted with children and adolescents as part of the formative work, but these data are not reported here.

Ethics approval for formative research was received from the Human Sciences Research Council’s (HSRC) Research Ethics Committee, approval number REC 10/20/11/13. Interviews were conducted between September 2014 and November 2014. All participants provided their informed consent for participating in in-depth interviews and for audio recording. Interviews were conducted in isiZulu by trained research assistants and translated into English. Transcripts were analyzed thematically (Braun, & Clarke, 2006) using a deductive-inductive approach. Credibility of the coding framework was assessed using investigator triangulation (Archibald, 2016). Approximately one third of the transcripts were independently coded by two expert researchers who reviewed the consistency of the codes across the transcripts that were double-coded. The coding framework was refined following the investigator triangulation process, and the remaining transcripts were coded using the final codebook. Coding and analysis were managed through QSR NVivo 10 qualitative data analysis software.

Results

The following section represents participants’ perceptions related to the ethics of the intervention content and implementation process. We cluster the data according to four key themes, namely, respect for community norms and cultural practices, identifying risks and benefits, ensuring voluntariness and capacity to consent, and maintaining confidentiality and privacy of participants and study communities.

Respect for Community Norms and Cultural Practices

Meaningfully engaging community stakeholders in “a transparent and meaningful participatory process” (UNAIDS & World Health Organization [WHO], 2012, p. 17) is considered a scientific and ethical imperative for research

(Newman et al., 2015), particularly in developing country contexts (Emanuel, Wendler, Killen, & Grady, 2004). Such engagement derives from the ethical principle of respect for communities, which “confers on the researcher an obligation to respect the values and interests of the community in research and, wherever possible, to protect the community from harm” (Weijer, Goldsand, & Emanuel, 1999, p. 275).

Some participants noted that early and ongoing engagement between the research site and the community prior to the implementation of the intervention, facilitates knowledge exchange and shared learning between researchers and participants. Such engagement enables community awareness and understanding of the intervention and improves researchers’ community literacy. These engagements were underlined as critical to the research process:

[I]t’s not easy to just go to our communities; they first need to be taught about awareness because it would be very difficult if you just go without them [the community] having [being] given information. (KI, female, 77)

In discussing the requirements for preparing the community for the delivery of an intervention and for improving acceptability of research, one participant emphasized the importance of engaging community leaders, again underscoring the importance of researchers understanding of community dynamics:

. . . it is working a lot with community leaders, all the community leaders that are in the area because they are one of the people that the community respects . . . So when the project comes and you are together with the people from the community where they have respect for them, I think that will help the project to go further. (KI, female, 34)

Community engagement was noted as critical for fostering trusting and open relationships with the community and for tailoring interventions and programs:

That will help you to be able to build a relationship. You see if a person is well trained you do not just enter. You do not just show up in a person’s house and talk. There are people who have rules in their house and that do not want to be told about their life. So they need to be people who understand other people’s cultures . . . You must understand even their language that they talk. You need to try to be in line with them. Even if they talk any way about HIV you must be in that level. Do not try to show that you know it all or you are better than them. You see. You must give them their space at all times. (KI, female, 36)

As suggested in the above quote, building a relationship with communities requires cultural sensitivity and entails being proficient in the language of the community—not only in terms of the spoken language but of community values as well. Engaging community stakeholders in formative research creates opportunities for such cultural

learnings and understandings of the social values and community norms. Some acknowledgment of power differentials between researchers and participants and the importance of acknowledging and minimizing these (“you must be in line with them” and “you must be in that level”) was also alluded to.

Participants also reflected on how cultural sensitivity is an important consideration for the implementation of the FBCT intervention in the community. Particularly, when approaching whole families in households, it was suggested that researchers should be cognizant of the traditional and cultural prescripts that guide household entry and permission: “. . . traditionally I think since we are African people the Zulus are traditional, the father is the head of the house” (CS, male, 46).

Cultural norms and practices inform and constrain discussions about sex between men and women, and elders and children or adolescents. Participants noted that there were additional requirements for sensitivity regarding inter-generational discussions about sex and other sensitive information, for example:

. . . there is also that parents think it is an embarrassment to talk to their child. You can’t speak to a child about sex . . . (CS, female, 28)

Most parents, I can’t say they stereotype but they still have “that thing” of saying that, “I have certain things that I discuss with my children; I have certain things that I do not discuss with my children”; concerning religion; concerning culture all of that. (KI, male, 32)

. . . when we were growing up we did not sit with adults and to talk while staring at them [in their eyes]. (CS, male, 36)

Therefore, community engagement was argued to have several benefits including building trust and community ownership of the research, improving acceptability, and ensuring that the research intervention and related implementation is culturally sensitive.

Identifying Potential Risks and Benefits of FBCT

The ethical principles of beneficence and nonmaleficence require that potential risks are identified and minimized, and benefits maximized (Emanuel et al., 2004). Participants weighed up the potential benefits of the FBCT intervention relative to facility-based HCT. FBCT was preferred for the convenience of its home-based delivery, the privacy and confidentiality afforded by the home-based approach, and the opportunity of testing together with family. The following excerpts illustrate these benefits:

They would indeed be happy because some families don’t have money for transport to take them to the clinic. (CS, female, 49)

[I]t's hard for a family as a family to all go and get tested for HIV at the clinic, if it is done from home a person will be doing this from their house everyone will know that even if they are positive they are the ones that will be able to know. No one will see that they are going to the clinic to test. (CS, male, 20)

Because when I go to the clinic, I go alone. Get tested alone. Leave the kids at home. But if I do it in front of the kids, they will realise it is the right thing to do. (CS, female, 31)

Participants specifically linked the value of FBCT with its stated objectives of improved potential for HCT uptake, improved family decision-making, and enhanced disclosure among families, which were argued to ultimately improve family cohesion, for example:

... so it helps because it makes them feel free because they are at their homes and they know everybody ... because I think by the time the healthcare givers encourage disclosure between themselves as a family they will support each other; unlike when a family member goes for testing at the clinic or the store. (KI, male, 24)

I think being tested together at home is good because it makes the family come together. (CS, female, 28)

The intervention comprised capacity building for parents (or change agents) to educate families on their health, including HIV, and to develop intergenerational communication skills to foster communication about sensitive issues between adults and adolescents. Educating and testing entire families in the unique approach of FBCT was also perceived positively by participants, including the potential for this intervention to delay sexual debut among adolescents or promote safe sex practices through discussion, disclosure, and education. For example,

Maybe that would help them since they are still young maybe some of them have not yet started having sex. Maybe they could get help and know what the consequences of doing "that" are. It is getting this virus. (KI, female, 32)

They will be aware that HIV is the existing illness and they will know that how do you get it and ways of protecting it so that they will grow educated ... (KI, female, 50)

Participants also identified potential risks associated with the FBCT intervention. Most of these coalesced on the disclosure component. Some were concerned about disclosure to children about parents' or their own HIV statuses. Some noted their worries that family members would inadvertently or deliberately disclose other family members' statuses to people outside the household:

... the fact that there are ages that cannot keep a secret, that are going to say "this lady was at my house and she said we have

HIV" or the uncle or the brother has it. I think it is important that this age be looked at. (KI, female, 34)

You can't tell granny that I have HIV because you know her. One day, they forget; she doesn't know what she is supposed to say and what she is not supposed to say, granny just speaks about anything. (CS, female, 28)

Another challenge the families on their own have, maybe you will find that aunt is talkative, and would gossip because the family is big, maybe family members do not get along well so this aunt will take the news from one to another and you will find them insulting each other in the streets live. (KI, male, 24)

Detrimental consequences include a loss of support, violence, and even suicide were described. Rather than improving family cohesion and support, some participants conveyed concerns that the intervention may result in "broken families" (KI, female, 34) and family discord.

Confidentiality, Privacy, and Forced Disclosure

Participants raised concerns about privacy and confidentiality of their HIV results. Although testing at home may afford some assurance of privacy and confidentiality, the use of community health workers as FBCT facilitators was considered to potentially compromise privacy and confidentiality:

Maybe the negative thing that I could highlight with using Community Health Workers is that they know the family and then the issue of trust and confidentiality. You see. Then maybe I think the negative thing about them is that it would be someone from the community who will also work within that community. I don't think that would be a good idea even those people in that family, they will not trust him or her. They will not be able to be open and disclose to them. (KI, female, 36)

Furthermore, there was some worry about the potential for forced or coerced disclosure of results among family members, particularly in light of power differentials (described below). For adolescents who independently consent to HIV testing, there was concern that "the parent can take the results by force" (CS, male, 26), even by resorting to abuse.

Voluntariness and Capacity to Consent

Informed consent, derived from the ethical principle of respect for autonomy (Beauchamp & Childress, 2013), is often a foremost concern in research ethics. In this study, concerns about informed consent did not relate to participation in research per se, but to voluntariness and capacity to consent to HCT, as well as the legal framework for adolescent access to HCT in South Africa.

Participants noted that deference to those perceived as having power in the family (older compared with younger family members; men versus women; those who earn an income and those who are reliant on them) may result in some undue pressure to test or not for HIV as described below:

We find it difficult to speak to our children because they fall under the category of child . . . we just inform our own children of the decision taken. (CS, male, 46)

Although in most instances the person who owns the most power may be the head of the household (typically the father), in some cases, it would be the person holding financial power, for example:

Sometimes you find that the families love the most those that work, they listen to them. So basically money means power mostly in the community. Even if child is the youngest but if she or he is working uncles will bow to her or him, they would listen to her/him and she or he will make rules more than father and the mother so those are things you find that when you come with the programme, when you won't get the family at the same time. (KI, male, 24)

The expansion of FBCT to include minors in the household was a key concern. Children were considered by some as not meeting capacity requirements for informed consent, with one participant drawing parallels with children's lack of "criminal capacity" (KI, female, 34). Some participants argued that children below 12 years of age had little ability to understand an HIV test result or the related implications, and that for these reasons proxy parental consent was necessary.

Key informant participants, in particular, discussed those aspects of the legal framework that are important for consideration when testing adolescents (defined in the intervention as children between 12 and 17 years old). First, it was noted that according to the South African legal framework, parental consent is required for all children below 12 years old to access an HIV test, with assent from the child. Furthermore, HIV counselors should be able to assess the maturity of the child to receive HIV test results, with parental support:

Most of the time a child does not test. It is parents that refuse on behalf of them . . . Everything relies on parents whether they agree or not. (KI, female, 34)

In testing minors, children aren't aware, some of them don't understand. So that's why parents need to be present so that the results may be furnished to the parent as the child wouldn't know. The over 12 years old would be able to deal, then the result would go to them directly and the parent would be there for support . . . For the under 12 minor, they need the parent's presence When the child is too young and knows little about

HIV then you can't bombard the child about being HIV positive. But then again, you have 8 year olds that are smart and knowledgeable. Hence it is important to fight these challenges where you find a child to be experiencing a breakdown and can't concentrate at school. You observe the child's maturity first, for the child to understand. If the child's too young, you do not mention anything at all, you only inform the parent. (KI, female, 30)

Actually a 12 year old child could not refuse because if a parent say go and get tested . . . that is what I have said that it depends on how you raised your children. If a child knows that he disagrees or argue with his parents he will refuse, I think the relationship will not be good if you he refuses to get tested when you come. Relationship will be bad between him and his mother if he refuses. (CS, male, 23)

In addition to concerns that children aged below 12 years do not have sufficient maturity to deal with the consequences of their test results, and the potential impact this may have on their psychosocial well-being, participants noted that, in this particular cultural context, children defer to their parents, and disagreements with parents are often considered a sign of disrespect.

Second, in South Africa, children 12 years and older can access HCT independently, that is, without parental consent. Testing these children in households would therefore require an awareness of the law and respect for privacy rights of children in a context where such access may be deemed to be culturally or religiously inappropriate. It was advised that intervention developers be aware that despite the law, independent testing of children 12 years and older (adolescents) may be negatively received by families, especially parents. Relatedly, adolescents' decisions to keep results private and not to disclose to parents may also be perceived as indicative of an HIV-positive serostatus:

But I feel like sometimes it's important that children are protected. The way that they can be protected is to make the family aware that when we talk about the law this is what we speaking about and if you know we need to understand that one has a right to their privacy and you know to also be protected and we as a family we end up doing things and children are not protected and they are not supported. (KI, male, 26)

I think the parents would question themselves about why so and so doesn't want to test because the parent knows that perhaps they gave birth to a negative child, I suppose it would be apparent that maybe the child is having sex. (CS, female, 28)

Because the parent will be convinced that the reason the child won't disclose is because their results came back positive. So they won't be at ease because their child is hiding this thing from them and it could be that they may be able to help the child and take them to the clinic. But now if the child does not disclose his/her results then it won't be a good thing. (CS, female, 31)

Given the cultural and religious mores of the community which limit children's autonomy, it was noted that counselors should be aware that enacting independent consent for adolescents may be contentious at household level.

Furthermore, despite the law, some participants were concerned about the potential of parents to "force" (CS, male, 37) or coerce their children to test:

... it will depend on how that teenager is being treated here in the family, because there are other teenagers that you find are the ones controlling the family, if they say I will not do that they will not do it for real. You will test all of them and you will not test them then it will be how the family set up is. Even if they can be rude but if you put them in front of their father they don't have a choice. You are able to do things but on the other hand legally are we allowed to test them without their consent, I think that it's a challenge. (KI, female, 34)

Discussion

This article describes how the qualitative formative work facilitated the refinement of ethical processes of the FBCT intervention. Participants' narratives were clustered into four thematic areas. These were reminders of the value of community engagement and being respectful of community norms and cultural practices; enabling communities and participants to weigh up the risks and benefits of their participation in research; maintaining confidentiality and privacy; and ensuring valid, voluntary, and informed consent.

Community engagement is increasingly recognized as fundamental to ethical research and a component of good participatory practice in research (UNAIDS & AVAC, 2011). The formative component of the research augmented the site's established community participation, engagement, and outreach activities—within the remit of the Community Programmes and Stakeholder Relations Unit (CPSRU). This unit is tasked with community preparedness, entry, and ensuring meaningful community participation. Through this unit, the site has an established community advisory board (CAB), which comprises community representatives who serve as a formal stakeholder advisory mechanism (UNAIDS & AVAC, 2011). Given participants concern about potential power differentials between researchers and communities in this study, CABs may provide a potential remedy by providing "a mechanism to harness the expertise of key stakeholders and offset potential power differentials that may exist between researchers and participating communities" (National Health Research Ethics Council [NHREC], 2012, p. 1).

Participants in this study echoed reasoning in ethics guidance (UNAIDS & AVAC, 2011) that formative research facilitates understanding of the sociocultural context in the community and local power dynamics (Sifunda, Reddy, Naidoo, James, & Buchanan, 2014). In particular, in terms of household entry, data from this study identified "fathers"

or elders in the family as the head of households. In cognizance of this familial dynamic, heads of households (fathers or the eldest person present) were asked for verbal permission to enter the household and inform family members about the intervention. In this way, the importance of cultural sensitivity underscored by participants in the formative research was recognized during intervention implementation.

In terms of identifying potential risks, participants grappled most with disclosure within family contexts. Disclosure was noted as a potential positive outcome of the intervention including in terms of improving family support and cohesion, as reported elsewhere (Rochat, Arteché, Stein, Mitchell, & Bland, 2015). In addition, the family-based approach affords an opportunity for improved disclosure and discussion among entire families, which is not feasible through facility-based approaches. Such open conversations about HIV among families may help those who are HIV-positive successfully deal with their diagnoses (Mburu et al., 2014). Similarly, research has found that disclosure in the family context facilitates both communication and children's capacity to cope with disclosures (Kennedy et al., 2010).

The World Health Organization (WHO) recommends that HIV-positive children be informed of their status by school-going age to support adherence (WHO, 2011). A systematic review of disclosure of parental HIV infection to children found that despite some negative consequences, in the main, disclosure impacted positively in the long-term on the well-being of the family in general, including parents and children (Qiao, Li, & Stanton, 2013). Disclosure has also been associated with improved ART adherence among adolescents (Cluver et al., 2015). In addition, the national HCT guidelines (South African National Department of Health, 2016) affirm that disclosure encourages child participation by enabling the child to develop responsibility for their own health.

Despite these potential positive outcomes, participants raised concerns about how to maintain confidentiality of family members' HIV statuses once they have disclosed to each other. This was most pronounced for disclosure to younger children who may not understand the risks associated with disclosure outside trusted familial contexts. Concerns that children may disclose to others have been identified as a key barrier with disclosing to children (Moodley, Myer, Michaels, & Cotton, 2006). In addition, commentators have noted other negative consequences associated with disclosure to young children including that they may experience negative emotional consequences due to becoming aware of their own or their parents' HIV statuses (Kennedy et al., 2010; van Rooyen et al., 2016). In response, the FBCT intervention was designed to enable multiple permutations for disclosure: between couples; between adult family members, within the larger family

group (van Rooyen et al., 2016), across the time period of the intervention. This approach carefully balanced the benefits of disclosure against participant's caveats regarding cultural taboos about intergenerational conversations on sensitive topics. It highlights the importance of developmentally and culturally appropriate interventions that support disclosure (Mburu et al., 2014; Qiao et al., 2013).

To address concerns about children unwittingly disclosing to others, an interactive and developmentally appropriate activity with children was included in the intervention (adapted from the Amagugu intervention), to help children identify those to whom they can disclose (van Rooyen et al., 2016). An additional optional session was added for high-risk situations, which included any household with (a) HIV-positive children aged 0 to 11 years; (b) HIV-positive adolescents where disclosure is an issue; (c) individuals with suicidal ideation or a crisis as a result of testing situation; and (d) households where there are other important risks, such as conflict, domestic violence, substance abuse, and serious mental health issues.

Informed consent is considered one of the cornerstones of ethical research, and is often raised as the most pressing ethical concern in research (Essack et al., 2010). Participants in this study raised concerns about the voluntariness of informed consent, given the potential for undue influence and even coercion (through threats of abuse) to test for HIV and to disclose results to family members—by parents or those who hold socioeconomic or influential power within the household. Given that the intervention focuses on households, some may argue that the potential for undue influence is amplified. This perspective is in line with historical approaches to valid informed consent which required that participants make the consent decisions alone—however, new approaches to informed consent support inclusive and participatory decision-making (Mamotte & Wassenaar, 2017), as encouraged in this intervention through multiple opportunities for disclosure to family members. In understanding cultural and familial dynamics, initial permission of the head of household was obtained to introduce the FBCT intervention to the family, and individual informed consent (or parental consent for minors) was sought from each intervention participant.

Voluntariness and capacity to consent to HCT, as well as the potential for forced disclosure of HCT results, were raised by participants. Coercion and undue influence compromise the voluntariness of research participation (Mamotte & Wassenaar, 2017). These concerns were amplified in relation to adolescent intervention participants. Regarding minors access to HCT, the Children's Act articulates that children 12 years and older are permitted to access an HIV test if the HIV test is in the child's best interest; furthermore, the child should receive pre- and posttest HIV counseling (van Rooyen, Strode, & Slack, 2016). In applying the best interest principle to HIV testing of children and adolescents,

the following factors should be considered: (a) first, the emotional impact of a child discovering their HIV status and potential support; (b) second, the confidential nature of testing and its implication on adolescents desire for privacy; and (c) third, "the child's age, level of maturity and ability to cope and the child's capacity to consent to the HIV test" (Strode, van Rooyen, & Makusha, 2013, p. 152). The right to independent HIV testing among adolescents is also accompanied by the rights to confidential testing and to privacy of test results (Slack & Strode, 2016). Previous research in South Africa found that parents were not aware of their children's rights to independently access sexual and reproductive health services as outlined in the Children's Act (Gwandure, Ross, Dhali, & Gardner, 2014). In addition, like health care providers, parents may perceive that adolescents are not engaging in sex, are at low-risk, and therefore do not need to test (Chikwari, Dringus, & Ferrand, 2018). For this reason, and in anticipation of the risks of undue influence from family members to test for HIV, the FBCT intervention included a session on intergenerational communication. This session provided training to the parent (or change agent) on communication skills, fostering positive relationships with adolescents and talking about sensitive issues. It also afforded an opportunity for facilitators to explain to parents adolescents' rights to access HIV testing independently and to confidentiality of their test results. However, there are limits to adolescents' rights to privacy, for example, in cases of abuse and certain categories of underage consensual sex (Essack & Toohey, 2018; van Rooyen, Strode & Slack, et al., 2016). All limits to confidentiality were spelled out to participants during the informed consent process.

The formative research reported on in this article helped guide and refine several aspects of the FBCT intervention implementation, including household entry, cascading testing from the least vulnerable (adults) to the most complex and/or vulnerable group (adolescents), and providing ongoing support to parents to facilitate independent consent for adolescent HCT. In recognition that many of the ethical concerns rely on some ethical finesse and skill by facilitators, all FBCT facilitators received ethics training as part of the protocol training activities, with a special focus on the ethical-legal framework for working with children and adolescents, informed consent, and issues of confidentiality.

Limitations

The study's primary limitation relates to translation and interpretation of the translated data. Readers should be aware that excerpts included were English translations of the original isiZulu transcripts. Despite audio recordings being subjected to a rigorous translation and backtranslation process by bilingual translators, it is possible for participants' statements to be translated incorrectly, particularly instances where equivalent words, terms, or phrases do not

exist between both languages (Mack, Ramirez, Friedland, & Nnko, 2013).

Conclusion

Data from formative research were used to refine the intervention and address stakeholders' concerns by engaging the community, training intervention staff on ethics, and incorporating independent consent mechanisms for adolescents that recognized their legal right to independent testing but allowed opportunities for family-based testing and disclosure. Formative data assisted the research team to address concerns prior to piloting the FBCT model and to address family, sociocultural, and community factors that may impact the effective delivery of a FBCT intervention.

Best Practices

Data from the FBCT study suggest that community engagement is an integral part of the research process. Community engagement increases community understanding of the issue under study, enhances the researcher's understanding of community priorities, and increases the need for culturally sensitive research approaches (Ahmed & Palermo, 2010). Therefore, during this process, it is crucial for the researchers to identify and engage with key informants within the community prior to engaging with potential participants. Establishing a strong relationship with the stakeholders in the community may reduce resistance from the community members regarding the study (McKenna & Main, 2013). To minimize potential for misunderstanding, researchers should continuously engage communities throughout the research process (Ahmed & Palermo, 2010). To add to this, researchers are encouraged to conduct a situational analysis involving the key informants within the community. This will encourage the key informants to actively participate and gain their buy-in of the research.

Taking HIV testing to entire families is an under-researched area in the South African context. Due to ethical concerns of HIV-related research involving adolescents, we recommend that researchers emphasize the informed consent process, highlighting the right to opt-out or withdraw from participating at any time during the study as well as adolescents' rights to privacy and confidentiality.

Research Agenda

The data from this study suggest that there is a need for future researchers to develop a practical assessment tool to assess an adolescent or child capacity to sufficiently consent to HIV testing. The MacArthur Competency Tool for Clinical Research (MacCAT-CR) may be useful and has been validated for consenting participants in clinical research. The tool measures "understanding, appreciation,

reasoning, and expressing a choice" (Grisso & Appelbaum, 1998, p. 1502). A context-specific adaptation of the tool with an adolescent population could ensure that adolescents who participate in research and HIV testing are able to fully comprehend their participation.

Educational Implications

This study has a number of educational implications. Staff working on interventions and providing HIV testing services should be equipped with skills and educated on the ethical-legal framework for working with children and adolescents, informed consent, and confidentiality issues. Future research may consider getting the participants and local community to reflect on learnings and skills training received from the study to improve their knowledge on the legal rights of adolescents regarding health care, family health promotion, and HIV testing and disclosure. This could strengthen and inform community voices in research processes in future.

Acknowledgments

The authors thank the study volunteers for their participation in this formative research and the stakeholders who participated in consultative workshops.


Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This research was supported by funding from the National Institutes of Mental Health (1 R21 MH103066-01). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. The views of the authors are also not necessarily the views of any committee or council with which the authors are affiliated.

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