Journal of Empirical Research on Human Research Ethics
2016, Vol. 11(4) 322–333

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DOI: 10.1177/1556264616675202
jre.sagepub.com

"... I've Gone Through This My Own Self, So I Practice What I Preach ...": Strategies to Enhance Understanding and Other Valued Outcomes in HIV Vaccine Trials in South Africa

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Abstract

There has not been enough study of the processes by which site staff help participating community members and potential participants to understand complicated concepts for HIV vaccine trials. This article describes strategies reported in six focus group discussions with Community Advisory Board members, educators, and consent counselors at an active HIV vaccine trial site in South Africa. Thematic analysis identified a considerable range of strategies, and findings suggest that such staff do not only try to promote understanding of critical information but also try to build trust in communicated information, to respect cultural differences, and to promote voluntariness. Findings also suggest occasional tensions between these implicit goals. Actual engagement and consent encounters at HIV vaccine trial sites should be observed, recorded, and analyzed; and the relationship between practices and valued outcomes should be assessed. These efforts may help to make consent-related encounters as "potent" as possible given finite resources.

Keywords

clinical trials, communication in research, comprehension, informed consent, stakeholder engagement, ethics in HIV-prevention trials

Research staff face considerable challenges ensuring that prospective participants understand what research participation will entail. Ethical–legal frameworks stipulate a long menu of concepts that must be understood, for example, the guidelines from Council for International Organizations of Medical Sciences (CIOMS, 2002) sets out over 30 key elements. Prior research has shown many deficiencies in participants' understanding across many research settings (Mandava, Pace, Campbell, Emanuel, & Grady, 2012), and some commentators have argued that consent is "widely valued" yet "imperfectly realized" (Grady, 2004, p. 467). It has been recommended that consent efforts be strengthened with adult education and communication principles (Meade, 1999; Penn & Evans, 2009). It also has been recommended that consent interactions be observed and analyzed using specialized observational frameworks (Gross-Cohn, Jia, Chapman Smith, Erwin, & Larson, 2011; Tomamichel, Sessa, Herzig, de Jong, Pagani, & Cavalli, 1995). Commentators have asserted that critical consent outcomes, such as understanding, are best understood as a function of the interaction between individual characteristics (e.g., educational attainment, literacy, familiarity with research) *and* the consent context, including the skills and strategies of communicators (cf. Fisher, 2010). Faden and Beauchamp drily observed in 1986 that "disclosure is the lawyer's entre to the world of informed consent, but it is a back-fence gate to that world, and a narrow one at that" (p. 307) arguing instead for the centrality of "effective communication" (p. 307).

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Consent challenges abound in trials of HIV vaccines where fairly complex concepts should be understood (Joint United Nations Programme on HIV and AIDS/ World Health Organization [UNAIDS/WHO], 2012; Lindegger, Milford, Slack, Quayle, Xaba, & Vardas, 2006; South African Medical Research Council [SA MRC], 2003). There have been many efforts to enhance understanding in such trials by developing sound written consent materials (Koblin et al., 2010; Lally, Goldsworthy, Sarr, Kahn, Brown, Peralta, & Zimet, 2014). However, commentators in this field also increasingly argue for attention to the processes by which these complex concepts are communicated (Koblin et al., 2010; Ndebele, Wassenaar, Masiye, & Munula-Nkandu, 2014; Rautenbach, Lindegger, Slack, Wallace, & Newman, 2015; Watermeyer & Penn, 2008). Yet, there is very little published work evaluating communication during consent interactions in HIV vaccine trials (Watermeyer & Penn, 2008). This article explores the strategies and practices being used by key vaccine stakeholders at an HIV vaccine trial site in South Africa to communicate complex research concepts to prospective participants in consent and engagement encounters in HIV vaccine trials, and the attendant challenges.

Aims and Method

Our overall study aimed to explore—with critical site constituencies—the representations of key research concepts in HIV vaccine trials, and strategies used to communicate concepts for such trials, and to consider the implications for consent processes. The overall study was approved by all Research Ethics Committees affiliated to the research team, the site, and the funders [University of KwaZulu-Natal Humanities and Social Sciences Research Ethics Committee (HSS 0554/012)]. Results related to "competing" versions of key concepts were presented in an earlier article (Rautenbach et al., 2015). The present article describes results regarding the strategies reportedly being used to communicate complex research concepts to prospective participants in consent and engagement encounters in HIV vaccine trials and complexities.

Ongoing outreach to the site underscored that there were various encounters in which research concepts are communicated. First, there were sessions in the community where Community Advisory Board (CAB) members and educators interact with participating community members about the site and research more generally. Second, there were group-discussion sessions at the site where educators interact with community members interested in research. Third, there were group-based consent-discussion groups, and individual sessions, at the site where consent counselors interact with potential participants about enrollment into specific trials. Representatives from these three site-related constituencies (namely, CAB members, educators, and consent counselors) took part in focus group discussions (FGDs) because all were well placed to shed light on how information is communicated about HIV vaccine trials. Specifically, we conducted two FGDs with 10 CAB members each (i.e., 20 CAB-enrollees) late in 2013. Then we conducted one FGD with eight educators also late in 2013 (i.e., eight educator-enrollees). Subsequently, we conducted three FGDs with consent counselors of seven, six, and eight members, respectively (comprising 10 counselor-enrollees because several consent counselors participated in more than one FGD). Consent counselor FGDs were conducted in early 2014, late 2015, and early 2016. Participation in any FGD depended on availability and interest, and we did not preclude any interested person from participation—given that our objective was in-depth exploration through an iterative process characteristic of qualitative research, rather than to achieve generalizability.

During FGDs, representatives from each of the three constituencies were asked to discuss key concepts, how key concepts are explained (including the use of analogies), and challenges or difficulties they experienced. Semistructured schedules with probes guided the FGDs (cf. Kvale, 1996). Also, facilitators and FGD-participants role-played the explanation of concepts to "mock" participating community members or "mock" potential participants and, subsequently, FGD-participants were invited to reflect on these role-plays to stimulate discussion about the concepts, how they are communicated, and challenges (cf. Rautenbach et al., 2015). All FGDs explored similar domains, but questions and prompts were tailored to the activities and roles of different trial constituencies.

FGDs were conducted between August 2013 and February 2016, as set out above. The data set consisted of six transcribed FGDs. Text was coded for practices using a deductive and inductive approach to thematic analysis, where some codes emerged from the literature and other codes emerged from engagement with the transcripts (cf. Braun & Clarke, 2006; Sandelowski, 2000). Practices were collated according to the interface being reported on, that is, CAB-participating community members, educator-interested community members, and consent counselor-potential participants and were finally clustered according to critical goals being pursued, such as comprehension. A sample of interviews was coded by an independent coder. Coding differences were resolved by "reconciliation discussions" (Boyatzis, 1998, p. 152). Written informed consent was obtained for participation in FGDs. Site leadership gave permission for site entry, and visits with various site constituencies were undertaken to plan the research in 2013. Three interactive feedback sessions were conducted in mid-2014, late 2014, and late 2015 to obtain feedback on the accuracy of the preliminary results (using anonymized data), to stimulate discussion about the preliminary

findings, to discuss the practical utility of the emerging results, and to plan avenues for future inquiry.

Results

CAB members, educators and consent counselors all described various practices to communicate key concepts in a way that enhanced understanding. However, in many instances, they appeared to be striving to reach other important goals, such as building trust in communicated information, respecting the culture of persons with whom they were interacting, and preserving the free choice of potential participants. Notably, in a few select instances, these goals appeared to be in tension. The results are organized into four sections representing overarching goals, and within each section, various strategies to achieve these goals are described.

Enhancing Comprehension

CAB members, educators, and consent counselors all reported that they "share"/"give" information ("inform") or "educate" potential participants and participating community members about key issues, such as HIV as a problem, the need for multiple HIV-prevention methods, the need for research, the nature of research, HIV vaccine trials, aims, procedures, risks, benefits, right to withdraw, and other concepts. This "informing" was explicitly linked to the goal of enhancing understanding, but more implicitly, they also seemed to view themselves as providing a kind of information service—to build knowledge and skills about HIV prevention. This information (the "what") was reportedly delivered using various practices (the "how") outlined below.

Representatives from most constituencies reportedly made efforts to "inform" without using unfamiliar or overly technical terms. Also, CAB members, educators, and consent counselors all discussed using analogies to explain difficult research-related concepts. This included, for example, referring to "soldiers" to help explain the role of antibodies ("Antibodies, I can make an example of the soldiers. Like, the army . . . the army is there to attack, the intruder" [FGD 3, Educators]). Various analogies were reportedly available to help explain different risks associated with being vaccinated with an experimental HIV vaccine in a clinical trial. For example, to help communicate the potential risk of increased susceptibility to HIV if vaccinated, the analogy of a "magnet" could help explain how an experimental vaccine might make people more susceptible to HIV infection. Participants also acknowledged the potential for confusion to arise from the use of some analogies.[1]

Furthermore, CAB members, educators, and consent counselors all reported using familiar examples—from everyday life—to explain *research* and its contribution to health (e.g., a popular local over-the-counter analgesic like Grandpa headache powder was alluded to as a product of research). They also frequently invoked familiar childhood vaccines (such as polio vaccine or tuberculosis (TB) vaccine) to explain the process and benefits of *vaccines*—how vaccines have controlled deadly diseases, and how their safety and efficacy must be explored with human volunteers ("you have to start with what they know, you have to start with the flu vaccine" [FGD 4, Consent Counselors]). Here, they were trying to build understanding of less familiar material by drawing on experiences with common medical interventions:

> . . . if you make mention of the vaccines about polio, measles and other diseases, it clears up their mind, and it gets into their understanding—"okay there *is* a vaccine for other diseases" so, there are, you make comparison, of the HIV vaccine to the vaccines that are available in the local clinics. (FGD 3, Educators)

In addition, site staff reported using various aids, for example, educators reported using PowerPoint presentations or pamphlets to ensure that participating community members have a visual representation of what is being verbally discussed. Consent counselors reported bringing instruments to the consent discussion (such as tubes for blood draws) to help potential participants better understand *procedures* they would undergo:

> So, another thing that's, that helps a lot, if you are going to talk about blood samples, visual aids help a lot. If you gonna talk about blood samples you cannot say "we gonna take this much blood," in their mind they cannot make up, how much blood you gonna take. You need to have those tubes in front of you . . . (FGD 4, Consent Counselors)

Also, educators and consent counselors reported using various techniques to increase discussion with, participation by, and contributions from, potential participants. Educators reported modeling the asking of challenging questions, and using group formats where question-asking would be modeled by other attendees. Consent counselors described building in "pauses" ("stops"), asking for questions, directly asking questions of attendees, working through consent forms, and using group formats for consent discussions where making inputs was modeled for other group attendees. Here, trying to get persons to interact with site staff seemed to be viewed as a good outcome in and of itself (possibly because it respected their status as adult learners, with an experiential base) but was also viewed as an important way to improve understanding by identifying knowledge needs and knowledge deficiencies:

> . . . we make sure that we do, when we are doing a consent discussion group, we have more people, maybe ten people, so that there can be more discussion and it will be the first time that they will be hearing about the study, so we expect that they will have many questions, so that they can be able to understand what will be going on in the study . . . (FGD 6, Consent Counselors)

Consent counselors observed that participants sometimes report that they understand even when they do not understand, linking this to potential power differentials (e.g., between participants and senior study staff like study clinicians), or to participants' desires to service the relationship with the counselor:

> . . . *like they will stare at you, and then when you ask questions they'll say, "no I'm ok."* You know what I mean, so that's why you need to prepare at first that, "we will interact, I will give you information, (there'll be) questions. If you don't ask me, I will ask you." (FGD 4, Consent Counselors)

In response, consent counselors described not necessarily accepting reports that participants understood, but rather attempting to check participants' understanding by asking them to explain research concepts in their own words, identifying gaps in understanding, and revisiting informational aspects, as highlighted in the quote below:

> . . . that is why from the very onset, when that participant comes to the site, when you are giving that information, you pause, and ask the participant "do you understand? Can you explain to me what exactly did you (take in), from what I was saying to you?" From there it's . . . pick up that ok, now the participant absorbed this information, this one didn't really go in. Then we know where to do the touch-ups . . . (FGD 5, Consent Counselors)

Furthermore, consent counselors reported making efforts to communicate with potential participants using their preferred language—to help get messages across thereby improving understanding. However, it seemed to also be used to achieve other more implicit goals such as making participants feel more comfortable (at ease) during the interaction, to equip them for the consent encounter and to respect them as choosing agents by showing them that their preferences would be respected. Sometimes the goal of improving understanding and the goal of respecting choices appeared to conflict—such as when counselors reported overriding preferences for English when it was clear that this would undermine comprehension, as seen in the following quote:

> . . . our participant would like to choose English . . . maybe they are fearing to be judged, by us . . . you'll find "no, sisi [sister], you don't understand English." *And, they said "no I understand" I said "ok fine, explain to me, what 'blood test' mean."* You know what I mean. (FGD 4, Consent Counselors)

Consent counselors also reported switching between languages to accommodate participants' language preferences. ("So you switch yourself you go for the language that is easy for him, you can go for the deeper language, you just accommodate" [FGD 4, counselors].) Educators and consent counselors reported doing on-the-spot translation of terminology into potential participants' home language—with some resulting challenges. As one counselor remarked, "Most of the scientific terms do not exist at all, in the indigenous language, so we have to make a sentence in order to define that word" (FGD 4, Consent Counselor). Consent counselors reportedly viewed the informed-consent process as an ongoing process with multiple opportunities to interact with participants and to reinforce information:

> . . . so *every visit they come, we review the informed consent*. We know mos it's a lot of information that we give them in the informed consent form—maybe they will forget . . . If they having some questions in that—because they have got their copies, to take home and to read it at home. Then, if they've got any questions, come back they answer/they ask the questions. And then each day . . . has got its own procedures. That is when you have to revisit the informed consent that we did at first . . . (FGD 5, Consent Counselors)

Consent counselors experienced some tension between sound understanding and the sheer volume of information that needed to be disclosed in the available time frame, and tensions between sound understanding, and the demands of working through several consent forms, for example, one for trial enrollment and another for stored samples. As one reported,

> So for us we find it is very strenuous but there are these clauses that limit us that come from the sponsor that part of these visits these are the consents. Cos we feel it's too much, really, doing different consents in one time . . . (FGD 4, Consent Counselors)

Educators and consent counselors also described identifying key characteristics of the persons they were educating and making efforts to accommodate these:

> . . . we need to understand this person or this group. You understand. Their level of understanding, a way of observing . . . these are the things that you always consider, you know prior you know starting a consent . . . (FGD 4, Consent Counselors)

Educators and consent counselors recognized that there may be preexisting ideas in the minds of potential participants or circulating in the community that might undermine understanding of important information, and that explanations have to be tailored to such misunderstandings:

> . . . we start explaining to the participant that, what exactly the Centre is doing. That we are a research centre unit, we are not taking blood as for donation . . . we are not giving people food parcels because some of them *they come with that mind-set that they are going to get food parcels*, so we need to explain to participants, some of them they will come and said, "I'm coming for VCT" [Voluntary Counseling and Testing] . . . (FGD 5, Consent Counselors)

Building Trust

CAB members, educators, and counselors all reported encountering information about key research concepts among community members and potential participants that is wrong or inaccurate. In response, they reported that they elaborate, explain, educate, invite for education, use specific terms, give the "right" or "correct" information, as well as track common suspicions. However, in addition to merely giving information that is "correct" (or simplified, or translated, or adequately discussed—as discussed under the "Enhancing Comprehension" section), they reported various strategies likely to build trust in the information that is given, that is, likely to strengthen the credibility of information that is given

For example, it was reported that ex-participants play a role in informing others about the research. This served not only to enhance understanding, by being able to detail the impacts of participation, but also, more implicitly, to build trust in the account because it derived from a credible source:

> And when I reach out to the community I explain to them that I am also, one of those participants on the site, so I practice what I actually preach to them . . . *I say "no, I've been I've gone through this my own self, so, I practice what I actually preach . . ."* (FGD 2, CAB members)

Furthermore, it was reported that educators and consent counselors employed at the site were drawn from similar cultural, racial, and linguistic backgrounds. This served not only to improve comprehension of transmitted information by, for example, using appropriate language but also to strengthen confidence that such information is trustworthy.

Representatives from most constituencies described various practices they viewed as critical in building interpersonal trust between themselves and participating community members or potential participants with whom they interact. CAB members and consent counselors reported the importance of being honest or transparent, and being consistent or reliable:

> you can never try to motivate behavior in the communities, if you talk this, and tomorrow you do the other . . . And it will really lose trust in you, because you telling us this, and you are not doing it yourself. (FGD 2 CAB)

In addition, consent counselors acknowledged the importance of respecting confidences, and generally treating potential participants right (such as greeting, welcoming, offering refreshments, and showing interest in their nonresearch lives). These latter aspects underscore the intrinsic importance of treating potential participants with respect:

> . . . then I'm like "have a seat, and relax," make that participant feel at home, and to try to communicate with the participant, try to feel what the participant is feeling, try to put yourself in their shoes. Then that's what makes the participant—the other thing is, speaking the same language with the participant . . . it makes him or her comfortable . . . (FGD 5, Consent Counselors)

Also, educators and consent counselors noted the importance of the site providing services to participating community members who are not enrolled in any research (e.g., health screening, counseling) and also to enrolled participants (e.g., ancillary care). Serving the community and potential participants, and describing such services when educating about trials, communicated that the site (and its staff) is not motivated merely by self-interest but can be trusted to further the nonresearch interests of the constituencies with whom it interacts.Serving acted as a balance to taking (time, goodwill) from such persons—it was a form of giving back, and an observable demonstration of sensitivity to their nonresearch lives:

> And then you ask them about social impacts, because there are so many things that are happening in our communities . . . So that makes a person feel very, very comfortable, *and see that you care for them*. So you don't just give them vaccine and just sit down and, you don't follow up on whatever happens in their lives. [And later] then you'll see that that *participant has hope that it's not about the study, that's it*, then you deal with the *other* issues that they have. (FGD 5, Consent Counselors)

In addition, CAB members, educators, and counselors all reported that they describe the site as a partner in the struggle against HIV—a struggle shared with community members. Here, the site was positioned as an ally doing its part against the epidemic, not only implying that a commensurate response from the participating community would be valued but also increasing trust in the site's broad motivation—HIV prevention. Also, as discussed earlier, CAB members, educators, and consent counselors frequently invoked proven childhood vaccines such as polio vaccine—which not only served to enhance understanding of the pathway for HIV vaccine research but also might serve to build trust in medical research as a whole, by citing significant contributions that research has made to improve the everyday lives, and health, of the most vulnerable societal members, namely, children.

Respecting Culture

Consent counselors reported recognizing that potential participants are drawn from cultures where norms governing how information can be discussed may differ from norms governing the research enterprise. There were instances where counselor efforts to improve understanding of research concepts appeared to conflict with demonstrating respect for participants' culture. In such instances, consent counselors reported seeking permission to break cultural boundaries—whereby they signaled to prospective participants that culturally sensitive material was imminent, justified the importance of the material in relation to its sensitivity, and sought implicit permission to proceed. In the quote below, the research *procedure* of rectal sampling is being discussed:

> . . . in our African people like if you say, to talk about, rectal sampling when you have to explain to them, it seems as if you being rude . . . so when you have to talk about anus and vaginas, and now when you have to explain it in Xhosa, it's becoming a big word, and her/in her ears. So you try to be like, *even when you talk to her and say, "This is going to be sensitive"* . . . because they start to be shocked when you try to explain these words to them. (FGD 4, Consent Counselors)

Preserving Free Choice

Consent counselors experienced some tensions when promoting understanding of key concepts such as *payment* for participation. They recognized that payment often acts as the initial motivator, so efforts are needed to broaden motivation by informing potential participants about beneficial study procedures, for example, health screens, as well as the overall purpose of HIV vaccine research:

> . . . we had a participant on (protocol name) . . . She said "you know what when I came in here, my intention was to get money, honestly, you understand. But now as the time goes by where I get educated by counselors, I start changing that attitude." That's the process of our most participants they follow . . . (FGD 4, Consent Counselors)

They experienced some conflict between, on one hand, their need for potential participants to understand study-related payments (and study-related benefits), and, on the other hand, their need for participants to concentrate on the right things when deciding about research enrollment:

> So, you have to explain *clear*, about that, not to put money first. Because if you put money first the participant will only come because they will get money, they will not concentrate or understand what's gonna, what is, going on . . . (FGD 5, Consent Counselors)

Consent counselors also reported emphasizing the concept of *voluntariness* in their interactions with potential participants, so that the right to refuse or withdraw is understood, even while recognizing that participants may fail to withdraw from studies (despite understanding their right to withdraw) because of complexities linked, paradoxically, to the high-quality relationship described under the "Building Trust" section:

> We always tell them, at the first, they have a right to withdraw at any time they want, this is their voluntary, but you will find out now, they are not doing their best, *because they want to impress us*, because we have built that kind of a relationship where we know them, on their first-name basis, now they want to impress us . . . (FGD 4, Consent Counselors)

Lastly, consent counselors (and, in fact, also educators and CAB members) reported appealing to altruism when encouraging support for trials, and even participation in trials. They described emphasizing that participation contributes positively to society as a whole, and that selfless acts are required in the fight against the HIV epidemic. They did not explicitly report concerns about the impact of such appeals on voluntary choices.

> . . . because we all know that HIV is killing all of us. And, I believe that as we are explaining the importance of using this (product) they will be, at some point or in some years to come, they will be happy and knowing that they were part of that clinical trials, that came up along with the product, that can prevent the HIV infections . . . at the end of the day it's gonna benefit many people, generations and generations of people to come . . . (FGD 4, Consent Counselors)

Discussion

Representatives from various constituencies in our study reported a range of strategies to promote understanding of key research concepts. However, they also appeared committed to building trust, showing cultural respect, and promoting voluntary consent for participation. In most instances, there was harmony among these goals, yet, in some instances, there was some tension between them. In this section, these goals are discussed in relation to relevant literature.

Promoting Comprehension

First, many of the practices reported to communicate trial information resonate with recommendations to inform educational and consent encounters with principles of adult education and principles of communication (Meade, 1999; Woodsong & Abdool Karim, 2005). For example, everyday examples and analogies were reportedly used—representing efforts to help people understand new ideas by relating these to the rich reservoir of information and experience they already possess as adult learners (Spezzini, 2010). The use of more than one language (code switching) was

described—recommended in adult education to not only present the subject matter clearly but also create a warmer, less alienating atmosphere for learning (Omidire, 2014). Efforts to increase interaction were reportedly used—representing efforts to tap into accumulated skills and awareness (Knowles, 1980). Critically for consent, "active participation" (where questions are asked, and concerns elicited) helps ensure participants "receive information that is personally material"—allowing them to act on personal values and desires (Faden & Beauchamp, 1986, p. 307)—ideally leading to better quality decision making.

Second, many of the reported strategies are consistent with ethical-guideline recommendations to be process-focused—namely, that research teams should strive to communicate key concepts, to promote the expression of participants' concerns and questions, to establish an optimal emotional context to explore information, to be sensitive to the interpersonal interaction, to be aware of social desirability, and to be culturally sensitive (UNAIDS/WHO, 2012; Joint United Nations Programme on HIV and AIDS [UNAIDS]2011; SA MRC, 2003).

Third, many of the reported practices are in accordance with empirical research underscoring the importance of discussion in enhancing comprehension of research. For research generally, Nishimura and colleagues (2013) found, in a systematic review of 54 consent interventions tested in randomized controlled trials, that discussion-based interventions were among the most effective at promoting understanding. Tamariz, Palacio, Robert, and Marcos (2012) found, in a systematic review of consent interventions for low-literacy participants, that more time in discussion was the most effective intervention. For HIV vaccine trials specifically, Coletti and colleagues (2003) found that an enhanced consent process among a subset of participants in a vaccine preparedness study was associated with substantial knowledge gains compared with a standard consent—the enhanced process included discussion of materials with educators, and additional discussion with trained staff members. However, Koblin et al. (2010) found no apparent advantage to a consent intervention (also comprising discussion) conceding this may have been due to the success of the standard consent. Other consent explorations in HIV vaccine trials point to success of educational sessions (Fitzgerald, Marotte, Verdier, Johnson, & Pape, 2002; Joseph, 2006). Notably, the communication strategies used in these discussions (and implicated in the positive outcomes) have not been analyzed or described in published research. We are aware of only one study for HIV vaccine trials—conducted by Watermeyer and Penn (2008)—that described communication practices being used in two taped consent discussions between counselors and potential participants. They reported finding several positive counselor practices, such as providing simple explanations at appropriate linguistic levels and creating personalized moments (humor, laughter). They also reported finding several negative counselor practices, such as dominating the session, allowing minimal participant contribution, and not making efforts to verify information. Yet, they did not explore the relationship of such practices to outcomes such as improved comprehension. It has been argued that—even for research as a whole—it is still not entirely clear what aspects of consent discussions or "person to person" interactions promote understanding (Flory & Emanuel, 2004, p. 1589).

Fourth, many of the strategies reported here underscore the recommendation in the HIV-prevention literature that informed-consent processes can be strengthened by prior and ongoing community engagement (UNAIDS, 2011; Woodsong & Abdool Karim, 2005). Strategies to communicate key concepts were reportedly implemented by engagement stakeholders (educators and CAB members) at earlier education sessions in the community and at the site, as well as by consent staff during consent discussions. This suggests that engagement and consent staff should be helped to develop and share accurate and consistent messaging for their communications. Even where sites do not use this "staggered" approach, they should be aware that potential participants might have been exposed to some concepts before they interact with consent staff in individual consent sessions, and that community-level ("on the street") understandings may have an impact on individual-level appraisals (cf. Woodsong & Abdool Karim, 2005, p. 414).

Also, some forms of effective communication may well be threatened by time and efficiency pressures. For example, interactive encounters are arguably more time-consuming and less "efficient" than conventional "lecture"-type interactions but may be associated with better outcomes (e.g., better attention or better motivation to learn; Knight & Wood, 2005). Continued frank discussion, during staff training, about potential threats to effective communication is important to ongoing efforts to strengthen key processes.

Finally, we found that several communication practices perceived to be important by site staff involved in consent encounters were not reflected in available observational frameworks for consent, such as the Process and Quality of Informed Consent instrument or P-QUIC (Gross-Cohn et al., 2011), for example, practices to demonstrate awareness of cultural differences. Available frameworks may benefit from adaptation based on empirical work with consent communicators.

Building Trust

Many of the practices reported here from both educational and consent encounters to build trust in the information being communicated (e.g., making use of trustworthy sources) show that site staff face considerable suspicion about medical research in general, about the site itself and even about themselves (Rautenbach et al., 2015). This

underscores the importance of the dual goals of building "research competency" ("literacy") *and* of building trusting relationships (cf. UNAIDS, 2011) and recognizes "mistrust" to be as important a barrier to involvement in trials as "misinformation" (cf. Andrasik et al., 2014; Newman & Rubincam, 2014; Newman et al., 2015). As noted by MacQueen, Bhan, Frohlich, Holzer, Sugarman et al. (2015), future research into engagement should evaluate the explicit contribution of various practices to various outcomes—not only increased trust but also increased understanding, cultural sensitivity, and contributions to research, as well as decreased controversy or conflict (MacQueen et al., 2015; Newman et al., 2015; Rubincam, Lacombe-Duncan, & Newman, 2016). This qualitative investigation cannot determine which practices actually have an impact on the desired outcome of increased trust (nor any other desired outcome), but can shed light on practices perceived by core stakeholders to be significant, for incorporation into future explorations. What this study does indicate is that a singular focus on information disclosure may elide crucial elements of trust building implicit in the education and consent process.

Respecting Culture

Several practices described by these constituents represent efforts to show respect for the culture of potential participants, such as using appropriate linguistic terms and carefully broaching sensitive topics (cf. Bayer, 1994; Rubincam et al., 2016). Interestingly, in instances where helping potential participants to understand what might happen to them in trials was expected to run counter to cultural norms about "who" can say "what," consent counselors "prepared the ground" for disclosure of sensitive information. This practice suggests that consent counselors do not uncritically accept cultural norms (cf. Bayer, 1994), such as those restricting women from discussing sensitive topics with men (e.g., sexual body parts). Instead, they acknowledge these norms and justify sensitively overruling them in the interests of participant understanding. Of course, it is not clear from this study whether such practices are actually effective in adjudicating between the goals of understanding and cultural respect, but they merit further attention in research and practice guidelines.

Promoting Voluntariness

Several practices described by these constituents (e.g., emphasizing voluntariness, discussing benefits) appear more relevant to promoting *voluntary* research participation, rather than *informed* research participation although voluntariness and benefits are obviously concepts to be understood in their own right. There were concerns about whether promoting understanding of benefits might come at a price—where decision making is somehow undermined. Mamotte and Wassenaar (2015) observed that voluntariness has generally been conceptualized poorly. Leading models assert that "offers" are not threats to voluntariness unless research-related risks are undervalued, ignored, or disregarded (Appelbaum, Lidz, & Klitzman, 2009a). Site staff may need reassurance that discussing payments or benefits (that themselves should be modest and well justified) with potential participants is not in and of itself ethically problematic unless risks are being overlooked. Some site staff described strategies to cultivate nonfinancial motivations for enrollment. These data suggest that site staff may value opportunities to practice communicating research-related risks skillfully to potential participants in such discussions. A recent study found that participants in two HIV clinical trials did not report payment as the main reason for participation, nor was payment associated with reduced voluntariness (Mamotte & Wassenaar, 2016).

The practice of appealing to altruism was not explicitly reported as a concern; however, its ethical acceptability will be briefly discussed here as this approach seemed to be frequently used. Appelbaum, Lidz, and Klitzman (2009a) argued that appealing to values such as "altruistic impulses" (p. 33) does not render a decision to enroll nonvoluntary, and "altruism is generally regarded as the least problematic motivation for participation" (Appelbaum, Lidz, & Klitzman, 2009b, p. 13). However, it stands to reason that appeals to altruism should not be at the expense of a thorough discussion of research risks, or be used to preempt individuals' stated concerns. Also, there are arguably many ways to express altruism in the HIV epidemicapart from trial enrollment, such as taking part in advocacy efforts for HIV prevention (UNAIDS, 2011).

Limitations

We explored reported practices at one site, and therefore, our results may not be generalizable across other HIV vaccine trial sites; however, it is possible that sites with similar approaches, staffing arrangements, and context may have similar experiences and may find aspects of this study applicable. Also, by design, FGDs were homogeneous to encourage openness and candor. Therefore, there was no opportunity for CABs, educators, and consent counselors to interact and compare across constituencies their practices (or challenges they face), which may further illuminate some of the issues described. Furthermore, FGDs were conducted across a period of time, during which staffing duties, personnel, and approaches may have shifted. Finally, as alluded to earlier, study methods used here cannot verify the actual practices being implemented. For example, it is possible that in practice, educators and consent counselors use less interactive techniques than they reported—because of social desirability pressures to report communication efforts and the contextual pressure in practice to transmit many

complex and legally required concepts in an efficient time frame. Also, merely because a strategy was not raised in a FGD does not necessarily mean it is not used. In addition, this study cannot shed light on which practices are effective in achieving desired goals. Last, we did not canvass the views of actual trial participants on these issues—this is a more challenging population to engage with given understandable concerns with additional research activities that may influence participant behaviors and the course of a trial. Our results do, however, reveal important challenges, unofficial strategies, and insights from uniquely positioned and understudied informants who play vital roles in directly interfacing with potential participants in HIV vaccine trials; and the results raise important issues for further research and engagement efforts.

Conclusion

Overall, site staff involved in engagement and consent processes—such as educators and consent counselors—were not merely trying to promote understanding of HIV vaccine trials but appeared committed to other valued goals, such as building trust, respecting culture, and promoting voluntariness. The range of strategies and practices reportedly used to promote these goals was quite considerable. In several instances, these goals appear to be in tension, such as respecting language choice while promoting understanding, promoting understanding of invasive procedures while respecting culture, or promoting understanding of study aspects like payment while preserving free choice. Also, for the goal of enhanced understanding, the need to transmit multiple, complex concepts in an "efficient" time frame may threaten those communication practices that are not necessarily "efficient."

Best Practices

Trial sites should continue to make the human-resource commitments needed to ensure that participating community members and potential participants are engaged in multiple activities designed to increase understanding of HIV-prevention trials. Sites should evaluate how well complex concepts are being communicated in consent and engagement encounters. Research Ethics Committees should ask for more detail about the interpersonal strategies that will be implemented to promote understanding (cf. Woodsong & Abdool Karim, 2005), in addition to scrutinizing the adequacy of written consent forms.

Research Agenda

Building on our findings, actual engagement and consent encounters at HIV vaccine trial sites should be observed, recorded, and analyzed. This might help open an important "black box" (cf. Wade, Donovan, Athene-Lane, Neal, & Hamdy, 2009, p. 2019). Observations could use existing frameworks, for example, the P-QUIC (Gross-Cohn et al., 2011), but these should be adapted based on empirical research with relevant communicators, such as the present study. Site staff themselves should be involved in developing user-friendly frameworks that allow them to observe simulated and real encounters, as part of their in-service training. Also, the relationship between practices being implemented in such encounters (e.g., promoting discussion) and outcomes (e.g., enhanced understanding) should be assessed in future research (cf. MacQueen et al., 2015; Meade, 1999; Newman et al., 2015) so that site staff can inform their encounters with empirically informed practices. Further qualitative research should more fully explore the similarities and differences in practices used across different site constituencies. Further qualitative research should explore more thoroughly implicit tensions between site staff members' multiple goals, such as whether describing services as part of trust building may be in tension with efforts to promote understanding of the site's central purpose to conduct research. Finally, research with enrolled trial participants (e.g., to explore the perceived usefulness of strategies such as using analogies) would enable triangulation of participant perspectives with those of site staff. In addition, it may be helpful to investigate changes in understanding and trust across various time points at clinical trial sites—to ascertain how such phenomena evolve throughout ongoing contacts. Research with enrolled participants could comprise ancillary studies attached to "parent" HIV vaccine trial protocols.

Educational Implications

Role-players at HIV vaccine sites involved in engagement and consent encounters should have access to training in core communicative competencies—ideally those with evidence for their usefulness, not only those informed by, for example, adult education principles. These efforts may help to make consent-related encounters as "potent" as possible given finite resources for such trials, and competing claims on resources. Pressure to transmit multiple, complex concepts "efficiently" should be faced head-on as a potential threat to effective communication, and best practices for resolving this tension should be shared. Further training and educational support should address other potential tensions identified empirically, for example, how to respect cultural choices about preferred language while still promoting understanding.

Acknowledgments

We thank all focus group participants for their time, insights, and contribution as well as various constituencies at the participating site for facilitating the study, such as site leadership and community representatives.

Authors' Note

The views expressed are those of the authors and do not represent the position or policy of Canadian Institutes of Health Research (CIHR). These views do not represent the position of any council or committee with which the authors may be affiliated.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Several authors are members of HAVEG which has received funding in the past from initatives that also provided funding for clinical trials of HIV vaccines. Two of the authors, professor Bekker and Dr Roux are involved in the conduct of clinical trials of HIV vaccines.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was made possible by funds from the Canadian Institutes of Health Research (CIHR) and Canadian HIV Vaccine Initiative (CHVI) (THA-118570; Principal Investigator [PI]: Newman).

Note

1. Site constituencies also have access to many educational materials that use analogies—for example, where prevention options are compared with a toolbox; Community Advisory Boards (CABs) are compared with the eyes and ears of the community, or with a bridge between the researchers and the community; and an HIV vaccine is compared with a photocopy or a scarecrow—implying it lacks the key ingredients to cause HIV infection.

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