I'm Positive, But I'm Negative: Competing Voices in Informed Consent and Implications for HIV Vaccine Trials

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Abstract

HIV vaccine trials (HVTs) are ethically complex, and sound informed consent processes should facilitate optimal decision-making for participants. This study aimed to explore representations of critical HVT-related concepts to enhance the consent process. Four focus group discussions were conducted with participants from key constituencies at a South African HVT site. Thematic analysis was employed to identify representations of key HVT-related concepts. The findings suggest that (potential) participants may negotiate multiple, competing versions of HVT-related concepts in a somewhat unrecognized process, which may have significant implications for the consent process. Stakeholders involved in consent and engagement activities at sites should be assisted to elicit, engage, and resolve competing representations of HVT-related concepts. More empirical research is needed to explore how such stakeholders address competing representations in their interactions with potential participants.

Keywords

research ethics, empirical data, informed consent, HIV vaccine trials, mental models, South Africa, culture, decision-making

South Africa has one of the highest burdens of HIV in the world (Joint United Nations Programme on HIV and AIDS [UNAIDS], 2013). As part of a comprehensive treatment and prevention response, the country has hosted approximately 10 HIV vaccine trials (HVTs). In many settings, securing consent for research participation is complex because of low educational or research literacy among potential participants, diverse cultural understandings (Marshall, 2006; Ndebele, Wassenaar, Munalula, & Masiye, 2012), diverse linguistic backgrounds (Penn & Evans, 2010), as well as power differentials between research staff and participants (Lindegger & Richter, 2000; Participants, 2013; Woodsong & Karim, 2005). Specifically, in HVTs, there are many complicated concepts to understand (e.g., "Vaccine-Induced Sero-Positivity" or VISP) that carry significant social and personal consequences. VISP refers to the manner in which vaccine recipients may test positive for HIV on certain HIV tests, despite not actually being infected with the virus.

It has long been recognized that consent should transcend concerns with legal indemnification and focus on promoting sound decision-making for participants, including of the personal consequences (Lindegger et al., 2006). Ethical guidelines governing HVTs recommend prior community engagement to tailor consent strategies, the training of dedicated staff, the use of sound written materials *and* interpersonal strategies to promote understanding, and formal assessment of understanding (AOU; South African Medical Research Council [MRC], 2003; UNAIDS/AVAC, 2011; UNAIDS/WHO, 2012). HIV prevention stakeholders have developed simplified consent forms, supplementary participant information booklets and materials, AOUs, and mechanisms for soliciting community-representative inputs into consent materials, as well as researched consent components (Coletti et al., 2003; Lally et al., 2014); however, securing authentic consent remains challenging.

An additional complexity is that representations of research-related concepts held by potential participants may conflict with those offered by researchers. It has been argued that participants' decision-making may be partially dependent on mental models (Newman, Seiden, Roberts, & Duan, 2009) understood as internal representations that

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have "in some abstract sense the same structure as the aspect . . . of external reality" that they represent (Colman, 2001, p. 440) or private cognitive representations (Coll &Treagust, 2003). For potential participants deciding about trial participation, various representations of research-related concepts may compete to be the dominant representation (cf. Drescher, 2010). However, scant attention has been paid to this issue.

Aim and Method

The present study aimed to explore representations of critical research-related concepts among key stakeholders in HVTs and to consider the implications for strengthening consent processes. A fuller description can be found in an online appendix (available at jre.sagepub.com/supplemental). In brief, four Focus Group Discussions (FGDs) were conducted with key constituencies at a South African HIV vaccine site, namely, Community Advisory Board (CAB) members, Vaccine Educators/Outreach Workers, and consent counselors (with approximately eight participants per group). The FGDs were digitally recorded with participants' permission, transcribed with identifiers redacted, organized using NVivo, and analyzed using thematic analysis (Braun & Clarke, 2006) to identify competing representations of key research concepts and key research stakeholders in the data. Competing versions were operationalized as conflicting versions (a) articulated by a single participant, (b) articulated between two or more participants, or (c) interpreted by the research team. Ethical approval was obtained from three Research Ethics Committees, individual consent was obtained for participation in the FGD, and relevant site stakeholders were engaged to build support for the study, enhance its implementation, and reflect on the findings.

Results

HVT-Related Concepts

Vaccines. HIV vaccines were occasionally positively (but inaccurately) represented by community members as "the cure" where "most people they confuse it, they think it's the cure medicine" (Focus Group Discussion [FGD] 1, CAB). Community members were also reported as having "preventive misconceptions":

> If I talk about in a vaccine, they think that "oh meaning if I'm vaccinated, no need to use a condom at all, no need to use contraceptive, at all, cos, I will I will be safe, with HIV I will be safe with pregnancy I will be safe." (FGD 3, Outreach Workers)

Community members reportedly saw vaccines as HIV causing: "Because you gonna get the HIV vaccine and then they think, 'Oh maybe I will, I might be infected they might inject you, inject me with HIV'" (FGD 3, Outreach workers).

VISP. VISP was reportedly a confusing concept for many stakeholders ("I'm positive, but I'm negative"; FGD 1, CAB). On one hand, some participants and community members reportedly accepted the conception of VISP as communicated by trial sites. On the other hand, some reportedly saw VISP as evidence that trial sites deliberately infect participants with HIV: "That center infects people with HIV. We can't, we can't go there because, when they get those, vaccines, then, it is about this uh, concept, the VISP . . . " (FGD 3, Outreach Workers). Furthermore, some role-players (such as clinic staff in primary health care facilities) reportedly saw VISP as an impossible and illusory phenomenon. In one such instance, a participant allegedly attempted to explain her HIV positive rapid test result as a function of VISP; however, "they [the clinic staff] didn't believe her . . . she was lying, she was in denial that she is HIV positive, she was in denial, there is no such thing (as VISP)" (FGD 4, Counselors). These latter views may complicate how information about VISP is understood or accepted by potential participants. As part of post-trial responsibilities, sites should capacitate third parties, such as clinics in the participating community, about VISP to offset potential burdens to participants.

Research Stakeholders

Trial participants. A key, common representation of participants was that of the "hero" with the potential to "make history" in the collective struggle against HIV (FGD 2, CAB). These representations served to invite community members to come forward for participation, as well as to affirm current participants. Participants were also represented as heroic martyrs—who endure risks and burdens—as set out by one CAB member who remarked, "We don't go to the communities and *lie* that this will bring heaven and earth. It's like milk and honey. We go to communities and say, 'it will be painful'" (FGD 2, CAB). Respondents also drew upon the language of "sacrifice" and "risk" to describe the fatigue associated with participation, thus positioning participants in an ostensibly heroic way. In contrast, participants were also represented as "untrustworthy." For example, participants were at times alleged to have misrepresented their condom-use and adherence behaviors to site staff, withheld their desire to withdraw, provided conflicting information to various site staff, and misrepresented their experience of trials to the community. For example, as one outreach worker stated, "You can see by stories or games that they are playing that they are not interested" (FGD 3, Outreach Workers). The data revealed numerous instances in which participants were represented as "guinea

pigs"—"commonly people say we make them guinea, guinea pigs" (FGD 2, CAB). Similar results have been found in Canadian HVTs (Newman, Daley, Halpenn, & Loufty, 2008). The latter representations in South Africa may be rooted in historical abuses by researchers under Apartheid. The representation that "trumps" (e.g., participant as guinea pig or hero) may lead to different outcomes about whether to seek further information about trials.

Research site. Our respondents reported several positive representations of the site. For example, they noted,

> To come to a research site, it's most welcomed clinic, than in a public hospital. You will get uh, soft drink, and then you will be welcomed, and then you will be served, as early as, possible. You won't sit here for the whole day.

Furthermore, the site was viewed as providing "good service," and if participants acquired HIV, they would be "properly referred" (FGD 2, CAB). In contrast to expensive private health care (including traditional African medicine) and inefficient public facilities, "when you come to the site, you can just come and say I need to make an appointment with so-and-so, so that the person can see me" (FGD 2, CAB). This suggests that ancillary-care responses for participants are positively characterized by these trial stakeholders. However, our respondents reported that there were numerous negative representations of the site as mysterious, untrustworthy and possibly dangerous, because community members had "no idea what is happening here" and that "people here are being given things, that there's not even known what it's going to do to them . . . " (FGD 4, Counselors). Our respondents reported that a common assumption among community members was that "if you go to that building [the site], you are HIV positive" (FGD 3, Outreach workers) or "you are given HIV here" (FGD 4, Counselors), and "if you go to that center, they will infect you with HIV" (FGD 3, Outreach Workers). Even the key trial component of confidentiality was reportedly viewed by community members as a form of secrecy to shield dangerous practices (even while some viewed confidentiality as a critical protection)—"when you go to communities or our societies when you talk about things that are confidential, they raise eyebrows," because "it seems that, serious, the site is killing the people" (FGD 1, CAB).

Research/ers. Representations of researchers by community members were reportedly predominantly suspicious. For example, researchers were viewed as "brainwashing" the community and participants ("they're just playing our minds") or as dubious individuals seeking to exploit communities. Representations of exploitative researchers were often overtly racialized, with poor, vulnerable "Black people" represented as potential victims of cunning "White" researchers, who could, for example, "sell our blood." Researchers were also represented as "foreign"—with one CAB member even suggesting that there was a need to "bring the scientist closer to the people . . . not something very easy" (FGD 2, CAB). Research was also viewed by community members as potentially "dangerous" and "risky": "I am told my risks of being in the study, I would be ssss*cared* maybe you know, because I would be told maybe I will get sick" (FGD 1, CAB). Community expectations that research should yield short-term benefits were also reported. To counter these views, CAB members and Vaccine Educators appealed to familiar and credible medicines and vaccines—such as Antiretroviral Therapy and the polio vaccine—to demonstrate the long-term benefits of research. CABs and Vaccine Educators also appealed to the cultural notion of "Ubuntu" to motivate community members to get involved in trials and to justify potential risks for long-term societal benefit. In contrast, most of our respondents supported the research enterprise, characterizing it as beneficial and even "history-making" (FGD 2, CAB), and frequently contested negative representations.

In contrast to representations of HVT-related concepts, the representations of research stakeholders found here may apply to, and have implications for, a broad diverse range of research contexts.

Discussion

Ethical guidelines for HIV prevention trials make a series of recommendations about how to promote genuine informed consent, including having staff members trained in interpersonal skills, such as how to overcome social desirability (MRC, 2003). Our findings endorse such recommendations but go further by illuminating an overlooked aspect of consent, notably the identification and negotiation of personal-, cultural-, and community-based representations of trials, which may compete with those offered by trial staff. We explore the possible consent-related implications in more detail below.

Information Disclosure

It has long been recognized that information to participants should be clear, accessible, and culturally appropriate, and not "overload" participants (Lindegger & Richter, 2000). This study suggests that potential participants may access many conflicting representations of key research concepts and may face the challenge of negotiating these—a challenge that cannot necessarily be resolved merely by simplifying or repeating or translating trial information.

Understanding

It has long been recognized that participants should understand what trial participation entails, especially the personal

implications (Lindegger et al., 2006; Wendler & Grady, 2008). Some have argued that extended discussion is the most effective way to promote understanding (Flory & Emanuel, 2004) because of its potential for "active engagement and responsiveness" to the individual needs of participants (p. 1599). This study suggests that extended discussion may be helpful because it affords greater opportunity to discuss and negotiate conflicting representations of key concepts and stakeholders. This study also suggests that consent discussions should identify those site explanations that are less likely to be trusted, or believed, or "accepted" as true (Gikonyo, Bejon, Marsh, & Molyneux, 2008; Molyneux, Peshu, & Marsh, 2005; Molyneux, Wassenaar, Peshu, & Marsh, 2005), which is somewhat distinct from whether site explanations are technically understood. How non-acceptance of site explanations can undermine participation has been recognized in other studies (Manafa, Lindegger, & IJsselmuiden, 2007).

Explicit Authorization

Potential participants weighing up whether or not to participate may experience the "push and pull" of positive versus negative representations, which may affect whether permission is ultimately given. Also, if competing versions are unresolved, it is possible that potential participants may sign consent forms yet continue to express doubt through other behaviors (e.g., failure to adhere to trial requirements) as described by Molyneux, Peshu, and Marsh (2004) in their account of "silent refusers."

Best Practices

It is unlikely that site-disseminated information about trials will be taken up uncritically by community members or potential participants, because it may compete with various pre-existing representations. Therefore, consent (and even engagement) staff should be skilled in eliciting, recognizing, and discussing various versions of critical concepts, especially as potential participants may not feel empowered enough to spontaneously volunteer these. They should also be well-versed in the general "reservoir" of prevailing representations and be able to elicit specific personalized representations in individual discussions. These recommendations recognize the importance of "interpersonal handling" skills for consent communicators (Molyneux et al., 2004, p. 2557). Participants themselves should also be equipped to counter competing versions in the community.

Educational Implications

Consent staff should be trained to elicit competing representations of trial concepts and stakeholders, and to incorporate their critical evaluation into consent discussions. This is likely to be demanding for such stakeholders who may need additional support and supervision. Emphasizing skills to manage the consent encounter will buttress ongoing efforts to craft improved consent forms.

Research Agenda

Sites should research how trial-related concepts are represented in the surrounding community. Also, more empirical research should be conducted to explore the psychosocial processes that underpin the negotiation of diverse competing versions as well as to identify interpersonal and communicative strategies that best resolve conflicting representations.

Conclusion

Informed consent is an integral ethical requirement of HVTs. While it is commonly assumed that consent requires transmitting information and facilitating understanding of this information, this study suggests the consent process likely involves negotiating multiple and diverse representations of research-related concepts. Consent and engagement staff play an under-recognized yet critical role in identifying and responding to these conflicting representations.

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