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Misreporting of Product Adherence in the MTN-003/VOICE Trial for HIV Prevention in Africa: Participants' Explanations for Dishonesty

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Abstract

Consistent over-reporting of product use limits researchers' ability to accurately measure adherence and estimate product efficacy in HIV prevention trials. While lying is a universal characteristic of the human condition, growing evidence of a stark discrepancy between self-reported product use and biologic or pharmacokinetic evidence demands examination of the reasons research participants frequently misrepresent product use in order to mitigate this challenge in future research. This study (VOICE-D) was an ancillary post-trial study of the vaginal and oral interventions to control the epidemic (VOICE) phase IIb trial (MTN 003). It was conducted in three African countries to elicit candid accounts from former VOICE trial participants about why actual product use was lower than reported. In total 171 participants were enrolled between December 2012 and March 2014 in South Africa (n = 47), Uganda (n = 59) and Zimbabwe (n = 65). Data suggested that participants understood the importance of daily product use and honest reporting, yet acknowledged that research participants typically lie. Participants cited multiple reasons for misreporting adherence, including human nature, self-presentation with study staff, fear of repercussions (study termination resulting in loss of benefits and experience of HIV-related stigma), a permissive environment in which it was easy to get away with misreporting, and avoiding inconvenient additional counseling. Some participants also reported mistrust of the staff and reciprocal dishonesty about the study products. Many suggested real-time blood-monitoring during trials would encourage greater fidelity to product use and honesty in reporting.

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Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Participants at all sites understood the importance of daily product use and honesty, while also acknowledging widespread misreporting of product use. Narratives of dishonesty may suggest a wider social context of hiding products from partners and distrust about research, influenced by rumors circulating in clinic waiting-rooms and surrounding communities. Prevailing power hierarchies between staff and participants may exacerbate misreporting. Participants recognized and suggested that objective, real-time feedback is needed to encourage honest reporting.

Keywords

HIV prevention; Women; Africa; Honesty; Adherence

Background

Adherence to medication is a well-documented and ongoing challenge for the prevention and treatment of many diseases and health conditions [1]. Furthermore, it has been recognized as a threat to the success of HIV pre-exposure prophylaxis as an HIV-prevention strategy, as evidenced by low study product use in several large, multisite HIV prevention trials among women in sub-Saharan Africa [2–5]. Equally challenging is the consistent over-reporting of product use, which gives false impressions during trial implementation, and limits researchers' ability to estimate efficacy in intent-to-treat and subset analyses. Growing evidence of a stark discrepancy between self-reported accounts of product use, and biologic or pharmacokinetic evidence of drug present in plasma [2, 6–8], demands that clinical trialists critically examine *the reasons* research participants are compelled to over-report and misrepresent their actual product use [9]. Put more simply, why do participants misreport adherence?

Dishonesty—whether conscious or not—is a pervasive, and often costly, human behavior [10–13]. Indeed, psychologists specializing in dishonesty describe that many people lie and cheat at least a little bit every day, even when in contradiction to their beliefs or values [13]. Individuals' reasons for lying are most commonly described to: avoid punishment, protect someone else or oneself from harm, win admiration, avoid embarrassment, maintain privacy, be polite or merely for the thrill of “getting away with it” [14]. Lying within the medical context has a particularly notorious reputation as an arena for deception, as our colleagues recently discussed in their anthropological analysis of participants' behavior in the Microbicide Trials Network's “VOICE” (MTN-003) trial [15]. The tradition of the so-called “medical lie”, in which a clinician might distort prognoses or patients may distort health-related behaviors such as medication adherence, can be further exacerbated in HIV prevention trial settings, that are characterized by complex constructs of power imbalance and moral order [15]. Indeed, a recent review of the social psychology and management literature underscored the evidence for the malleability and dynamism of “morality” around honest behavior, and the powerful influences of situational, non-individual, factors on “dishonest” behavior [13]. The authors further describe how influences are particularly pronounced when hierarchical relationships (e.g., researcher–participant) are present and when dishonesty is exhibited by other members of an individual's social group [12].

In response to the null effectiveness results and evidence of low product use from pharmacokinetic drug testing in VOICE, the VOICE-D (MTN 003D) ancillary study was designed and implemented to better understand sources of efficacy dilution, including nonadherence [2]. VOICE-D used a variety of methodological strategies to elicit candid accounts about why participants didn't use their study products, and why they concealed their non-use [16]. In this paper we present participants' explanations for over-reporting of product use, including the broader context of deception and misrepresentation in participants' lives. Understanding motivations for misreporting provides important insights into study implementation that can help mitigate nonadherence and threats to both efficacy and its measurement. We offer potential strategies to address these challenges in future research.

Methods

Parent Trial (VOICE) Design

VOICE was a phase IIB, five-arm, placebo-controlled trial evaluating the safety and effectiveness of oral tenofovir and Truvada™ tablets and vaginal tenofovir gel or their matched placebos for preventing HIV. 5029 sexually active HIV-uninfected women, 18–45 years old, were enrolled at 15 sites in Uganda, Zimbabwe, and South Africa [2]. Participants were instructed to take tablets or insert gel daily, and at each monthly visit, they returned excess products and received a resupply along with product adherence counseling. Participants were followed for up to 36 months of study product use. At each visit, women were encouraged to honestly report their actual product use in questionnaires administered both face-to-face and by audio computer-assisted self-interviewing (ACASI), and assured that they could stay in the study irrespective of their responses. Monthly individual client-centered adherence counseling focused on barriers, facilitators and women's needs [17].

VOICE-D

VOICE-D was a two-staged qualitative study designed to explore sensitive issues that may have led to null effectiveness results during the VOICE trial, including high risk sexual practices and low adherence to daily study product use. VOICE-D was conducted at four of the 15 VOICE trial sites, including at least one site from each of the three VOICE trial countries: South Africa, Uganda and Zimbabwe. In the first stage of VOICE-D, participants were interviewed using an in-depth interview (IDI) guide that explored two main topics related to potential sources of efficacy dilution: heterosexual anal sex and misreporting the use of study product. Participants were randomly selected from a list of those permitting further research contact after completion of the parent trial who met pre-specified eligibility characteristics [16]. In Stage 2, following availability of individual plasma tenofovir level tests indicating widespread low use of the study products [2], participants were presented with their plasma drug level results and qualitative IDI and focus group discussions (FGD) were used for further discussion of adherence challenges [16]. Study eligibility criteria for Stage 2 were modified to include only participants on active product during VOICE who had PK data available, and random selection was stratified by dosing regimen and PK level. In both study stages interviewers explored reasons for misreporting of product use that were both accidental and intentional. In order to elicit candid responses, the interviewers were

unaffiliated with VOICE-D and interviews were conducted in environments that felt safe and neutral to participants. Recognizing that discussions about “lying” could be sensitive, interview guides were designed to be noncritical and nonaccusatory, for example using language about, “reporting” (which might be intentional or nonintentional), rather than overtly asking about “lying”. That said, english transcripts of African language interviews suggested that participants readily employed use of the term “lying” (or its African language equivalent). As such, unless otherwise specified, throughout this paper we discuss intentional misreporting or misrepresentation as synonymous with “lying”.

In total, data from a sample of 171 former VOICE participants, enrolled between December 2012 and March 2014 in South Africa (n = 47), Uganda (n = 59) and Zimbabwe (n = 65), were analyzed. Data from 156 IDIs and 12 FGDs collected in the two study stages were audio-recorded, transcribed and translated from local languages. Interviews were conducted by non-VOICE social scientists in offsite locations, intended to be neutral.

Transcripts were coded and analyzed thematically in NVivo 10 by trained social science analysts. Transcripts were coded using NVivo software and followed a structured codebook. Throughout the coding process, 10% of transcripts were independently coded by each member of the coding team, and inter-coder reliability (ICR) was reviewed on a subset of key codes that were most representative of the main research questions and themes of the study. If the ICR agreement fell below 80%, the coding team would discuss over email or phone, review applicable segments of the transcript, and come to consensus. Data pertaining to explanations for, and experiences with mis-reporting of product use, as well as text excerpts where “lying”, “truth” and “honesty” or their opposite, e.g., “dishonesty” were described, were coded as “HONESTY”. Summary reports of transcript passages were generated and exported into Word. All co-authors independently reviewed and summarized data from Stages 1 and 2 separately. Because the thematic findings were the same across stages, results were combined for presentation, with study stage notated for each quote. Consensus on the interpretation of the data was achieved through electronic correspondence and teleconference meetings.

Results

Participant Characteristics

Characteristics of the study sample (n = 171) are presented in Table 1, in aggregate and by study country. At time of their interview, participants were on average 28 years old, 54% were married and 40% had completed secondary school education. The majority were Christian (87%) and many attended religious services once a week (53%) or more than once a week (36%). Participants were evenly distributed across study countries, with slightly more participants in Uganda and Zimbabwe than in South Africa. There are several differences in the study sample by country, for example women in Uganda had more lifetime sex partners and were less educated, women in South Africa were younger and not married, and women in Zimbabwe were less likely to earn their own incomes and more likely to attend religious services. A subset of this study sample (n = 127, 74%—all interviewed in Stage 2 of VOICE-D) had pharmacokinetic data of tenofovir present in plasma at select points during VOICE. Among these, 62% had no detectable tenofovir during study

participation (0% of visits) and were classified as having “low PK” or no evidence of use, while 16% had drug detected at 75% or more of their visits and were classified as “high adherers”. The remainder were considered to have “inconsistent” evidence of use.

The study results below are organized into three broad domains: (1) how participants explained their misreporting of product use, both in terms of participants’ own motivations and their explanations for other participants’ behavior; (2) the context of dishonesty, which offers evidence of a larger social–cultural environment of lying, both within the research clinic setting and in participants’ households and their communities; and (3) “minimizing dishonesty”, where participants’ suggestions for addressing dishonest reporting in future studies are presented.

Explanations for Product Use Misreporting

Participants at all sites reported understanding the importance of daily product use and honest reporting, but widely acknowledged that research participants lied. The five most common reasons/explanations advanced by participants for lying were (1) that it is an intrinsic characteristic of human nature, that people lie; (2) self-presentation: participants did not want to look bad or be reprimanded by study staff; (3) fear of negative consequences: participants did not want to be prematurely exited from the study and lose access to ancillary benefits provided by the trial; (4) a permissive environment: those who lied were not “caught”, and could get away with it; and (5) ease: it was less burdensome to lie than to tell the truth. Additionally, some participants offered explanations highlighting alternative understandings of the “truth”, e.g. their interpretation of high adherence differed from that of researchers, suggesting perhaps an issue with misinterpretation rather than intentional dishonesty, as the other five explanations implied. Each of these reasons is discussed below.

Some participants felt that lying was just part of human nature: *There is nothing you can do. Women just don’t tell the whole truth (IDI#1018, Stage 1, Durban)*. They described other participants as “habitual liars” who were dishonest, either innately or because of upbringing:

You can’t change people. If someone is a liar they will just lie. If a person lies to you when you ask her questions as you are asking me and she knows you are not going to beat her up if she hadn’t used the product, then there is nothing you can do to change her. (IDI#2001, Stage 1, Durban)

She can lie because it is in her blood. That is what I can say. It depends on the kind of family one was brought up in. That is what causes some to lie. (IDI#4015, Stage 1, Kampala)

Participants were occasionally described by their peers as being childish or characterized as “bad” women who drink and argue with others. There also were suggestions that participants in other studies could not be trusted. During their interviews VOICE-D participants frequently accused other participants of being dishonest and described them as cheaters, shift, or wanting to intentionally sabotage the research. Furthermore, they revealed that dishonesty, which provided a socially appealing picture of one’s character, was not limited to misreporting product use. One woman admitted to lying about the number of sex partners

she had because she felt she had been “naughty” and wanted to convince herself it wasn’t true: she misreported to look virtuous in her own eyes.

Well sometimes you can convince yourself of something that is not true...It’s because I could see that what I did was wrong, so I told myself that I will just say that I had one partner even though I was being naughty. (IDI#1008, Stage 1, Durban)

Many women communicated self-presentation as a primary motivation for misreporting adherence. They emphasized that telling the truth about product nonuse was “very difficult” and described how participants felt ashamed of admitting nonuse because they had not followed study instructions. Women were afraid of being reprimanded, “talked about” or scolded by trial staff, particularly nurses. Yet most concurrently acknowledged that trial staff were friendly, and non-punitive. Many narratives highlighted a clear hierarchy, power differentials and social distance between staff and participants. Consequently, participants sought approval from staff, and wanted their behavior to appear “good”. This impulse was also described as a desire to please or impress the staff, akin to pupil-teacher relationship dynamics:

She would want them to say she is doing well. It’s just the same with a teacher, a pupil can lie to a teacher that she did well, yet know that it’s not the truth. (IDI#3007, Stage 1, Harare)

Some women—although not the majority—said it was difficult to explain their behavior to the study staff, implying that the staff would get impatient, annoyed, or uptight, and thus shut down the participants. This further contributed to misreporting, even if participants were initially up front.

If the women return the medication, they should not be asked why they did not use it. They would then speak the truth. Because of the hostile reception at the pharmacy, they were forced to lie. (IDI#4020, Stage 1, Kampala)

The difficulty in disclosing product nonuse—the feelings surrounding such an admission—was exacerbated for some by the knowledge that unused product had not been returned intact but subsequently “wasted” (discarded), given away or sold—all behaviors explicitly proscribed by the VOICE protocol. A few participants also described how feelings of being interrogated or being treated poorly encouraged lying about product use, as articulated in the following quotes:

Yes, and they put me in a room and ask you, “Why haven’t you been swallowing the tablets?” You stay there being interrogated. “What is wrong with you? What happened?” And things of the like. (IDI#4013, Stage 1, Kampala)

Related to fears around telling the truth about product nonuse, participants described a common fear that accurate, honest reporting of product nonuse would result in being shouted at and/or kicked out of the study—both of which were undesirable outcomes. Early study termination was primarily undesirable because of reimbursement money, free health benefits and not wanting to “fail”.

They will be lying so that they stay in the program...So that they, others wanted to be treated for free or to be given the money that we were being given, the ten dollars. (IDI#3008, Stage 1, Harare)

An important additional reason that participants at some sites indicated that they did not want to get kicked out was because it could generate gossip and stigma. Participants described that others in the community may perceive them as having become HIV-positive (seroconverted) if they prematurely exited the trial. As one woman in Zimbabwe said, “the truth kills”:

But with what the other women were saying in the waiting room that “the truth kills”....Haa they said there were times for lying and for telling the truth but this wasn’t the situation to tell the truth because you could be dropped. People would see that you are no longer with the study, and the community would start saying that you have contracted HIV... Or maybe these are the ones messing up the study. So people were afraid of the stigma of being painted as the one messing up the study. Or that you had contracted HIV that is in the community. (IDI#3043, Stage 2, Harare)

Participants also pointed out that the trials’ permissive environment made it easy to conceal the truth. Adherence monitoring through an objective measure was not conducted during trial implementation. Knowing this, participants spoke frequently of how other participants in waiting rooms admitted nonuse amongst themselves, and worked out how to “game” the system by counting products and disposing of the correct number of tablets or gel applicators to match the story they reported at the clinic. These dishonest stories fostered norms of non- or low adherence amongst peers, and seemingly discouraged many from persisting with product use. Further it gave individuals permission to lie, as it was clear that the majority was “lying” too. Participants realized that they would not be caught if they didn’t use, which indeed they were not— some even said they would lie and wait and see if they were caught by their blood tests.

There was no one who was checking, you wouldn’t know whether a person actually used the product or didn’t. (IDI#3006, Stage 1, Harare)

Participants also explained that the burden of truth was greater than that of concealing it. Telling the truth would lead to more questions from study staff and a need for explanations, and possibly more adherence counseling. The waiting time and study visit durations were already a large source of complaint among participants, and thus, they wanted to avoid further procedures that would lengthen the visits.

They lied because they knew they were going to be asked why they hadn’t used it...”Why are you not using it?” Oh no, must you always come and ask me why am I not using it? ... Some other days you [as participants] would come and just tell them you used it. ... She is afraid that they will start following up on her and of being asked questions about why she didn’t use it. (IDI#1014, Stage 1, Durban)

The time burden of telling the truth was not always described as an intentional attempt to mislead staff. For instance, one participant described being in a hurry to complete ACASI to finish her visit. In her hurry she would press any button to complete the task. Another

described that she tried to tell the truth that she was too busy with work to take the products, but felt unheard by staff, which led her to change her story to what she thought the staff wanted to hear:

I tried telling them but they did not want to listen. I realised that I should just lie to them and say I am taking it [study product] even though I was not. (FGD “Sibongile”, Stage 2, Durban)

Finally, some participants communicated a misinterpretation of adherence rather than intentional dishonesty. Some who used the product inconsistently indicated that if they used the products sometimes, they were not lying if they said they were adherent. Indeed, they had actually used the product, so reported use was at least a partial truth. For example, a woman in Zimbabwe spoke of both taking tablets and disposing of her unused tablets down anthills:

When I put the tablets in (the) hole...It doesn't mean I wasn't taking them. I didn't use them every day but I took my tablets. (FGD#302, Stage 2, Harare)

Other instances of this type of misrepresentation related to misunderstanding the interview questions. For example, participants were asked to rate their taking of product on a scale from “excellent” to “very poor”. However, occasionally the terminology for the categories was not clear or distinct in participants’ views. Some participants insisted that they did not understand, whereas others had either an incorrect interpretation of the questions or one that may have been inconsistent with the study staff’s interpretation of a given category. For example, one woman who admitted to stopping product use “maybe twice a month” at times when her male partner was around, when she felt nauseous, and when she had friends visiting said she always chose “very good” as her response to the rating scale. She said “... I just gave “very good” as my answer because “good”, “very good” and “excellent” were the same to me.” (IDI#2012, Stage 1, Durban)

Context of Dishonesty

Participants’ narratives regarding dishonesty about product use also referred to a wider social context where actual and perceived dishonesty and partial-truths circulated in daily lives. Consistent with a model of human nature in which lying is considered normative, this context may have served as a rationale for participants’ own misreporting of product use in the clinic, and to reinforce beliefs about reciprocal dishonesty—that the trial staff were lying to participants. For example, within the study setting, participants described misrepresenting information to study staff in order to meet eligibility criteria, or to stay in the study, such as instances when participants were said to have sold urine to each other to avoid pregnancies being detected. One woman describes lying about one’s profession as a sex worker, because she might feel ashamed if she saw a staff member, outside of the clinic walls.

For example, if someone asks me what kind of job I do. I may be afraid thinking that if I told her the truth and found her outside of this place, I would be ashamed. I would tell her that I sell green bananas [but not sex]. (IDI#4020, Stage 1, Kampala)

Medical mistrust both in general and specific to the trial, was common, and was reinforced by suspicious male partners and rumors circulating in clinic waiting-rooms and surrounding

communities. Despite their participation and expressions of hope that the products would work, there was an undercurrent of uncertainty and distrust about the true intention of the research, a belief akin to perceptions of the “medical lie”—that medical professionals will downplay harm or bad news—as one participant articulates:

It’s the same as when a doctor, when you are ill, will never tell you that you are dying. You will just die. He won’t tell you the truth, but will just tell you to buy more tablets. So that’s what would happen with some, they thought they (information from study) were lies. (IDI#3043, Stage 2, Harare)

Participants specifically described a sense that the study staff were lying to them about the products, and this was entwined with a fundamental lack of understanding about the purpose and design of a placebo-controlled trial. Participants believed that staff were dishonest about the product not working or that they were hiding the fact that there wasn’t actually a placebo product.

They were lying. All the gels had the medication; we had to use them and do the same thing... If it was about the security, we all had to be on the same security because there is no one who can give you a placebo, how will you be healed? (FGD, “Annet”, Stage 2, Harare)

The decision to stop two of the products for futility in the VOICE trial may have exacerbated mistrust [2]. One participant admitted that the interim stoppage of products, as recommended by the DSMB made her feel as if the study staff had been dishonest because “they said it works to prevent [HIV].... Yes, but in the end I figured that, that wasn’t true... I don’t feel alright.... yes it is as if they lied, they lied; it’s as if they lied.” (IDI#1025, Stage 2, Durban).

Outside of the trial setting, participants concealed or hid study participation and product use from family, friends, partners, and community members, for various reasons including a desire for privacy, wanting to avoid comments or suspicions, or knowing disclosure could cause arguments or necessitate leaving the study.

Like I told you, I had to tell lies at home ... About where I was going... I had to make an effort to show that I was sick ... Or I had to say that I had something painning me and then come. (IDI#4059, Stage 2, Kampala)

Some said that if they tell their husbands the truth they would forbid them to join the study... Some would be afraid to tell the truth because they thought they will be expelled from the study. (IDI#3011, Stage 1, Harare)

Participants’ Recommendations for Minimizing Dishonest Reporting

Throughout discussions about dishonest reporting, several participant-driven suggestions to minimize dishonesty in reporting emerged. These centered on staff characteristics and attitudes, the modality of the interview, and improved accountability through objective, real-time drug monitoring.

Staff Characteristics and Attitudes—How questions were asked and by whom were discussed in relation to what encouraged or discouraged honest reporting. The gender and

personality of the interviewer, whether the question was asked in ACASI or face-to-face, and the straightforwardness and repetitiveness of the questions themselves were all discussed. There was no clear consensus about many of these issues, though participants often preferred female staff and those who were “nice” and not rushed or harsh. As one woman states: “There are people you just can’t communicate well with them... Like males. You can’t talk to them... There are questions you just find it hard to ask them.” (IDI#1013, Stage 1, Durban).

The age of participants also mattered, a participant in Uganda mentioned that it was difficult to report how many times she had had sex to someone who was her mother’s age—she feared she would be perceived as “loose”. Many noted that research staff encouraged women to be honest, but in some cases there was a fear of certain “strict” staff members. In general, participants seem to suggest that more neutral and less judgmental staff attitudes could encourage greater honesty, yet participants also acknowledged that this was not an easy task or a guaranteed solution:

The problem is everyone wants to give the impression that they are good, so no one will step up and say their weaknesses when it comes to taking the tablets... So what is needed is for them to persuade people to share... They have to put it in black and white that if you see yourself failing to take the tablets like this and that, you must come to the clinic and tell us. But it’s not easy again because people are difficult by nature [laughing]. (IDI#3005, Stage 1, Harare)

The interview mode was also discussed. Perspectives on responding to ACASI versus face-to-face were evenly split: some participants felt it is easier to tell the truth to a computer, others contended that they could not lie when directly faced with a person. The ease with which participants could tell the truth to a staff member, rather than computer, was influenced by the attitudes, age, and gender of staff (as discussed above) as well as by their ability to reassure participants of confidentiality, and that no deleterious consequences would ensue, e.g., getting kicked out of the study for admitting nonuse. One participant expresses her feelings about both modalities:

Yes. I would prefer it if I answered through a computer and after that sat down and talked to a person like I’m talking to you now. Then you can ask me to tell the truth and [assure] me that you won’t reveal my secrets to anyone else, just as you said before. And I would tell you the truth about my use of the product. (IDI#1012, Stage 1, Durban)

Real-Time Feedback and Drug-Level Monitoring—Several participants suggested that future studies should use real-time drug monitoring or directly-observed methods. As one woman states:

Instead of giving us pills to drink only for us to lie about having drunk them, I think it would be better for you to get us tested on each and every visit so as to make sure that we have really drunk them. I think that is what can be done to prevent the lying. (IDI#1016, Stage 1, Durban)

Furthermore, in at least one focus group there was lively, open discussion that participants did not want “self-administered” products, and could not be trusted to use them. User independent methods, such as injectables were recommended instead. In the following focus group two participants explain this:

Ahh if they want to change (the study outcome), they (researchers) should make participants use the products at the clinic, because we can't be trusted [All laughing] because even if they [the tablets] were smaller you might not take them [over talk]. (FGD “Tatenda,” Stage 2, Harare)

Haa I just want to say that if there are any products and that are coming, don't give us the products that can be removed or those that we have to use on our own at home haaa don't give us [All laughing] because we know that a lot of cheating goes on. (FGD “Chido,” Stage 2, Harare)

Other participants described specific ways that staff could test their blood and give them personalized feedback about those results in order to get a true picture of adherence. Participant narratives additionally suggested that if nurses or counselors talked one-on-one and privately with participants about their test results, they would hear the truth, and participants would be encouraged to use the products as they are meant to.

I think that...if a person's blood is found to not have the product in it, that person should sit down with a nurse like this... You could sit down with a person and say to her, “Your blood shows that you have not been using the product.” If you talk to her face to face, privately, she will tell you the truth. (IDI#1012, Stage 1, Durban)

Ironically, at least two participants pointed out that the research staff themselves should be more direct and truthful about what they can see—or not—in their blood, emphasizing the need for real-time feedback, and *mutual honesty*.

Perhaps if they had made it a policy that immediately after telling a participant her test [PK] results, they would also confront and tell her directly, where applicable, that she had been lying about her responses to the questions...Tell her directly and truthfully that they cannot see any evidence...of the drug in her blood. (IDI#3024, Stage 1, Harare)

I: Ok, so you are saying they were supposed to look at their bloods?

R: Our blood to see if I am taking the drug or if I am not taking, if I am not taking you tell me the truth, don't lie to us. (IDI#3009, Stage 1, Harare)

Discussion

In this study, participants provided several reasons to explain why they themselves, and their fellow participants, were compelled to distort reporting of their adherence behaviors. Understanding these findings is important for several reasons. The first is that tangible reasons such as fears about being kicked out of the trial, or lengthening visits, offer avenues to address procedures and mitigate dishonesty in future research. The second is that these data provide a strong rationale for the development and implementation of more objective measures of product use in future research. Finally, these data provide an important reminder

that multinational clinical trials, particularly those involving a stigmatized sexually-transmitted disease such as HIV, *create* a complex social dynamic amongst trial participants, their social networks, and the trial staff, *and are nested within* an already complex social environment. Researchers must recognize that interpersonal dynamics, information channels and other individual and situational influences external to the trial, may be just as critical to study outcomes as perfect implementation of the standard operating procedures and protocol.

Many participants in this study described fears that they would be expelled from the trial if they admitted nonuse, which in turn would entail losing trial benefits such as free quality healthcare and reimbursements and could lead to assumptions that they were HIV-positive. Staff very well may have assured participants that they would not be withdrawn for product nonuse, but many participants also admitted to not wanting to “look bad” to staff, or a fear of being yelled at [18]. The fears reported by study participants are strikingly similar to the reasons for over-reporting of pill use expressed in a qualitative post-trial study among Kenyan and South African women enrolled in Fem-PrEP [9]. They are also consistent with psychological theory that people lie most often to avoid punishment or embarrassment, and to encourage admiration [14]. Further, as has also been documented in the literature, participants often discussed honest and dishonest reporting in moral terms; Gino et al. [12] describing those who misreported adherence as liars lacking in moral character and portraying honesty as faithfulness to the trial. In this context, participants endeavor to perform the role of adherence, or faithfulness, within the trial. The fears participants described in VOICE-D, and reasons for dishonesty, reflected both internalized fears of maintaining a morally sound and virtuous image to oneself, and also expressions of fear of one’s external image to staff in the clinic and members of the community. These findings resonate with those of Stadler et al., who, using a critical anthropological approach, examined qualitative data from another sub study to VOICE [19] and argued that participants engaged with the trial in a way that maintained their sense of moral wellbeing and virtuousness [15, 19]. Indeed, many of the interpretations put forward in that analysis, which were based on data collected during VOICE from 1 site [19], are directly corroborated through the quotations obtained in this post-trial study conducted at four different sites.

The narratives expressed in this study—discourse on fears of being shouted at, reprimanded, or interrogated—also suggested a stark power differential between research staff and participants. Such power differentials could affect participant’s behavior in terms of adherence and reporting. Fears of trial staff suggesting hierarchical differences may have emerged as a more salient theme because the data were collected post-trial with non-VOICE interviewers in non-VOICE settings. The Fem-PrEP post-study was similarly designed, and participants likewise reported reasons for over-reporting related to trial staff [9]. However, of note, participant beliefs they would be “scolded”, and reports of wanting to please staff were high at one site, but not the other, reinforcing the importance of the specific social context in shaping normative behavior around honest reporting [9, 13].

In VOICE, as observed in this study and in a previous analysis, participant peers exerted a powerful (and generally discouraging) influence on one another’s adherence [16]. It is less clear from the data presented here how peers influenced one another to lie about their

product use (e.g., overt peer pressure), and if participants cared whether a fellow participant knew she was misreporting use. During extended waiting room periods, already well-documented settings for frustration, the trial environment readily offered the situational time and space for participants to share negative trial and product use experiences. As such, it may be productive for research staff to proactively organize peer and group activities, such as the participant engagement activities in the MTN ASPIRE trial and the FACTS trial ‘adherence clubs’, to offer a forum for participants to interact in a constructive manner that airs concerns, worries, and rumors and directs peer influence towards a more positive direction for protocol outcomes [20].

These data also highlight a perception among some participants that dishonest reporting in the study was a two-way street. Several participants described suspicions about the purpose of the research, and a belief that study staff were “lying” to them. Suspicions and lack of understanding about the intent of research, particularly trials sponsored by foreigners with investigational agents, are ongoing challenges that studies aim to address through community engagement, informed consent processes and other strategies. However, because the study did not confront participants about their product nonuse in real-time, this was perceived by some as a form of lying by staff. Indeed, it suggests that both the participant and the provider were enacting a pretend play, as has been previously described [15], and argues for more direct, honest, and real-time feedback to participants about their product use. More objective measures of adherence are increasingly the norm in biomedical HIV prevention trials, and efforts to provide these results in aggregate or (if feasible) to individuals, will likely encourage higher adherence and more accurate reporting. Indeed, several participants in this study suggested that objective testing with consequences, such as study termination, would be the best way to ensure participants took study products. While participants had diverging opinions on the pros and cons of face to face (FTF) versus ACASI modalities for improving honest responses, independent data from VOICE indicate that none of the behavioral assessments in the trial had any accuracy in estimating product use [8, 21].

The IDI responses also suggest that the trial is nested within a broader context of dishonesty and secrecy about sexual relations and trial participation. Several participants described hiding study participation from their male partners or other members of their households, most often justified in terms of not wanting participation to elicit questions, suspicions or perceived accusations about HIV risk. It is perhaps important for researchers to remember that misreporting product use may not be perceived as particularly problematic or egregious within this broader social context. And as suggested above, when they may also suspect the researchers are obstructing some truths. In other words, when lying is normative, participants may not perceive the consequences of their own dishonesty to be particularly severe; at the same time there may be deleterious consequences to telling the truth.

Limitations

Several limitations of this analysis should be addressed. The first is that participants were being asked to explain a socially undesirable behavior of lying and misreporting and it is likely that responses were at least partially biased. Although the study team took several steps to minimize this bias such as conducting interviews in non-trial locations with non-trial

staff, it is likely that social desirability bias still existed. That said, a strength of these data is that participants did admit to dishonest behaviors, suggesting achievement of a “more honest” truth about product nonuse. This was particularly the case in the second stage of data collection when PK results were available, and participant narratives shifted from anecdotes of others’ reasons for nonuse, to personal accounts [16, 22]. However, it is also possible that the methodology of presenting women with their PK data in Stage 2, which may introduced an additional layer of power differential between the researcher and participant, biased narratives in other ways. It is also important to note that interviews focused on discussion of adherence behavior during the VOICE trial, and these data were captured 18–33 months after trial completion. As such, bias related to inaccurate recall of attitudes and actions may have distorted findings. Nevertheless, the focus of the interviews was less on isolated instances of nonuse, and more about general reasons for systemic misreporting, and thus is not particularly dependent on recall of specific events.

In conclusion, the results of this study provide valuable insight into the reasons for, and context in which, participants misreported product adherence in the VOICE trial. This data contributes to the broader literature on product adherence in the clinical trial context by exploring the rationale and justification behind misreporting. The findings can be used to inform improved trial implementation, including addressing participant misperceptions about losing trial benefits, and to improve study messages and participant-staff interactions. These results support provision of objective, real-time and straightforward feedback to participants about their product use—to encourage both improved adherence itself, and a more honest dialogue and trusting relationship between participant and researcher.

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Table 1

Characteristics of VOICE-D study sample, overall and by site (Stages 1 and 2, n = 171)

	N	%	Durban, South Africa (n = 47, 27%)	Harare, Zimbabwe (n = 65, 38%)	Kampala, Uganda (n = 59, 35%)
At time of VOICE-D interview					
Age: median (mean, range)	28 (28.9, 20–41)		25 (26.8, 20–40)	29 (29.6, 21–41)	29 (29.9, 20–41)
Currently married	92	54	0	57 (88%)	35 (59%)
Has current primary sex partner or is married	160	94	43 (91%)	63 (97%)	54 (91%)
Lifetime partners: median (mean, range) ^a	3 (10.8, 1–99)		2 (3.4, 1–15)	1 (2.4, 1–35)	5 (26.1, 2–99)
Completed secondary school or more	68	40	27 (57%)	37 (57%)	4 (7%)
Earns her own Income	125	73	40 (85%)	35 (54%)	50 (85%)
Religion					
Christian	149	87	44 (94%)	63 (97%)	42 (71%)
Muslim	17	10	0	0	17 (29%)
Other/none	5	3	3 (6%)	2 (3%)	0
Attends religious services					
More than once a week	60	36	9 (20%)	38 (60%)	13 (22%)
Once a week	89	53	31 (67%)	25 (40%)	33 (56%)
Less than once a week or Never	19	12	6 (13%)	0	13 (22%)
HIV negative	155	91	38 (81%)	62 (95%)	55 (93%)
During VOICE trial					
VOICE study products group					
Tablets	87	51	23 (49%)	34 (52%)	30 (51%)
Gel	84	49	24 (51%)	31 (48%)	29 (49%)
PK group ^b					
Low	79	62	20 (67%)	25 (52%)	34 (69%)
Inconsistent	28	22	7 (23%)	14 (29%)	7 (14%)
High	20	16	3 (10%)	9 (19%)	8 (16%)

^aParticipants with 99 or more sex partners were checked as “99”

For those in Stage 2 (n = 127) only
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