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The significance of benefit perceptions for the ethics of HIV research involving adolescents in Kenya

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Abstract

Assessment of benefits is traditionally regarded as crucial to the ethical evaluation of research involving human participants. We conducted focus group discussions (FGDs) with health and other professionals engaged with adolescents, caregivers/parents, and adolescents in Siaya County, Kenya to solicit opinions about appropriate ways of conducting HIV research with adolescents. Our data revealed that many focus group participants have a profoundly positive conception of participation in health research, including studies conferring seemingly few benefits. In this paper, we identify and analyze five different but interrelated types of benefits as perceived by Kenyan adolescent and adult stakeholders in HIV research, and discuss their ethical significance. Our findings suggest that future empirical and conceptual research should concentrate on factors that may trigger researcher obligations to improve benefit perceptions among research participants.

Keywords

research ethics; benefits; adolescents; HIV/AIDS; Kenya

Introduction

Research involving adolescents, particularly on sexual health, is both necessary and ethically complex. Adolescents differ from adults biologically, cognitively and behaviorally such that research on adults cannot always be reliably extrapolated to this population (Fatusi and

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Hindin, 2010). HIV research with adolescents is particularly important considering that the WHO estimates that 5 million adolescents live with HIV/AIDS worldwide, and 32% of all new infections occur among young people aged 15–24 (World Health Organization and Joint United Nations Programme on HIV/AIDS, 2016). At the same time, involving adolescents in research is challenging because this population is undergoing cognitive, psychosocial and physical transitions that may heighten study-related risk and compromise decision-making. Background conditions of poverty and instability can add further layers of vulnerability (Bekker, Slack, Lee, Shah, and Kapogiannis, 2014). For these reasons, national regulations, including those in Kenya, often place legal constraints on recruitment of adolescents (National Ministry of Health, Directorate General of Health Planning and Research, Research Directorate, 2008). On the other hand, as Santelli et al. (2003) point out, adolescents may experience benefits associated with their developmental needs, including increased self-reflection from surveys, increased self-control arising from consent decisions, and increased decision-making capacity. In this paper, we report findings on perceptions of benefits among stakeholders in HIV research involving adolescents in Kenya, and examine their ethical implications.

The assessment of risks and benefits by research ethics committees and participants is traditionally regarded as crucial to the ethical evaluation of research involving human participants. There are three key reasons for this (King and Churchill, 2011). First, the assessment helps determine if the research has a likelihood of producing a social benefit in terms of knowledge gained and/or potentially beneficial interventions. Second, the assessment helps determine whether the research risks posed to participants are reasonable in relation to the social or individual benefits. Third, assessments of risks and benefits help participants make reasoned decisions about joining and staying in particular research studies.

In the research ethics literature, as well as regulatory guidance, attention traditionally has been devoted to the determination of risks more than issues related to benefits. An important exception are discussions surrounding ‘therapeutic misconception’, i.e. participants failing to appreciate that research is meant to produce generalizable knowledge for the future, rather than (say) provide direct medical benefits for the individuals participating (Henderson et al., 2007). Misunderstanding the purpose of research is traditionally thought to undermine valid informed consent. A related issue, closer to our topic here, is participant misperceptions of benefits in research. Individuals may harbor false beliefs about the benefits they can reasonably expect when participating in a research study, or more specifically, participants may have correct or less than correct perceptions about direct, collateral or aspirational research benefits. *Direct benefits* are benefits that arise from the intervention being studied. *Collateral benefits* are benefits that participants receive from study participation but not the study intervention, such as a free physical exam and testing, free medical care, or the personal gratification of altruism. *Aspirational benefits* are the benefits that the results of the study may have for society or future patients (King, 2000). Like therapeutic misconception, mistaken perceptions of benefit would *prima facie* seem to undermine the validity of informed consent. We will return to this point in the discussion section.

Previous studies have been conducted on research ethics issues in Kenya, some of which have touched on perceptions of benefit among researchers, research participants, field workers and civil society organizations. Molyneux, Mulupi, Mbaabu, and Marsh (2012) conducted interviews, focus group discussions (FGDs) and questionnaires with front-line staff, principal investigators and project managers on benefits and incentives to participate in research. Research stakeholders felt obliged to provide 'fair benefits' to research participants given their socio-economic circumstances, where benefits most commonly took the forms of medical care, lunch and snacks. (Food is not traditionally regarded as a benefit from an ethical perspective, even if participants find it highly advantageous.) Kamuya et al. (2013) observed that in community-engaged research, fieldworkers can be regarded as sources of a wide variety of benefits. A study by Lairumbi, Parker, Fitzpatrick, and English (2011) of key stakeholders (researchers, policy makers, research ethics committees, civil society organizations and community advisory boards) showed strong shared expectations of benefit from research beyond benefits for research participants, including community benefits in the forms of technology transfer, training of local staff, employment opportunities, provision of equipment, and awareness raising on health issues. In the study by Vreeman et al. (2012) about perceptions of research involving children in Western Kenya, community members largely assumed research would significantly benefit children or the community in many different ways, such as providing school tuition, new water sources, seeds for farming, drugs for illnesses, and health literacy. A genetic epidemiological study in Ghana similarly revealed a noticeable gap between the benefits research participants believed were on offer and the benefits that could be reasonably expected from participation (Appiah-Poku, Newton, and Kass, 2011). Most of the benefits in the Kenyan studies were inclusion or aspirational benefits, but interestingly some community benefits (such as employment opportunities or tuition aid) did not fit neatly into the categories established by King. A common theme was that providing benefits in research, while well-intentioned, also raised challenges, including: determining who is eligible for benefits, explaining the motive of providing them, and why levels of benefit can be different in different studies.

Our study, described below, differs from the existing scientific literature in that it concentrates on perceptions of benefit from the community perspective, rather than research teams, research ethics committees or other formal research stakeholders. Also, unlike previous studies, it focuses on perceptions of benefit in HIV-related studies involving adolescents and their caregivers in the Kenyan context.

Methods

Background and Setting

This ethics study is part of a larger research project on the effects of HIV testing and disclosure in the context of a research study on adolescent behavior and psychosocial well-being. To solicit community feedback and buy-in and to inform protocols for the parent study, an adult Community Advisory Board (CAB) and Youth Advisory Board (YAB) were created to examine stakeholder perceptions about recruitment, informed consent, HIV testing and disclosure of results, and compensation/inducements for HIV-related studies

involving adolescents. From April to August 2015, we conducted two rounds of FGDs with each of these boards.

The study was conducted in three regions of Siaya County in Western Kenya: Asembo, Karemo, and Yimbo. The county has the third highest HIV prevalence rate in Kenya, with an estimated 18% of residents living with HIV (NASCO, 2014). The Asembo and Karemo study sites have been part of KEMRI's demographic and surveillance system (DSS) for several years. Residents in these two areas are likely to have participated in surveillance, epidemiologic, and interventions studies for malaria, HIV, TB and other tropical diseases. They are also likely to have been involved in various health systems research studies in their health facilities.

Participants

A total of 68 individuals participated in Round 1 and/or Round 2 of the FGDs. Of the 68 participants, 28 were CAB members and 40 were YAB members. Of the 28 CAB members, 18 participated in a CAB specifically of parents and 10 participated in a CAB specifically of professionals. All 10 of the participants in the CAB of professionals worked with adolescents, and the group was comprised of 3 teachers, 2 peer educators, 2 counselors or social workers, 1 health care provider, 1 community mobilization worker, and 1 other professional. Of the 40 YAB members, 20 were minors (younger than 18 years old). The number of participants per session ranged from 7 to 11.

Protection of human participants

Informed consent: Parent/guardian consent and youth assent was obtained for adolescents younger than 18 years old; individuals 18 years or older provided consent. The discussion sessions took place in a private meeting room convenient to participants. Participants provided demographic information about themselves (e.g., age, sex, education, HIV status of the adolescents, if known) individually to research staff prior to the first session. *Risks and benefits:* the chief risks were the disclosure of HIV status by participants in the FGDs and the disclosure of what was discussed in the FGDs to others. Youth were advised not to disclose their HIV status during the course of the FGD. All FGD participants were encouraged not to share opinions expressed during the discussion to third parties. Participants were told that they were unlikely to receive any personal benefit from their participation, though the information about the effects of HIV testing and disclosure on adolescent behavior and psychosocial well-being could be valuable to the community. To ease potential burdens on participants, they were provided with compensation for their transport costs and time (800 Kenya shillings, approximately 8 US dollars at each session). *Independent review:* study procedures and materials were approved by the institutional review boards of the [blinded] and the [blinded].

Procedures

We recruited participants for both the CAB and YAB FGDs by consulting staff of institutions working with youth (e.g., government offices, churches, non-governmental organizations, HIV comprehensive care centers, compassion homes that care for disadvantaged children, and schools). We recruited youth across a number of different

categories: sex, age group (15–17 or 18–19 years old), HIV status, and whether or not they were currently enrolled in school. From making contacts and consultations with the stakeholder institutions, a number of individuals who work with adolescents were nominated as potential CAB members. Parent CAB participants were not parents of the YAB members but could be parent/guardians of adolescents who either were living with HIV or not living with HIV. After the first parent CAB session was conducted as part of Round 1, it was discovered that 5 of the 9 members had prior experience participating in a research study. Therefore, an additional Round 1 FGD CAB of research-naïve parents (never had participated in a research study; n=9) was conducted. The research-naïve parent CAB did not participate in Round 2.

The investigators used semi-structured guides to conduct the FGDs. In Round 1, we used a vignette to solicit views on the participation of a hypothetical adolescent (identified as ‘Rita’ or ‘Tom’) in research. The guide, by means of story-telling, worked progressively from general questions about the acceptability of adolescent research on HIV, to appropriate means of recruiting adolescents, acceptability of joining studies without parental permission, different approaches to HIV testing and disclosure of status, provision of ancillary medical services, and potential community responses to Tom or Rita’s involvement in HIV-related research. Through the vignette, FDG participants were told that: the research study was about HIV; male and female adolescents between 15–17 were being recruited; parents or guardians must give their permission; HIV testing would be involved and both parent/guardians and adolescents would be told the results; and participants (in accordance with Kenyan HIV testing policy) would be offered services such as referrals for HIV treatment (if found HIV-positive) or counseling on sexually transmitted diseases. During the narrative, investigators probed participants in regards to potential social or psychological risks such as harms related to disclosure of a HIV positive result, advertising of HIV-related studies in public places, rumors in the community related to study participation, and possible familial or spousal conflicts. At no point did the narrative include reference to a study drug or intervention with promise of personal medical benefit. For an excerpt of the FGD guide, see Box 1.

Box 1

Focus group discussion guide with vignette: an excerpt

For the past few months, several activities have been held near Rita’s home to inform the community about an ongoing HIV research study and to recruit female and male adolescents aged 15–19 years for the study. Rita’s mother has seen posters with information about the study at the nearby health facility and on walls at the shopping center. Some researchers also talked about the study at the last baraza at the chief’s camp and told people in the community what to do if they were interested in participating in the study. Announcements about the study were also made at some worship places and fliers with information about the study were given to everyone in the worship place that day. Yesterday, Rita came home with a similar flier about the same study that she was given at school.

- What are your thoughts about these strategies for providing adolescents like Rita and their parents with information about an HIV research study? (*Probes: Tell me about any concerns you have. Tell me about any preferences you have.*)
- What are other ways that adolescents age 15–19, like Rita, can be recruited for an HIV research study? (*Probe about adolescents in boarding school and those who have dropped out of school*)
- Is it acceptable or unacceptable to include the word “HIV” in the posters, fliers and announcements in worship places?
 - For what reasons do you think it is acceptable/unacceptable?
- Is there other information you think is important to give in flyers or other recruitment materials? ? (*Probe what information they would want to know about the study that could be put on a flyer, poster or other recruitment material*)
- Is there anything that should NOT be said?

In Round 2, we did not use a vignette. We asked questions that built upon our findings from Round 1 and delved deeper into issues related to parental involvement. We also asked questions about risks and benefits of research, recruitment, and compensation.

The FGDs were facilitated by one or two trained research personnel: the PI, study coordinator or research assistants. Each FGD lasted approximately 2 – 3 hours. In both rounds, we conducted 4 separate FGDs with youth, stratified by age and gender (15–17-year-old females, 15–17-year-old males, 18–19-year-old females, and 18–19-year-old males). We also conducted 2 FGDs with professionals (1 in each round) and 3 FGDs with parents/caregivers (2 in Round 1 and 1 in Round 2). Focus group guides were prepared in English, Luo, and Kiswahili. Facilitators were available for speaking in the language preferred by participants; most sessions were conducted using a mixture of the three languages. Participants could speak in their choice of language.

FGDs were audio recorded, and one or two research staff members also took notes during the session. Research staff had a debriefing session among themselves after the FGD participants left. A staff member who had been present at the session transcribed the audio recording. Transcripts were prepared of all sessions (including debriefing notes) and were reviewed by the PI and other team members for accuracy.

Analysis

Analysis in this descriptive qualitative study proceeded in several phases. First, after extensive reading of the data (Bernard, 2012), we used categorizing strategies (Maxwell and Miller, 2008) to analyze our data. We categorized our data by developing and applying inductive and deductive codes to all transcripts using Atlas.ti® software. Deductive codes were based on the field guide instruments and the key research questions. Inductive codes were derived through team meetings to capture emergent themes. We then used matrices to

further facilitate comparisons across different types of participants (Miles and Huberman, 1994). Quotes on benefit perceptions from adult participants (professionals and parents) and adolescents (male and females in the different age groups) were separated into columns in an Excel spreadsheet and compared in terms of form of benefit and beneficiary. Lastly, the study team convened, discussed and wrote memos regarding the significance of the benefit perceptions for the ethics of adolescent HIV research in the Kenyan context.

Results

Participants in all FGDs regarded participation in research as largely beneficial for individual study participants and their communities. In the first round of FGDs, our research team was struck by the overwhelmingly strong perceptions of research benefit among the respondents. For this reason, in the second round of FGDs we added a direct question: “Are there always benefits in research?” The typical response to this question was affirmative:

I think there is no research where you do not learn since those researches are mostly those that teach people. So you cannot go for a research where nothing is being taught. That one is not a research because when you go to a research, you are taught there. You cannot find a research that you don't get skills. You have to come out with something. (Adolescent male 15–17)

Only a few participants in the FGDs suggested that research participation is not straightforwardly beneficial:

Participants should not get benefits all the time because sometimes you conduct research and don't find what you expected (Parent)

I think all researches are done so that we can get their benefits. It is the benefits which are always many, some other things just come as a by the way. For example when someone goes for VMMC, he is doing so to get the good side of it but he might end up being cut wrongly and get a permanent scar that he never intended. That might be the bad side of it but the research is always carried out because of its benefit. (Parents)

When doubts or more nuanced views about study-related benefits emerged, they tended to focus on research involving HIV testing and compensation issues. More specifically, respondents were worried about negative reactions connected to adolescents being tested and found HIV positive in the context of a research study. Loss of self-esteem, potential suicidal thoughts or actions, stigmatization by others or family turmoil were generally regarded as the key risks. A few respondents asserted that the shocking news of HIV positive status could cause the adolescent's life to end prematurely or die spontaneously. Opinions about appropriate ways to manage these risks differed considerably. Some respondents believed these risks justified home-based HIV testing approaches rather than at clinics, hospitals or schools; others argued that these risks justified strong parental involvement in HIV research involving adolescents.

With regard to compensation, some participants acknowledged that providing compensation in research could have adverse effects in impoverished communities, such as participants

giving incorrect information in order to be enrolled in studies and gain whatever compensation was offered. Some also felt that providing compensation to participants could lead to suspicions about the motivations behind the research, especially when the compensation was seen as ‘excessive’ and the research was felt to be undemanding. Apart from these reservations about HIV testing results and compensation, however, participants in the FGDs overwhelmingly regarded participation in research as a beneficial activity for individual participants, their partners, their families and/or their communities.

What are the benefits?

In our analysis, we identified five interrelated benefit types: informational, existential, emotional, medical and material. Below, we will describe what is meant by each of the benefit types, as well as how participants portrayed them. The benefits described would likely fall into the categories of collateral or aspirational according to the general classification of King (2000). We have used more fine grained benefit types to capture more precisely how participants perceived different ‘non-direct’ benefits. It should be noted that participants spoke about all the benefits described below both descriptively (as benefits that are provided in their experience) and normatively (as benefits that ought to be provided).

Informational benefits

Virtually all participants stated that research provides participants with valuable information that they would otherwise not (or not easily) have access to. This included information about: HIV prevention and prevention of sexual assault; health services; HIV status; other sexually transmitted diseases; changes during pubescence (for adolescents); and information about the sexual behaviors of their children (for caregivers). Stress on informational benefits was relatively most marked among adolescent males and females aged 18–19. In general, respondents often framed research participation as a form of ‘education’:

Education. When you get into research, you get to learn many things that you did not know and in this way you get educated. (Young adult male 18–19)

I think Tom’s mother won’t be having problems. When his child has obtained education from the researchers, he may use the education he has gotten from there to teach others so that they can also be helped. (Adolescent male 15–17)

Participants did not only perceive access to health information as beneficial; there was also the impression that such information, due to its origins within a research context, would be more accurate or objective than other sources. One parent participant used the metaphor of a weighing scale to express this point:

Research is like a weighing machine in the market where as you pass you drop some money in order to know your weight. (Parent)

Participation in research can provide an entrée to trustworthy information that cannot as readily be obtained in everyday life.

As suggested earlier, there was an expectation that research would not only provide valuable information to participants, but a further expectation that participants could (or should) share this precious information with others in their community.

If you engage her in research she will be an example to the school. She can also help some of her schoolmates and classmates and she will also encourage her younger siblings. (Professional)

It should not be for individual. If you put it as individual benefit then it will not benefit the other people. You must share with others. My friend may wish to come but the parent refuses. She will be eager to know what we have been taught, so I will tell her what we are taught for her also to benefit. (Young adult female 18–19)

FGDs with parents in particular mentioned the potential benefits associated with knowledge of their child's HIV status, and the child knowing his/her own status. This was largely seen as a research benefit tied to individuals and households, rather than a community benefit.

Existential benefits

Many of the participants stated that research does not just provide participants with valuable information, but also helps participants with the development of certain life skills. Among the different groups, male adolescents aged 15–17 mentioned life skill benefits more frequently, and regarded the beneficiaries as the participants themselves, not family, peers or the larger community. The description of life skills included: problem-solving; navigating social interactions; ability to deal with peer pressure; gaining self-confidence; and seeing new places:

It is acceptable [to participate in research] because adolescent girls face some challenges. Let us say that when you are in the boarding school and you don't have money, you can engage in sex and you can get HIV. So if you engage in the research you can know how to avoid these things. You can teach your friends importance of the research and how it helps people to avoid engaging in things that can make you to get HIV. (Young adult female 18–19)

Another benefit is that it helps us to socialize with many people because when you are doing a research, you interact with people from different parts of the country. (Adolescent male 15–17)

A number of FGD participants, across different groups, suggested that research participation was an entrance into an unfamiliar and privileged environment, where one could come into contact with and have to adapt to the demands of a different social network, including people from other villages and well-educated outsiders from the research community. Some thought that the skills acquired by involvement in research could be transferable to other, non-research contexts:

You will learn ways of solving problems if you encountered one and also learn how to help others in case they also encounter a similar problem. (Young adult male 18–19)

After the research, you can gain some knowledge and skills that you can use in your life so that you can prosper. (Adolescent male 15–17)

Emotional benefits

A number of FGD participants, more so among the adolescents than the adults, saw a positive relationship between participation in research and mental health. Mental health was typically described in terms of well-being, feeling loved or ‘being treated like a brother’ as a research subject. From this perspective, study visits were seen as forms of attention that can affirm a person’s value, against the background of HIV as a stigmatizing disease:

You have also said that he will be visited two or more times. What makes many people to die from the disease is not the virus but the stigma. If a person is visited, you will be eradicating the stigma and hence prolonging the lifespan of that person. So at some point that person will be helped a lot. That is my opinion. (Young adult male 18–19)

I think the services that have been offered to Tom are good. Just as [my colleague] has said, he will feel that everybody cares for him and not the mother alone. He will relax if everybody is caring for him. Those services will help him to live a better life in the future. (Young adult male 18–19)

Health benefits

In the vignettes, participants in the FGDs were told that the adolescent characters ‘Tom’ or ‘Rita’ may receive some services as part of the research study they are in, but these services were not described in detail. This encouraged the FGD participants to reflect on what they thought ‘Tom’ or ‘Rita’ ought to receive, or what (if any) health benefits participants in research should expect to receive in general. The benefits identified by FGD participants included: support for adherence to medicines; referrals to health services; access to antiretroviral treatment and voluntary medical male circumcision; and a less compromising way of obtaining condoms than having to buy them from shops. Professionals in the FGDs emphasized these benefits (closely tied to informational benefits) more than any other group. Particular to the FGDs with professionals, the conversation turned to a comparison between health services provided within a research study versus health services provided by government-run voluntary testing and counseling (VCT) centers. Several participants stated that referral networks established and utilized by research studies offered better quality care than the standard public medical services.

Material benefits

Lastly, a number of participants in the FGDs expressed the belief that those who join research studies commonly receive, or should receive, useful non-medical goods. These goods took the forms of: employment, food, t-shirts, soda, and money. Overall, the young adults and adolescents made mention of material benefits far more than adults in the FGDs, and when adults talked about material benefits such as employment, these were conceived as benefits to the community rather than for individuals alone. The material goods – again particularly for the youth -- also appears to have more than mere utility value: items that connected participants with research projects such as t-shirts, employment or photos taken with research staff also appeared to function as status symbols. It should be noted that, despite participant’s perceptions, such forms of payment or reimbursement are not

considered by research ethics committees or ethical guidance as benefits to be weighed against the risks of research (Koen, Slack, Barsdorf, and Essack, 2008; Largent, 2017).

Discussion

Our study indicates that key stakeholders in HIV research involving adolescents in Kenya see a broad and robust range of collateral and aspirational benefits in studies that (as described) do not hold out much potential for direct personal benefit. To some extent, the findings reveal a disconnect between what participants perceive or desire in regards to research-related benefits, and what could be reasonably expected. The findings also indicate that study-related risks are not a prominent concern; even when provoked to discuss risks through the use of probes, respondents tended to see them as outweighed by perceived benefits.

As such, our study results raise at least two important questions: (1) do these results show a pattern consistent with other studies about benefit perceptions, particularly in research conducted in low-resource settings and involving adolescents? (2) What are the ethical implications of these perceptions, i.e. should they be considered ethically problematic?

Studies on benefit perceptions among adolescent research participants are very rare. However, our findings are consistent with a previous study conducted among relatively resource-poor parents in developed countries. Ott, Rosenberger, and Fortenberry (2010) conducted surveys with parents of female adolescents participating in a longitudinal sexually transmitted infections (STI) study whose sole direct medical benefit was increased STI screening. The parents believed their children would receive ‘contact benefits’ (their child being in contact with a health professional) and ‘developmental benefits’ (their child gaining useful information by being in the study) and considered these to be significant reasons to permit their children to join the study, despite neither of these being identified as benefits in the consent form or process (Ott et al., 2010). Similarly, in our study, participants in the FGDs largely viewed research as highly beneficial, despite the vignettes used to stimulate discussion only offering minimal reference to study-related benefits. For example, informational benefits were never mentioned in the narratives that guided the FGDs, but these were the kinds of benefits most frequently mentioned by participants overall. This suggests that in research involving adolescents, there may be a presumption that the latter will benefit from learning new information. Our findings are also consistent with Vreeman et al.’s (2012) study of community attitudes towards research with children in Western Kenya, where there was a strong assumption that research with minors will be significantly beneficial for participants, families, peers or communities.

Related to the point above, the data seem to reveal a slippage between descriptive and normative views on benefits. Participants would move freely between beliefs about benefits that research studies *commonly provide* in Kenya, and beliefs about what sort of benefits studies *ought to provide*. It is tempting to postulate that the socio-economic circumstances of the participants may be impacting benefit perceptions in some cases: the more precarious the lives of research participants, the more they see, or want to see, benefits when they or their children join research studies. Ott et al. (2010) similarly hypothesized a relationship between

parents regarding their children being ‘at-risk’, coming from a resource-constrained environment, and perceptions of research-related benefit for their children. Low-income parents who saw their children at risk for STIs tended to view involvement in a longitudinal study as beneficial for their children in many ways.

In our study, participants sometimes had less than accurate beliefs about benefits. For example, participants in our FGDs often mentioned the potential benefits of skills development and obtaining information about HIV, neither of which featured in the hypothetical research study that was described to them. The phenomenon of research participants occasionally perceiving ‘phantom’ benefits is not unheard of. Appiah-Poku, Newton, and Kass (2011) describe in-depth interviews conducted with participants in a genetic epidemiological study in Ghana. The epidemiological study focused on genetic factors associated with contracting tuberculosis. Treatment for TB was provided as a collateral benefit to those identified by the study as having TB. However, interviews revealed that participants associated the research with a great many benefits, some of them beyond what the researchers actually offered: production of new knowledge, protection of those without TB, education about TB and the discovery of a new, shorter TB regimen. Some of these benefits were reasonable to expect (provision of TB information) while others were not (find a shorter TB treatment in a purely epidemiological study) (Appiah-Poku et al., 2011). Like our study, the participants seemed to hold a mix of accurate and less than accurate beliefs about research benefits.

What is the ethical significance of inaccurate benefit beliefs, particularly in studies involving adolescents in low-resource settings on a stigmatized infection? Should they be regarded a matter of concern, and if so, what (if anything) should be done about them? There are two competing arguments in contemporary research ethics.

According to the standard view, expressed in a number of influential guidelines such as the Declaration of Helsinki (World Medical Association, 2013) and those of the Council of International Organizations of Medical Sciences (Council of International Organizations of Medical Sciences [CIOMS], 2016), researchers have an obligation to appropriately disclose in the consent process all study information relevant to prospective participants making an informed decision. In addition, valid informed consent requires that the prospective participant fully understand what has been disclosed. In this view, any false beliefs about benefits are likely to skew the risk/benefit assessments participants make when deciding to join studies, casting doubt on the validity of their consent. This position is explicitly expressed by a number of influential authors (Beauchamp and Childress, 2012; Faden and Beauchamp, 1986; Levine, 1988) and other guidance documents (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

According to a more recent and controversial view, researchers have an obligation to disclose accurate study information, but less than full understanding (including false beliefs) may be compatible with valid informed consent (Sreenivasan, 2003). The argument is based on empirical data that shows very poor understanding on the part of research participants, even about the most basic elements: study purpose, risks and benefits, alternatives to participation, and right to withdraw. If researchers were obliged to ensure a high standard of

comprehension among participants, a great many (otherwise meritorious) studies would be rendered unethical. According to some proponents of this view, valid informed consent is compatible with imperfect (even poor) understanding, as long as the participant was given a fair opportunity to understand and was not subject to manipulation. If researchers want to improve participant understanding – including correcting mistaken beliefs about benefits – this is an ethical aspiration, not an obligation, on their part (Bromwich and Millum, 2016). The issue of risk adds a further complication: it has been argued that obligations to ensure comprehension are stronger in high-risk studies, and lower in minimal risk research (Sreenivasan, 2003). However, no one to our knowledge has argued that high-risk studies are only ethically acceptable if participants demonstrate faultless understanding.

Our study contributes to this ongoing discussion in the following way. To date, discussions about comprehension have tended to be abstract, largely focused on competent adults, and presumed developed world background conditions, with few exceptions (Fitzgerald, Marotte, Verdier, Johnson, and Pape, 2002; Krosin, Klitzman, Levin, Cheng, and Ranney, 2006). The question is whether correcting errant beliefs about study benefits may be obligatory in special circumstances of vulnerability, such as those in our study of HIV research with adolescents in Kenya. As suggested above, errant beliefs about benefits can have multiple sources in this context: poverty and hopes for life improvement, adolescent tendencies to discount risks, parent and caregiver trust in research institutions, low research literacy, lack of alternative access to quality health services, and scarce educational opportunities. Trust is fundamental in researcher-participant relationships (Gilson, Palmer, and Schneider, 2005), and it is possible that the reputation of the Kenya Medical Research Institute (KEMRI) as a trustworthy organization concerned with giving ‘fair benefits’ to individuals and communities may lead to a strong presumption of personal or community benefit in research – a case of unintended undesirable consequences. If such factors are known to undermine the quality of informed consent, could an argument be made for an obligation to ensure comprehension and correct inaccurate beliefs?

While it seems unreasonable to expect research participants to understand everything, or even much, of what a research study involves, one could argue that there must be a threshold of understanding below which faulty comprehension becomes a pressing moral concern. Both the Declaration of Helsinki (2013) and the CIOMS guidelines (CIOMS, 2016) state that researchers must ensure that participants adequately understand consent information, without detailing what constitutes ‘ensuring’ or ‘adequacy’. In low-resource settings, participants may have not had educational opportunities to improve their capacity to absorb the kind of information that researchers disclose to them, and their perceptions may also be distorted by environmental factors beyond their control. For this reason, it seems implausible that researchers only have obligations to provide non-fraudulent information, and never have obligations to ensure or improve the comprehension of research participants. Even those who argue that *full* comprehension of what is disclosed in the consent process is not necessary for valid informed consent concede that at least *something* must be understood for consent to be valid (Bromwich and Millum, 2013). Progress has been made in the assessment of research participant understanding (Lindegger, et al. 2006), and the use of metaphor and culturally appropriate language may help improve understanding (Ndebele, Wassenaar, Munalula, and Masiye, 2012) in settings like Kenya. Community engagement

activities may also enhance the understanding of research before individuals are approached to join studies (MacQueen, 2015).

However, our study shows the need for more empirical research and conceptual analysis into what conditions might, in certain cases, trigger researcher obligations to improve sub-optimal perceptions of benefit. It may be that some essential elements have to be understood (purpose of research, key risks and benefits, right to leave the study) to validate consent depending on contextual factors such as population studied, research question, and magnitude and likelihood of risks. In addition, researchers may have good reason to improve inadequate participant understanding for purely pragmatic reasons. Profound misunderstandings of research risks and benefits can engender community rumor and distrust, which in turn can derail studies (Singh and Mills, 2005).

Limitations

This qualitative study on benefit perceptions surrounding HIV research with adolescents in Kenya had a small sample size and its findings are unlikely to be easily generalizable to other settings. However, there are some patterns in the existing literature, focusing on low-resource settings, which similarly point to somewhat inflated perceptions of study-related benefits. It is also possible that when participants identified certain benefits, they may have been thinking about real benefits they personally obtained in past surveillance, epidemiologic, and interventions studies, or had heard about from others. Our vignette was silent on the issue of benefits, rather than explicitly stating that there were no study benefits, which may have led some participants to think that there might be such benefits. The vignettes also did not clearly state levels of risk, though it could reasonably be surmised from the narrative that risks were low. Responses might have been different if lack of benefit and risk level were explicitly and repeatedly emphasized. In addition, participants may not have been attempting to identify benefits ‘Rita’ and ‘Tom’ were likely to receive in the study discussed in the FGD, but were rather expressing shared expectations (or hopes) in the community. Although it is difficult to ascertain, some participants (particularly those with more research experience) may also have been reluctant to express concerns about risk due to fears of being excluded from future research studies and their associated benefits. However, since our sample included research-naïve as well as research-experienced participants, it is not clear the extent to which the positive views about research benefits may have been due to social desirability bias. With regard to the slippage between descriptive and normative views about benefit, this could have been due to the phrasing of the questions, the moderation of the focus groups, or linguistic differences.

Best Practices

In HIV-related research, adolescents are an important, under-researched but vulnerable study population. The responsible conduct of research with this particular group is imperative, particularly in low-resource settings. Biomedical and behavioral researchers should be aware that communities in which they are conducting adolescent research may have strong assumptions or expectations about the benefits of research participation. Knowledge of background socio-economic conditions is essential to understanding the potential for benefit

perceptions that include expectations for aid or health care into the research context. In order to minimize potential for misunderstanding, researchers should engage with communities early in the research and continuously throughout to better understand and appreciate what adolescent participants and their families expect from research participation. Engagement with communities for this purpose could take different forms, including the *mabaraza* (traditional community assemblies) mentioned by Vreeman et. al. (2012) or formative research using vignettes to elicit benefit perceptions (cf. Tindana, Kass, and Akweongo, 2006). This could also be usefully extended to exploration of research-related risks, especially to the extent that awareness of risk is ‘crowded out’ by assumptions of benefit. Knowledge thus obtained needs to be taken into account when designing recruitment methods and consent processes.

Educational Implications

This study on perceptions of benefit in adolescent research in Kenya has a number of educational implications. First, strong assumptions about benefits associated with research participation may be prevalent in low-resource settings beyond the Kenyan context. To the extent that this is true, training on this particular point should be incorporated into research ethics education. Researchers and study personnel need to be aware of this phenomenon and integrate it into their practices, particularly those of recruitment, consent and assent. Second, this information could be useful for research ethics committees in their process of determining favorable relationships between study risks and benefits. Particularly in regards to international research collaborations, if the goal is to minimize potential for exploitation (Emanuel, Wendler, Killen, and Grady, 2004), it is important for research ethics committees to have a sense of how beneficial communities believe individual research studies are. Thirdly, local communities themselves may find it useful to reflect, in educational fora, on commonly-held benefit perceptions. This could strengthen and inform the community voice in negotiating with research collaborators in the future.

Research Agenda

In this study, we conducted FGDs with health professionals, caregivers/parents, and adolescents in Kenya to solicit opinions about appropriate ways of conducting HIV research among youth. In the course of doing so, we noticed that participants identified a variety of collateral and aspirational benefits not in keeping with the vignettes we used to stimulate discussion. Overall, participants appeared to view the research enterprise as overwhelmingly beneficial in ways that raised ethical concerns about their understanding of research. While some bioethicists argue against obligations to enhance comprehension among research participants, further research on benefit perceptions in low-resource settings with vulnerable groups may support an argument for such obligations in certain cases. In addition, more empirical research is needed on the relationship between socio-economic conditions (including those related to health and health care) and the perceptions of benefit in adolescent research among youth, parents and others. Future social science studies on ethics of adolescent health research should concentrate on the complex relationships between perceptions of benefit, perceptions of risk, and background socio-economic circumstances.

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