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Is there "Therapeutic Misconception" in HIV/AIDS and Clinical Research in Western Kenya?

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Abstract

In research ethics community, the 'bright line' between health care and health research continues to be emphasized as important. While this distinction may be clear for many health researchers and practitioners, it may not be clear to research participants. In the case of HIV/AIDS care in resource-limited settings where healthcare is not affordable, individuals and communities are burdened with high rates of infectious diseases, inadequate health conditions, and insufficient or inaccessible medical care. Under these circumstances people are desperate to access better healthcare through any possible means. Participating in clinical research may be seen as one way of accessing care. Even though measures are taken to ensure that participants in health research get into this activity only after a consenting process, some may enter into research for the purpose of accessing treatment or health care. The objective of the study was to investigate specific reasons why participants engage in ongoing IREC/IRB-approved international HIV research in Western Kenya. The main reasons given for participating in research were contextual: the HIV/AIDS condition, access to better healthcare, and financial poverty were identified. Clinical researchers indicated that their research projects had provisions for healthcare and better services and facilities than in the standard healthcare in terms of individual attention and follow up. Study participants in ongoing research in Western Kenya believe that their participation in HIV/AIDS research enables them to access better healthcare. In the context of limited resources and HIV/AIDS, patients' beliefs, extra-medical attention and follow up translate into better healthcare. These observations suggest that in practice there may not be a bright line between research and clinical care (no "therapeutic misconception") and suggest the need for more stringent efforts to make this distinction clear in processes of informed consent in such settings.

Abbreviations and Acronyms: AIDS: Acquired Immunodeficiency Syndrome; AMPATH: Academic Model of Providing Access To Healthcare; CIOMS: Council for International Organizations of Medical Sciences; FGDs: Focus Group Discussions; GOK: Government of Kenya; FIC: Fogarty International Center; HIV: Human immune deficiency virus; IRB: Institutional Review Boards; IREC: Institutional Research and Ethics Committee; IU-MU AREP: Indiana University-Moi University Academic Research Ethics Partnership; MTRH: Moi Teaching and Referral hospital; MU: Moi University; MTRH: Moi Teaching and Referral Hospital; MUSOM: Moi University School of Medicine; NCST: National Council for Science and technology; PHI: Protected Health Information; PI: Principal Investigator; UNAIDS: United Nations Programme on AIDS; WHO: World Health Organization

Introduction

Over 20 years after the first case of AIDS was reported, HIV remains a global health priority. At the end of 2011, 34.2 million people were living with HIV globally, up from 33.5 million at the end of 2010 [1]. A persistent trend of HIV is the geographic variation between and within nations and regions with Sub-Saharan Africa continuing to be the epicenter with a staggering 91% of all global cases of children under 15 living with HIV [1]. According to UNAIDS global factsheet released on World Aids Day 2012, nearly one in every twenty adults is living with HIV. This has seen increasing HIV clinical research. Like all health research involving human participants, clinical research requires to be ethical if it is to be scientifically valid and reliable.

The challenges of ethical research practice are more in cross cultural and multi-cultural contexts. Essentially, this is because the process of informed Consent implies voluntariness, competence and understanding of what participation in the research involves and yet, levels of voluntariness, competence and understanding vary from one cultural context to another. Western Kenya, the setting of this study, characterized by resource limitations, patriarchal traditions, and multi and cross cultural attitudes and practices, the process of ensuring IC are complex and challenging. The complexity of the context is worsened by the reality of HIV/AIDS: HIV stigma, AIDS incurability, outdated traditional values on sex and sexuality, among others.

The clinical context of HIV/AIDS has been investigated and acknowledged through various studies [2]. However, the challenge of HIV in the context of research ethics is still at infancy in related discourses. While emphasis has been laid on the importance of appropriate research methods for validity and reliability of medical research findings, the need for ethical research practice has not been given commensurate attention. Yet, valid and reliable methods make no sense in the absence of sound ethical practice. Moreover, the essence of medical research is to improve medical practice for human good.

The basic question under study here is whether there is therapeutic misconception in HIV research in Western Kenya or not. Many studies have suggested that there is therapeutic misconception especially in resource limited, settings where there is high level of illiteracy. Mutua et al. [3] for example suggest that illiteracy and lack of proper

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informed consent affect participation and nonparticipation in research. The importance of valid informed consent processes can never be overestimated. As observed by Mariner:

The subject's consent is not a luxury; it is the "ethical prerequisite to entering research. Without a valid and reliable methodology for ensuring that the subject's consent is voluntary, informed and understanding, it is impossible to know whether the subject has actually consented" and consequently if the data is valid and reliable [4].

While these authors appreciate the rapid expansion of clinical HIV research in Kenya they also recognize that this expansion if unchecked, could, retrospectively, provide and escalate grounds for unethical research practice. The National Council of Science and Technology in Kenya is therefore, called upon, through planning and policy development, to "position itself strategically in order to efficiently and effectively coordinate all research in this area" [5]. Such strategic positioning can only be done with adequate information regarding specific challenges of biomedical research involving human persons in Kenya as can e contributed to through such studies as undertaken herein.

Driven by the desire to dialogue ethical research practice by exploring avenues for improving the process of IC, we investigated some of the reasons why research participants in HIV projects in Western Kenya engage in research. The objective was to investigate specific reasons why participants in select ongoing IREC/IRB approved international HIV projects in Western Kenya gave consent to engage in the projects.

Research Methodology

Study design

This was a cross sectional qualitative exploratory research. Field research, primary data was collected from across a population sample identified over one period in order to investigate reasons for engaging in research.

Study area

Field research was carried out over the months of February to May 2012 within the USAID sponsored Academic Model for Providing Access to HealthCare (USAID-AMPATH) program in Eldoret, Western Kenya[1].

Target population

The target population included research proposal reviewers, principal investigators, community opinion leaders, and participants in on-going International HIV clinical research involving human participants in Western Kenya.

Sample population and sampling procedures

In-depth oral interviews with twelve individual participants and four focus group discussions comprising 7-9 participants were carried out. These were distributed as follows:

[1]USAID-AMPATH is the largest HIV/AIDS program in East Africa, with more than 140,000 enrolled adult and pediatric patients. The central AMPATH clinic is located in Eldoret, Kenya, within the Moi Teaching and Referral Hospital, the second largest referral hospital in Kenya after Kenyatta National Hospital, Nairobi. The MTRH catchment area includes Nyanza Province with a population of 4.39 million, North Rift Valley Province and Western Province with a population of 3.35 million people, for a total of over 40% of the Kenya population. Currently, AMPATH has 35 research sites and over 26 satellites clinics.

i) 2 persons Moi University/Moi Teaching and Referral Hospital – Institutional Review Ethics Committee (MU/MTRH – IREC). These are most conversant with the process of ethical review of research within the area of study.

ii) 4 Principal Investigators (PIs) of select ongoing International HIV research projects in Western Kenya. Using purposive non probability sampling the projects were selected from a list of Institutional Research Ethics Committee/Institutional Review Board (IREC/IRB) approved ongoing international HIV research in Western Kenya to include two in HIV prevention and two in HIV intervention

iii) 4 participants (two from each of the two categories of selected on-going International HIV projects) were identified during focus group discussions and interviewed further on a one to one basis.

iv) 2 community opinion leaders (one male and one female) in Western Kenya were identified through snowball sampling. . These provided expert judgment on the subject of study from a local community perspective.

Inclusion criteria: Men and women then participating in IREC/IRB approved on-going International HIV research project in western Kenya under AMPATH were included. Principal researchers in selected ongoing studies, IREC reviewers and community leaders were included.

Exclusion criteria: Children were not involved in this study. Adult men and women with mental disorders were also excluded. None of the persons approached refused to participate.

Methods of data collection

Given the dearth of literature on reasons why persons in Western Kenya consent to participate in international HIV research, it was not possible to develop quantitative tools for data collection. Therefore we chose to carry out the following methodological procedures:

In-depth oral interview: with persons identified as having quality information on the subject matter under investigation. This was undertaken on a one-to-one basis by using oral interview schedules specifically designed for each category.

a. Principal investigators

b. Ethical reviewers

c. Community opinion leaders

Focus group discussions: Considering the sensitivity of the subject of HIV, oral interviews were complemented with focus group discussions. Research staff working with ongoing HIV research teams composed the FGD groups to include both men and women. They also scheduled the discussions to coincide with clinic days so that they could participate in research as they came for their regular clinic. A focus discussion schedule appropriate for them was used.

Participants in on-going HIV research freely discussed issues as by the schedule without feeling intimidated or that the focus was unduly on them as individuals.

Data management and analysis

Data management and analysis was manually done: Data from researchers and study participants in ongoing HIV research in Western Kenya were analyzed as they related to the study questions: why do participants engage in international HIV research in Western Kenya?

Manual data analysis allowed for analytic (*etic)* coding which was compared with *in vivo* coding. This was undertaken from a comparative analysis approach at two levels:

Transcription, identification and classification of themes: All data collected through audio taping was transcribed systematically and keyed into a computer under different categories:

Oral interviews: These were classified further into categories with principal investigators, IREC reviewers, research participants and community opinion leaders, ,

Focus group discussions: These were classified further into categories of those involved in HIV prevention research and those involved in HIV intervention research.

i. Each group of the transcripts was systematically read making line-by-line analysis for identifying and highlighting themes and ideas relating to each of the study objectives.

ii. The themes and ideas were compared and complemented with what emerged with notes taken at the interview or discussion sessions.

iii. For participants in HIV research, the themes and ideas emerging from oral interviews were compared with those emerging from focus group discussions.

iv. Nearly all results of the analysis were identical for both the authors and the independent analyst. There were no significant disagreements between the analysts but on two occasions, analysts listened together to audio replay of interviews for consensus on the understandings.

Triangulation: Data collected by various instruments across different categories of participants with specific focus on reasons for participating in research was compared and contrasted:

a) Data collected from researchers were compared with what was collected from reviewers and from participants in HIV research to get in-depth and complementary perspectives to the reasons obtained regarding the study question and objective.

b) All the data were interpreted and tabulated for reference, comparisons, and cross checking before presentation in prose.

Limitation of the study

For this study, only participants who were involved in HIV research in Western Kenya at the time of data collection could participate since, for logistical reasons, those who have completed participation could not be accessed. It was therefore, expected that some of the participants in complete studies would not be willing to participate in the study because of logistics and research burden. However, the required sample size was small and with the support of members of research teams of various projects involved, the sample was easily accessed.

Study validity and reliability

The research questions in all the instruments were pretested to ensure that right questions would be asked in the right way. Triangulation allowed for confirmation of information collected by different tools from different the categories of participants. Moreover, thematic saturation supported study validity and two colleagues served as independent analysts of transcriptions. A summary of findings was availed in soft copies to researchers and IRB reviewers. This process also allowed for validation of findings.

Ethical considerations

Before embarking on the study, the research protocol was submitted to IREC for review and approval. With an approved protocol, permission was sought to carry out the research from the AMPATH, Moi University School of medicine (MUSOM), and MTRH administration.

The process of informed consent was followed as spelt out by IREC. It was made clear to the participants at the beginning of every session that these researchers were not medical practitioners but social behavioral researchers in order to avoid any possible influence and bias in their responses. It was clearly explained that any participant wishing to drop out of the study at any stage was free to. Anonymity and confidentiality was ensured throughout the study.

No Protected Health Information (PHI) was used in the study. Data collected from study participants is accessible only to the principal investigator and IREC or its designee. All data is however locked in cabinets and only password protected files were used for this study.

Findings

Demographic characteristics of study participants

The following Table 1 presents the demographic characteristics of participants in on-going international HIV research involved in this study.

As presented in Table 1, there were more female participants in FGDs. Majority of the participants were Luhyia followed closely by the Kalenjin and the Kikuyu. The 32 participants involved in FGDs were aged between 25 and 52. None of them was a professional. Only two of these had studied beyond secondary level of education. Most of them said they were farmers and housewives with four among them indicating that they run small businesses.

Reasons for participating in HIV Research

The following findings emerged from this study as to why the participants engage in HIV research in Western Kenya:

	Male	Female	Total
Age			
25-30	2	6	8
31- 40	9	10	19
41- 52	3	2	5
	14	**18**	**32**
Marital status			
Single	7		
Married	25		
Level of education			
None	0		
Primary	19		
Secondary	11		
Tertiary	2		
Main Occupation			
Housewifery	14		
Farming	9		
Business	4		
Casual Worker	2		
Others	3		
Tribe			
Kalenjin	9		
Kikuyu	7		
Luhyia	9		
Luo	5		
Others	2		

Table 1: Demographic characteristics of participants involved in HIV research in Western Kenya.

Access to health care: Nearly all participants in on-going international HIV projects described health research as if it were health care. One female participant in an intervention study described research as: "*Doctors trying to see how medicine works*"; while another female in prevention study described it as "*testing if people can take drugs*" as prescribed. Other descriptions given include: "*finding out how to help sick people*"; "*treating people*"; and '*finding out what sick people think*". Participants indicated that they agreed to participate in research in order to access any and/or better health services. Asked to expound on this, one male participant in a FGD said: "*I cannot afford to attend regular clinics… you need money to come all the time*". Costs of healthcare mentioned include payment for health services, purchase of drugs, transport expenses and opportunity costs. Others indicated that they agreed to participate because they get special attention in research clinics, which they would not in a regular hospital environment. One participant said:

They call me every now and then to ask how I am doing and they also call to remind me to take my drugs or to tell me that it is time to come to the clinic and they send to me money for transport which I would otherwise not have. (Male participant involved in intervention research)

Another one said

*The doctors talk to me and advise me a lot and that way I get to know, more about myself and my disease, my health and my psychological wellbeing. Up there (referring to regular AMPATH clinic sites) you are seen by a doctor without anybody bothering much about you. Here I get close attention of my health and the staff is warm. They take time to talk to us here. I feel better taken care of here. (F*emale participant involved in intervention research in FGD)

Other participants indicated that they take shorter waiting time for services at the clinic when they are in a research project.

Both researchers and reviewers involved in this study generally concurred with those engaged in HIV research that participating in research translates into access to better healthcare. A reviewer almost used the same words as by a participant in an on-going HIV prevention study:

While refusal to participate in research does not imply denial of standard of care treatment (and may be explained clearly to potential participants before they are recruited), there is better follow up for clients on research than for those who are not. Somebody will be calling to ask them how they are doing. There is personalized follow up over the phone and this makes the client feel that somebody cares for them. (Interview with a social behavioral reviewer).

The reviewer indicated that since research is about systematic investigation, clinical researchers have to keep monitoring body functions more closely than they would do in health care clinics.

A researcher expounded on this by indicating the influence of research contexts on participants' perceptions thus:

Health research is carried out in hospital environments, which make it difficult for individual persons to differentiate between healthcare and health research. For many of them, this is a 'hospital within a hospital". However, unlike an ordinary hospital setting, which is crowded and dirty, health research settings are clean and holistic attention is given to participants. (Interview with male biomedical researcher)

Financial Poverty: Financial poverty came up as what influences some people to participate in research. Nearly all persons participating in ongoing HIV research in Western Kenya consider themselves financially poor. Many of them explained that they would not afford health services in a public government hospital and that their participation in research enables them to access health services. But there were different perspectives to this. Some participants in ongoing HIV research cited compensation for transport, lunch and time as one of the factors that make participation in research attractive.

One community opinion leader concurred: "*… some people participate in research just for the money. They will walk from home and pocket what they get as transport money.*" However, some participants do not consider compensation as a major benefit because as one male participant said:

"*You use a lot of that money on transport and any way if you did not go to the clinic you would have done some work to get ugali (food) for your family*". He added: "*The big benefit is that we can afford to visit hospitals for treatment as often as required…. but some participants are in research to get some money to use for other needs.*"

At least two researchers and two reviewers explicitly indicated that some participants engage in research because of the compensation that researchers offer. A male biomedical researcher in HIV preventive study said: *"some of them are poor and the little money that we give them for every visit is money they could otherwise earn in a week*". Other researchers indicated that they sometimes feel economically exploited by research participants. One said:

..Sometimes you can provide facility for participants to come and stay in a hotel as they wait to be attended in research clinics then some of them extend their stay so that as a researcher you end up paying for their holiday. Others demand that you send them money for transport and when you send the money they do not come to the health research clinic as requested. …others unnecessarily inflate their budget expenses … you can tell this from the receipts that they submit for refund… this is corruption which is demeaning, which means that research can be demeaning. This makes me feel very bad. Surely you are ethically obligated to help but at the same time you do not want to induce people to participate in research and then there is that feeling that as a researcher I am being exploited by participants …it is a very bad feeling. (A male biomedical researcher involved in HIV prevention research)

A male biomedical reviewer indicated that this is a tricky issue because:

"*it is hard to know how much money is enough compensation to study participants and how much could be referred to as inducement.*"

On the other hand research participants indicated that they feel exploited by researchers because when they receive just enough money to take care of their transport to and from home, they lose out because if they did not come to the research site, they would have earned some income for their families. It could be that while there are some participants who seek to make the most monetary profit out of their research participation, others are actually sacrificing.

The HIV/AIDS Context: HIV/AIDS presents a unique health context especially because of its association with sexual promiscuity. As mentioned earlier in the introduction to this paper, it is characterized by stigma. The HIV/AIDS context refers came up as an influencing factor on potential participants to agree to participate in research. One participant said:

I was very sick when I was referred to AMPATH from the Nyayo wards. I was desperate and when a sister (a nurse) told me that they wanted me to participate in this research, I had no choice. I was convinced

when she told me that some other patients had gone into the research project in worse health conditions than mine and they had significantly improved. I agreed to participate hoping that I too would feel better. And it is true. I have improved a lot. When I first came I could not even walk without support. Now you can see me. I am very healthy. (A female involved in intervention research sharing in a FGD)

Others said that their condition left them wanting to try anything. One female in FGD said:

"*I was waiting for death so when I got a chance to try something new I agreed*."

A male opinion leader observed:

"*… by the time the person is asked to participate, he or she is so sick that she or he is ready to try anything. The patient surrenders to the doctors*".

One female asked in FGD:

"*I am already so sick, what can I do?"*

And a male participant in the same FGD said:

"*When I was brought to hospital I was so sick that my relatives had given up. It is a miracle that am back to life. This research has helped me a lot*".

Another male participant in preventive research said that HIV stigma prevents many people from visiting hospitals associated with HIV care. He said the following in a focused group discussion:

"*I am happy to access health services far from home*" and a female participant spontaneously made a rejoinder: "*At home, everybody knows me. How can I go to a HIV clinic where they know me*?"

At least five participants in one FGD in prevention research located away from the AMPATH centre indicated they were encouraged to participate in the current research because they do not have to go the AMPATH centre which they said is stigmatizing.

All reviewers and researchers concurred that the HIV/AIDS condition influences consent. One female reviewer said:

"*Some participants are happy to get an opportunity to serve community as a way of atoning for what they think may be their sins against community. They are happy to be of some use now*".

A male participant in intervention research sounded fatalistic:

"*Of what use am I? I am as good as dead. People can do what they want with me*."

Two researchers (one biomedical and one social behavioral) said that such psychiatric health conditions can interfere with the process of informed consent.

Post-colonial mentality: Like in all post colonial contexts, people in western Kenya have a certain mentality to white health care providers and researchers and anybody associated with them. All biomedical and behavioral researchers and reviewers involved in this study concurred that this mentality influences potential participants' decision to participate in HIV clinical research though they differed on the extent. They said that the mentality is manifested in suspicion and lack of trust but at the same time in confidence and trust of white doctors and researchers. Some participants in ongoing HIV research think that, as one male participant in intervention research put it: "*… there is better diagnosis coming from the West*". He added that people are enthusiastic to participate in research where their blood and other samples will be drawn because they think that sending "*… my blood to America means better exploration of my disease*". At least three researchers explicitly concurred with HIV research participants on these mixed perceptions of white researchers/doctors.

A participant observed that this attitude is rife in health research as well as in health care:

When we are doing ward rounds some patients will tell you: "mzungu aliniona akasema…, (a white person) saw me and said…), you know that kind of talk"… it's pretty unfortunate … but I think in the case of AMPATH it is more of organizational structure and the success that the program has had It is very rare to find mzungu treating patients … may be in Mosoriot once a week. (A male biomedical researcher involved in HIV intervention research)

The researcher emphasized that there is a lot of erroneous association of AMPATH with *mzungu.*

Specifically on post-colonialism is Kenya, he added:

I totally agree. … my own father when he takes Brufen from Kenya his backache never disappears but when my brother sends him Brufen from the US he gets well very quickly. I keep telling him that this is psychological.

Yet, some of the HIV study participants who have some relatively high level of education tend to mistrust white people and express fears of exploitation in research. One male participant involved in HIV intervention research asked: "*Why do they want to send my blood to America*?"

Also associated with post-colonialism is the understanding that fellow community members who are highly educated and highly placed in terms of professions may be exploitative of local community in their collaborative activities with *mzungu*. Thus there is the concept of benefactor and yet feelings of mistrust not only for *mzungu*-associated research but also for university-associated research.

Contradictory perceptions prevail on Kenyan doctors and researchers working with white doctors and researchers. One biomedical researcher said:

"*some participants think that a local researcher working with mzungu makes a lot of money but does not compensate them adequately*". Another biomedical researcher said: "*… some patients talk carelessly saying that we are using them like guinea pigs*". *They say local researchers work with mzungu to exploit local people by taking their samples out there*".

Yet another researcher indicated that he always worry that community is telling him what he expects to hear rather than what is actually the case. He said that some participants compare researchers to the '*colonial chief phenomenon*", in that the chief (read researcher) "*sells his people to get a little token from the colonial authorities*".

Socio-cultural factors: Some of the participants indicated that significant others like family members and friends made the decision for them to participate in the current research projects. One female participant said: – "*my brother said I should join, basi nikakubali (so I agreed)*". Another indicated that her mother in-law asked her to consent to participate and "*once my mother-in-law had said it, I had to do it*".

A social behavioral reviewer involved in this study concurred with these participants on the influence of '*significant others*' and indicated having heard a client say: "*My brother asked me to come*". Other participants indicated that they were told by other people about the

benefits of participating in research. At least two cited fellow AMPATH clients who had already participated in earlier research projects or had already consented to the same research that they are now on while others cited people that they trust like their relatives and friends in their communities. One participant shared the following:

You know when I was asked if I could participate, I went and talked to a friend of mine. I asked her what this would mean. My friend told me that it would mean better health services for me because there are many Americans involved in research and they have better drugs which they reserve for those who agree to participate in research. When I went back for my next clinic I told my doctor that I wanted to participate. (A female participant involved in intervention HIV research contributing in an FGD)

One male community opinion leader reported

"*People often come to me to ask for my opinion on behalf of their sick relatives. I encourage them to participate for their own good.*"

Other socio-cultural issues had to do with unequal gender relations in patriarchal traditions prevalent in western Kenya. Female participants indicated they would have to get permission from their husbands before giving consent to participate in the research. One participant in biomedical research said: "*I must get authority from my husband. I had to ask before I came to participate in the current research*". Only one man said he would have to consult his wife but not necessarily for permission.

But unequal power relations were not limited to private social relations but were also found in public life among professional medical persons and non-professionals. Participants in ongoing HIV research as well as researchers and reviewers seemed clear that doctors and other health practitioners like nurses wield a lot of power over their patients. Thus, whatever the doctor says is received more or less like a command by the patients. One male researcher refers to the '*white coat*' phenomenon as something that many people outside the profession consider as '*enigmatic*'. Another male reviewer corroborated this and indicated that some persons have poor understanding of their rights and may be unable to say "No' in a clinical environment.

Nearly all researchers and reviewers observed that some people agree to participate in research because of influence from significant others resulting mainly from unequal power relations and social statuses. Relations between fathers and their children, older siblings and younger siblings, brothers and sisters were mentioned. One female reviewer said that a person will say:

"*My father brought me to hospital and said I participate in this research so when the doctor asked me if I wanted to participate I had to agree*".

But not all participants in ongoing HIV research said that they consulted with others before they agreed to participate in research. A heated debate emerged in one of the focus group discussions on prevention research when one person suggested that IC forms should be given early and people allowed consulting with significant others before making decisions on whether to participate in research. Some participants seemed to agree with this but other persons were categorical that they would not want to consult but would prefer to make individual choices. One participant shouted almost spontaneously:

"*I don't want to be given a form to take home. What will people say when they see the form? They will know everything about me and they cannot help me. I am the only one who can help myself.*" Another one said: "*Family relationship and sexual issues are not for open talking*";

While yet another said

"*Asking other people is useless. Some will discourage you and others will encourage you and finally you still have to choose who to listen to and who not to listen to.*"

But the situation was different in one of the group discussion in intervention research where participants were almost unanimous that the Informed consent form should be introduced early and people allowed talking to others before they agree to participate.

Religion as a socio-cultural reality also emerged as a significant factor. Some participants indicated that their religious values affect their decision to participate or not participate in research. They observed that some religions do not approve of giving blood and so some people may not agree to participate in research where there is drawing of blood. Other religions do not allow use of condoms. This was mentioned by participants in ongoing HIV preventive health research. They indicated that some participants may tell the researcher that they are using condoms in order to remain enrolled in the research but they may not be using the condoms because of religious beliefs. Yet others indicated that some participants may not adhere to research requirements because they may encounter a faith healing session and think they have been healed.

To contribute to health research: Only two male and one female participants in FGDs indicated that research is about study and indicated that they agreed to participate in research in order to "*help in finding a drug*"; "*help so that the doctors know more about the disease*"; and "*for the benefit of others who can benefit from my participation*". One of these, a woman in intervention research, probed in an oral interview explicitly observed that research may not necessarily help participants but may generate information that will be useful for "*my children and my children's children*". But the two male participants were not as clear as this woman. For them, participation in research helps them access healthcare but in the process, as one of them put it: "*doctors can see which drug works better and which one has many side effects*".

Both reviewers and researchers concurred that a significant number of participants understand that research is part of the process of generating scientific health knowledge and they know that their participation is good contribution to this process. One male researcher said: "*Some people participate in order to contribute to the process of generating new knowledge*".

This provides opportunity for partnerships with community one of the ethical principles for multinational clinical research as expounded by Emanuel et al. [6].

At least one reviewer and one researcher indicated that some people participate in research in order to feel useful. One interviewee said:

In the context of HIV/AIDS, some persons living with HIV may feel like society condemns them as immoral for being HIV positive and participation in research may be seen as a way to moralize themselves; to pay back for their sins with a good act by making positive contribution to society. (A social behavioral reviewer)

Curiosity

At least two participants indicated that they actually did not know what they were consenting to and they agreed to participate so that they could get to know more about research. In the words of one male FGD participant, "*I joined the study to see what was going to happen*".

Discussions

This study identifies seven (7) key reasons why informants chose to participate in HIV studies. These include: access to perceived health care; financial poverty, the HIV/AIDS context; postcolonial mentality; socio-cultural factors; contribution to health research; and curiosity. Of these seven reasons, five speak directly to exposure to vulnerability. Various scholars and researchers have pointed at each of the issues behind these reasons though none has referred to all of them working together [2-4,7,8]. Without ranking the significance of each of the reasons, we observe that the participants, especially from resource limited settings, have complex challenges to contend with. Decision as to whether to participate or not participate is catalyzed by factors beyond the actual appreciation and desire to contribute to the fulfillment of set research goals.

The findings of this study further indicate a different approach pointing at the need to rethink vulnerability as an index and measurement of human respect in health research ethics. For example, findings under factors regarding financial poverty; the HIV/AIDS context; postcolonial mentality; and socio-cultural factors are not specifically demographic yet they elicit factors that render the participants vulnerable. These are vulnerabilities that derive from the dispositions of participants who otherwise do not directly fall under the traditional identification of the vulnerable categories as variously identified in policy and guideline discourses. Poverty, stigma, apathy, ignorance and marginalization render participants contextually vulnerable thus opening them up to liability for coercion, abuse and exploitation. They often find themselves not in control of their consenting processes however much informed they might be the ethical requirement in health research is set upon three main principles: respect for persons, beneficence, and justice. The basic requirement under the principle of justice is that there should be fair selection of participants in health research and that the distribution of the outcome of the research should benefit society and more so the participating research community [5]. However, what may draw some level of interest is the requirement under the principle of beneficence; there should be favorable risk-benefit ratio in health research. The main purpose of undertaking any health research is to benefit the society in terms of improvement of health care and treatment, offering better services and attention to patients and generally ensuring that the well being of the society is maintained and improved.

Alongside benefit, the issue of risk is emphasized. Ideally, ethical research involving humans requires that the research be scientifically sound, that the autonomy of persons be respected, and that the research not involve any unacceptable risk to the participants. In the context of health research risk is understood as "the 'probability' of risk and the 'magnitude' of that risk should it occur and their long-term consequences [5,9]. Central to ensuring that the basic ethical principles are upheld, seeking informed consent from the potential participants is primary. The assumption of the informed consent process is that potential participants are clear on the meaning of research in general and of the specific objectives of specific projects, and that they are not coerced or induced to participate in research.

However, interpretation of the meaning of research is left to the professional stakeholders in research including researchers, reviewers and members of the research ethics board. Thus, "Current practice relies on research ethics committees to assess whether the risks of participating in a research study are outweighed by the expected benefits for the participant and/or by the expected benefits from the knowledge gained [10]." There is little involvement of research participants and communities on what may entail risk in a particular context. In this case, participation in HIV clinical research with an aim of getting a particular medical attention may pass as something that may be an occasion of risk according to the standards of health research professionals. In fact it is emphasized that participants should get into research with proper motive which is made clear with the whole process of IC. However what may pass as an occasion that may be risky from the set standards and professional ethical guidelines may not be a reflection of the perception of a people concerning the same.

Biller-Andorno observes that the research ethics committees [10] might reject research that involves acceptable risk and has important social value as being too risky. This could be interpreted to mean that the perception of risk by the professional community in health research may be different from what a people in a particular context of research may be having.

International research organizations recognize the vulnerabilities of limited resource settings. For example, the Council for International Organizations of Medical Sciences (CIOMS) recognizes the vulnerabilities of limited resource settings to provide ethical guidelines on research in populations and communities with limited resources. Guideline No 10 states:

Before undertaking research in population or community with limited resources, the sponsor and the investigator must make every effort to ensure that:

- The research is responsive to the needs and priorities of the population or community in which it is to be carried out; and,

-Any intervention or product developed or knowledge generated will be made reasonably available for the benefit of that population or community [11].

As has been dialogued therefore, in the context of HIV clinical research in Western Kenya, a resource limited settings characterized by vulnerabilities, this study sought to establish why participants engage in clinical HIV research.

In the previous section, the various reasons why participants in ongoing HIV research projects in western Kenya agreed to be engage in research are presented independently one after the other. But this is only for purposes of simplicity and clarity. It emerges from the presentation above that in real life, the reasons are multiple and overwhelmingly interact to influence decisions on whether to participate or not participate in research.

For example, a participant may agree to engage in research because of his incurable and stigmatizing HIV condition with the hope that he will access better healthcare which he would otherwise not access because of his low financial status. But his decision may have been influenced by information from significant other persons (family or/and friend) who may have presented the services offered at AMPATH as exceptional because *mzungu* is involved. At the same time, the participant may be curious to participate in clinical research to see what happens and at the same time be of value (researchers emphasize the usefulness of participation).

As mentioned earlier, reasons given by participants in this study on why person living with HIV consent to participate in international HIV research imply aspects of vulnerability that are more psychosocial and socioeconomic than is traditionally recognized in regulations and declarations. Engagement in the consenting process for meeting the informed consent parameter in ethical research ends up being complex while taking on contextualized dimensions that go beyond

mere identification. It therefore becomes imperative that we concur with the position of the Presidential Commission in highlighting the importance of approaching ethical standards in light of "modern human research ethics against the researchers' understanding of medical ethics practices and practices of the day" [12], by appreciating socio-culturally induced moral ignorance, culturally available moral concerns and other moral or otherwise concerns that render the participant vulnerable. This concurs with Bhutta [13] proposal that researchers should move beyond informed consent to develop instruments that acknowledge and integrate culturally relevant informed consents and consenting processes that are not necessarily written.

A study by Appelbaum et al. on informed consent in psychiatric research suggests that there is therapeutic misconception among study participants demonstrated by poor understanding of the process of randomization and double blind techniques [14]. But, given the reasons given by participants as to why they agree to participate in HIV research, we ask, is there therapeutic misconception in HIV clinical research in western Kenya?

The findings presented above suggest that study participants know that HIV is incurable. But they are clear that the condition can be managed so that a person lives comfortably with the virus. For this management, participants think that they get better care when they are enrolled in clinical research. All participants indicated that their health had improved significantly since they enrolled in their current research not only because of the medicine that they receive but also because they receive a lot of attention which is in it therapeutic. This is often not a misconception. As it emerges from the findings, some participants involved in HIV research would never access any health care or better health care if they were not involved in HIV research for various reasons. Researchers and reviewers concurred on this.

It would appear that many of the participants enrolled in HIV clinical research would not afford healthcare because of their low financial status. Note that as in nearly all research projects; participants in ongoing HIV research involved in this study are from low social class. For these, affordability of healthcare is not only in terms of paying for the services and buying drugs but also in terms of meeting the costs associated with this such as transport expenses and loss of opportunity to earn daily living.

Many participants live from hand to mouth and so time is spent in seeking healthcare translate into lost opportunity to earn food for the day. But when people are involved in research they can access healthcare because the researcher compensates them for transport.

The findings suggest that some participants would not access healthcare because of fear of HIV stigma. Some of the participants in this study indicated that they are happy to attend clinics far from home and avoid stigma. Others said they were happy to attend a clinic away from AMPATH. Other responses by the participants on why they engage in research suggest that they think that there is better treatment in the clinical research sites than in regular healthcare clinics. Indeed, medical researchers involved in this study indicated that the environment of clinical research sites is much better than that of healthcare clinics especially in terms of cleanliness, general attention to clients, and shorter queues. Moreover, health services at clinical research sites are much better than in health clinics in terms of availability of drugs and equipment, closer medical attention to clients, and better follow up. Clinical researchers interviewed confirmed that indeed, many participants would not access standard health care without some form of support provided by research projects such as transport and other compensations. Moreover, the confirmed that research clinics often have better facilities than healthcare clinics.

Conclusions

One of major conclusions derived from the findings of this study within the context of the objective pursued is that many research participants do not appreciate the difference between health care and health research. Most participants think that engagement in research translates to access or better access to healthcare. But often, this is not a misconception especially in the context of HIV in resource-poor settings. Indeed, participation in research translates into better access of healthcare faculties and services. This is so because without participating in research many people would not afford health care because of their low financial status, while others would not access healthcare because of HIV stigma and lack of hope and trust. Besides, better services and facilities are available in health research clinics especially in terms of patient attention and availability of drugs.

This implies that for researchers to obtain valid informed consent, it is important for them to not only understand the theoretical process of administering IC but also the specifics of the context within which they recruit participants. In this case, the HIV/AIDS context, the economic context and the socio-cultural and postcolonial context have bearing on whether potential participants agree to participate in research or not. Further, community engagement on research would be required to clarify the distinction between health care and health research

It is clear from this study that, in a complex context like Western Kenya, the discretion of HIV researcher is often more practical than seeking to follow ethical rules and guidelines strictly. This calls for virtue ethics, which draws from rational and moral resources within the individual researcher, rather than legalistic ethics drawn from policy documents, regulations and research guidelines.

Further, efforts to provide research ethical guidelines at international and national level should be seen to reflect reciprocal effort by institutions - individual and/or corporate - in order to facilitate adaptation, adoption and/or domestication of existing regulations in order to provide for specific and contextualized ethics landscapes that will sufficiently inform and catalyze the IC processes. This in itself is an immense challenge, especially when awareness and discourse on research ethics issues, especially in the developing world is still very much at infancy and dependent on long histories of international trends that can not only be alienating and marginalizing but also out of context.

This was a small scale qualitative study focused on reasons why participants in select on-going HIV prevention and intervention project at AMPATH agreed to engage in the projects. Thus, the findings are limited and may not be conclusive. However, the findings provide opportunity for generation of hypotheses towards intensive study of HIV research contexts not only in Western Kenya but all over the world for improved contextual relevance and validity of informed consent processes and instruments.

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