

Challenges Encounter
By Researchers In HIV
Research At AMPATH –
MTRH On Application
Of The Principle Of
Justice

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ABSTRACT

Background: During research activities there is need to apply ethical principle of justice where justice is about doing what is morally right and proper treatment of persons. It is not easy to maintain justice in research in poor resource setting. The objective of this study was to explore the challenges encountered by MTRH health researchers at AMPATH on application of the principle justice in HIV research. **Method:** Between June and August 2016 in-depth interviews were conducted using unstructured interview guide with 16 researchers from MTRH who worked at AMPATH purposively selected to participate in a cross sectional exploratory qualitative study. Interviews were audio- recorded transcribed and content manually analyzed. **Results:** The researchers considered IREC requirements for approving research proposal, how to engage participants in ethical research process and the knowledge of community members about ethical research process. One of the challenges researchers encountered was their perception that IREC hindered their progress in ethical research process. The researchers had a challenge with poverty levels within the community which is closely associated with illiteracy and culture of handouts. **Conclusion:** Though researchers are knowledgeable about the principle of justice in ethical research process there challenges are centered on challenges associated with low income in the communities, there' attitudes and lack of practical skills. There is need to train researchers on the skills of carrying out ethical research in specific contexts and sensitizes them on the role of IREC as a facilitator of ethical research.

Keyword: Justice, researchers, poverty, handouts, challenges,

1. INTRODUCTION

1.1 BACKGROUND INFORMATION

The Human Immunodeficiency Virus (HIV) has been a big challenge to provision of health services all over the world for over 30 years. The epidemic has had widespread social and economic consequences, not only in the health sector but also in education, industry and the wider economy. By the year 2012 about 1.6 million people had been infected with HIV and roughly 57,000 people died from HIV related illness (UNAIDS 2013) in Kenya.

Moi Teaching and Referral Hospital (MTRH) in Eldoret is one of the referral hospitals in Kenya serving a population of over 5 million people. The Academic Model Providing Access to Healthcare (AMPATH) was initiated in 2001, initially as a response to HIV/ AIDS only with private philanthropic support to provide care for HIV/AIDS patients. AMPATH has enrolled 158,000 HIV infected adults and children in its satellite clinics in Western Kenya (AMPATH, 2014). It is noted that research studies involving AIDS patients are profoundly on increase trend involving many health institutions and researchers.

Respect, beneficence and justice are the basic principles which form the foundation of all regulations or guidelines governing ethics of carrying out research with human participants (Family Health International, 2007). The principle of justice is about ensuring reasonable, non-exploitative and carefully considered procedures and their fair administration, fair distribution of the costs and benefits among persons and groups (Rice, 2008). Justice for the participants during ethical research process is ensured by institutional research ethics committees (Pogge, 2003). For AMPATH ethical research process is regulated by guidelines from the Moi University College of Health Sciences and Moi Teaching and Referral Hospital, Institutional Research and Ethic Committee (IREC).

To attain capacity for research in resource-poor settings is a challenge for the activity involved require finances which may not be available; (Jinadu, 1997; Crawley & Himmich, 2000; Kovacic & Laaser, 2001; Nchinda, 2002, 2003; Lo & Bayer, 2003; Chandiwana & Ornbjerg, 2003; Lavery, 2004). Farmer and colleagues in a study on AIDS drugs in Haiti realized that capacity for research could be developed and sustained through improved structural situation and payment; (Farmer, 1997, 2003). The researchers have to plan, organize and implement ethical research process through the financial assistance from the research partners which are not easy to come by.

Collaborative partnership with communities by researchers is a challenge due to cultural orientation of the researched communities (Lo & Bayer, 2003; Chandiwana). Those challenges may be solved through alliances between professionals and community representatives in the study areas in both public and private sectors; (Benatar, 2000).

There was lack of accurate information for considering the local and the international standards of care in clinical trials in developing countries. This point to possibility of exploitation of participants in resource limited setting (Angell, 1997; Lurie & Wolfe, 1997; Varmus & Satcher, 1997; Bloom, 1998; Levine 1998; Lie, 1998; Luna, 2001; Macklin, 2001; Killen *et al.*, 2002). Adherence to state of the art therapy for research participants which is a justice issue regardless of sustainability of treatment is a challenge; (Angell, 1997, 2000; Lurie & Wolf, 1997; Rothman, 2000; Annas, 2001; Shapiro & Meslin, 2001). Practically, adherence to certain requirements might need certain support which may not be forth coming and it is not documented on how this adherence to state of the art will be achieved by the researchers.

Scientific necessity, the relevance of the study for the host community, fair level of benefit for the communities participating in the study and improvement of the general status of the community are the four conditions to be ensured by the IRBs and fulfilled by the researchers for attainment of justice for research participants (Wendler *et. al*, 2004).

The study question was whether the HIV health researchers encounter any challenges in fulfilling the principle of justice to research participants at AMPATH.

This study was undertaken to establish the challenges researchers encounter in application of the principle of justice in HIV research at AMPATH MTRH. Specifically the objective was to explore the challenges encountered by MTRH health researchers in applying the principle of justice in HIV research process at AMPATH. Understanding challenges encountered by researchers for HIV will help in grounding structures for application of justice to research participants in Kenya and other resource limited countries.

2. METHODS

2.1 SITE

The study was conducted at AMPATH HIV clinic at MTRH in Eldoret town in Uasin Gishu county of Kenya. Over 100 biomedical and social behavioral researchers providing care and doing health research could give rich encounters of research experiences for this study.

2.2 STUDY POPULATION

This study targeted researchers at AMPATH - MTRH in Eldoret to understand their experiences in application of the principle of justice to HIV research participants. The Researchers should have been involved in HIV research at AMPATH for one year and above. This ensured that researchers could provide accurate information.

2.3 TARGET POPULATION

Researchers participating in HIV research at AMPATH – MTRH.

2.4 SAMPLE POPULATION AND SAMPLING PROCEDURE

This study involved 16 researchers' respondents. The study had initially targeted 28 researchers. After interviewing 14 researchers saturation was reached and two more participants were interviewed to confirm the saturation of the in-depth interviews totaling to 16 researchers. The distribution of the respondents was as illustrated in the section of the results.

Purposive sampling was used to select participants from MTRH biomedical and social behavioral health researchers at AMPATH. Based on the sample size for this study and the sections of interest as mentioned in the distribution of the participants for the study area, researchers were identified to participate in the study. The investigator selected both female and male in equal numbers to ensure gender balance in sharing in their experiences. Biomedical and social behavioral researchers were selected in equal numbers to participate in the study. This was important for the two groups, biomedical and social behavioral play different roles in research. This means that they could be having different experiences. Two sets were for female biomedical and social behavioral researchers and the remaining two sets were for male biomedical and social behavioral researchers. They were approached, requested and invited to participate verbally. The invitations explained the purpose of the study and all the procedures involved. The individuals who consented to participate were notified in one week's time before the day of the interviews. This was to enable the participants to prepare for the interview.

2.5 INCLUSION CRITERIA

MTRH researchers taking part in HIV research and had been at AMPATH set up for one year and above and were willing were included.

2.6 EXCLUSION CRITERIA

The exclusion criteria included MTRH researchers at AMPATH who were participating in HIV research activities but were not on duty during the period of data collection.

2.7 STUDY DESIGN

This was a cross-sectional, exploratory, qualitative study which involved MTRH researchers at AMPATH in Eldoret. The primary data was collected a cross a population sampled over one period to investigate and to understand the challenges encountered by researchers on application of the principle of justice to HIV research participants. The investigator sampled researchers at AMPATH to explore their experiences with HIV research participants at AMPATH and interacted with them through interviews, between May and August 2016. The investigator focused on the encounters of the researchers on applying the principle of justices in HIV research.

2.8 METHODS AND INSTRUMENTS OF DATA COLLECTION

The data collection process involved an interaction between the researchers and the investigator through interviews. The interview sessions took between 45minutes and one hour. Unstructured interview guides were generated from various themes on the application of principle of justice to participants in HIV research. During this process of data collection the key points on IREC research guidelines, factors researchers consider in ethical research process and the challenges researchers encounter in fulfilling justice in research process were addressed. The researchers were probed with both information from the guide and information they gave out during the interview process. The interview process took place in the participant's offices which was convenient for the participants to avoid disruption. This was supportive enough for researchers to open up and give information undisrupted. Throughout the interview process the investigator was an active listener offering verbal mirror to affirm the clarity of the information given by the researchers. The investigator's silence was utilized as a spring board into important topic of discussion for silence was an instance for thoughtful punctuation. The interviews were conducted in English.

2.9 PILOTING OF THE DATA COLLECTION TOOL

The data collection tool (interview guide) was piloted prior to the actual study. Four health researchers were sampled from MTRH, to test the interview guides. This was to ensure they were well phrased, culturally sensitive, and captured the objectives of the study. The results showed no need to carry out any adjustment on the tool before rolling out the interviews.

2.10 DATA MANAGEMENT AND ANALYSIS

Data management and analysis was manually done from interpretive analysis approach at two levels. At level one transcription, identification and classification of themes was done. At level two of analysis triangulation of data was done. IREC guidelines were analyzed by the investigator by going through the Standard Operating Procedures for the Institutional Research and Ethics Committee (IREC). The Reviewers Guide Form was also looked into. This was with a view of identifying the challenges in applying those guidelines in a practical situation. A comparison with national guidelines already on record was also made.

3. DATA ANALYSIS AND PRESENTATION

3.1 LEVEL ONE

Data was collected from the researchers through audio-recording and written short notes and it was manually managed. The interview recordings were transcribed verbatim. An interpretive approach was used to analyze data item by item where content analysis was performed. Overlapping issues from each interview were matched to individual subjects. Then all the interview data was compiled and themes identified highlighting areas of concern with the instrument. The findings were presented as summaries including selected quotes. The themes identified were:-

- application of both local and international guidelines of research
- factors researchers consider in applying the principle of justice in HIV research
- the challenges encountered by researchers in fulfilling justice for HIV research participants

The process was largely inductive, inquiring generating meaning from the data collected in the field through themes and emerging concepts and theories.

3.2 LEVEL TWO - TRIANGULATION

Focusing on the study question data collected by various instruments across different categories of participants was compared and contrasted. This was to enhance in depth understanding of complementary information about the ethical experiences researchers encounter in a researcher process. It was noted that perception for various similar concerns were interpreted differently by the researchers. For example one of the researchers expressed enough being done to achieve the principle of justice in HIV researcher. However another researcher expressed negative asserting that more needs to be done to achieve justice in HIV research. This implies that either there is lack of understanding of certain aspects of ethical research process or there exists breakdown in communication at certain levels of research process.

Data was interpreted and tabulated for reference, comparison and cross checking before presentation in prose as by different levels of analysis.

3.3 LIMITATIONS OF THE STUDY

This study involved a smaller number of HIV researchers. This was not representative enough for Kenya's research population. The study focuses on, the individual's insights own perspective and meaning of experiences. Consequently, this work is not generalizable beyond its current context. In spite of these limitations, this study is important because it provides fertile grounds for future research on the application of the principle of justice in research. It also provides researchers an opportunity to share their understanding on the subject matter and the challenges they encounter.

3.4 STUDY VALIDITY AND RELIABILITY

To ensure that research question would be asked in the right way it was pretested through a pilot study. Through triangulation conformation collected by different tools from different categories of participants was allowed. Thematic saturation supported the study validity while classmates and colleagues played the role of independent analysts of transcription. Participants were availed soft copies of the summary of the findings. Validation of the findings was allowed through this process.

3.5 ETHICAL CONSIDERATIONS

Before the commencement of the study, the proposal was submitted to (IREC) for approval. Participation was voluntary with the autonomy to withdraw from the study at any time. All participants gave written informed consent before participating in the study. Anonymity was assured by using coded interviewer guides and ensured that no names of respondents were indicated but, instead unique numbers were used to conceal names of participants.

4. RESULTS

This study involved 16 researchers, after interviewing 14 researchers saturation was reached and two more participants were interviewed to confirm the saturation of the in-depth interviews totaling to 16 researchers. The distribution of the respondents was as illustrated below.

Table 1: Demographic characteristics of researchers from MTRH/CHS MU working at AMPATH in Eldoret Kenya

Respondents	Age in years	Sex	Occupation	Period in years at AMPATH
01 RB	51 – 60	F	Behavioral Researcher	3 years
02 RB	61 – 70	M	Behavioral Researcher	2 years
03 RB	51 – 60	M	Behavioral Researcher	5 years
04 RB	31 – 40	F	Behavioral Researcher	6 –years
05 RM	41 – 50	F	Biomedical Researcher	2 years
06 RM	41 – 50	M	Biomedical Researcher	3 years
07 RM	41 – 50	M	Biomedical Researcher	3 years
08 RM	31 – 40	M	Biomedical Researcher	4 years
09 RM	31 – 40	M	Biomedical Researcher	4 years
10 RM	31 – 40	F	Biomedical Researcher	3 years
11 RM	51 – 60	M	Biomedical Researcher	2 years
12 RB	41 – 50	F	Behavioral Researcher	5 years
13 RB	41 – 50	F	Behavioral Researcher	3 years
14 RB	31 – 40	F	Behavioral Researcher	4 years

15 RB	31 – 40	F	Behavioral Researcher	6 years
16 RB	41 – 50	M	Behavioral Researcher	3 years

Data was collected using unstructured interview guide from sixteen researchers as shown above. There were equal numbers of female and male researchers eight for each. Their ages ranged between thirty one years and seventy years. Biomedical researchers were six in number and behavioral researchers were ten. All the researchers had worked at AMPATH for more than two years.

4.1 THEMES AND SUBTHEMES

Table 2: Organization and process of data analysis - Themes and subthemes

Themes	Subthemes
Barriers of attaining the principle of justice in HIV research at AMPATH.	<ul style="list-style-type: none"> - challenges encountered by researchers - application of both local and international guidelines of research - factors researchers consider in applying the principle of justice in HIV research

During this process of data collection the key points on the challenges researchers encounter in fulfilling justice in research process were addressed. The researchers were probed with both information from the guide and information they gave out during the interview process. Here are some of the quotes from those interviews.

Some reviewers take a very long time to review a proposal compromising IREC performance of feedback within two weeks as stipulated by the SOPs; this makes the researchers to perceive IREC as an obstacle to their progress.

“IREC depends on professionals who are not members of IREC to review research proposals for members are few– less control over them ... reviewers are overloaded with work which has no direct benefits.”(R 02 - RI)

It was also explained by one of social behavioral researcher that one needs to understand the cultural aspects of the community before engaging it in research process:

“... community is a very challenging area..., ... need to clearly explain to stakeholders to avoid misunderstanding, misinterpretation and misrepresentation of your intentions....Cultural orientations are also a challenge need to understand before engagement in research...”(R 01 - RB)

“...the culture of hand outs and dependence syndrome in most community is a challenge.... Poverty is a challenge – one may easily make a decision without understanding what the study is all about in order to be assisted”.(R 02 – RB and 15 - RB)

One behavioral research respondent expressed that there existed very high expectations from the population being engaged in research. This fosters the negative attitude of (munatutumia) you are using us:

“... high expectation from the population is a challenge... over researched community members developing negative attitude..., say munatutumia...”(R 13 - RB)

They expressed that it is on this premises that one can easily conclude that a participant is being exploited;

“...AMPATH only cares for poor people... ... chances of the poor participating in studies at AMPATH to be coerced to participate... not ethical and therefore no justice...”(R 05 – RB and 06 - RM)

“...poverty among study population hind the realization of justice, ...we are dealing with poor people... out of the clinical trials the patients cannot afford drugs that are used for their care...may be coming for trials because ... only alternative for getting care..., ... looks like enticement ... not ethical. ...some of drugs given in the clinical trials cannot be found anywhere else”.(R 09 – RM and 08 RM)

One of the social behavioral respondents asserted that some misunderstanding around finances and gifts existed within the community;

... some of option leaders in the community demand for tokens... paying research participants is unethical... the researchers who do not pay participants meet resistance from the community they are thought to be keeping funds meant to pay participants...”(R 03 - RB)

One of the social behavioral respondents alluded on the community entry as a challenge;

“...attitude of some community members and poor community entry by researchers leads to refusal to participate.... most of the community members have limited knowledge about the importance of research”.(R 14 - RB)

5. DISCUSSION

At research implementation level the main stakeholders are the researchers and researched. For the researched the entry point is the consenting stage. Consenting is a global challenge in resource poor countries like Kenya (National Bioethics Advisory Commission, 2001). It is mentioned in this study that this can lead to research misconduct by researchers. The researched may give consent without appropriate consideration of what participation entails. Researchers attributed this to poverty, the fact that participants can consent without consideration of what is involved which is a challenge in attaining justice for research participants.

At AMPATH researchers expressed that there were high expectations from the community leading to dependent syndrome. The researchers acknowledged that the research participants are poor. It requires careful planning a lot of keenness to achieve balance in sharing benefits and burdens. In the absence of careful consideration of a practical interaction between the researcher and researched one may imagine existence of exploitation. Yet in a practical situation some of the benefits researched population gains are beyond reach out of the research process, for example the drugs used in treatment of HIV are very expensive to afford.

There is the issue of equity which implies giving as much advantage, consideration to one part as it is given to another, (Rice, 2008). In HIV research the generated knowledge is used to care for all regardless of whether one has participated in research or not. Only benefits are shared and not equally but burdens are mostly carried by the research participants. However the ethical aspect here is that the participants of research should benefit from the knowledge generated.

It was important to note that researchers appreciated the significance of understanding the community being researched. It was expressed by (Emanuel et al, 2004 and Marshall and Rotimi, 2001) that collaborative partnership between the researchers and the community is the key to ethical research. Understanding the dynamics of the community is the foundation to the community entry. The reception and therefore co-operation

one will be accorded will depend on the community entry strategy. Researchers at AMPATH expressed how working with the community was a challenge. Some expressed that some of the community members were uncooperative requiring communication through proxy (through their leaders). Some of the community members alluded to being used by the researchers (*munatutumia*). Those are indication of a relationship that requires improvement to foster smooth interaction between the researchers and the community members. If there is a challenge on co-operation then there are chances of justice missing for research participants. Education, need assessments and feedback to the community could improve this interaction levels. Involving the community throughout the research process as suggested by; (Marshall and Rotini, 2001) could give a valid partnership. This will help to undo the myth that researchers use the community members as means to achieve certain ends. Researchers at AMPATH expressed that it requires a lot of effort to accomplish an ethical research process.

Following the implementation of research there are expected outcomes. According to (CIOMS, 2002) and (UNAIDS, 2000) effective trial drugs should be made available to participants. The situation at AMPATH is that most of the research participants are economically weak. They cannot afford those drugs given during trial when the study ends. The manufactures of those drugs are found in faraway locations and if the drug is effective there are issues of patent and therefore it cannot be manufactured locally by any other companies. It was expressed by one respondent that it was a challenge for the participants to benefit from what they helped to generate when the study ends because of affordability. This is justice issue therefore ethical issue (Marshall and Koenig, 2004). The essence of research is that knowledge generated from research should benefit all who need to benefit.

Some researchers expected IREC to educate them on what IREC consider on approving research proposal which is the researcher's responsibility to find out before engaging in research activity. This creates an impression that IREC is not supportive enough which may not be the case and this could be handled by attitude change by researchers. Some researchers expressed that they do not do enough after attaining research knowledge due to other responsibilities – clinical work. Researchers' attitude should help them to balance between research and clinical work.

Most of these research activities are done in remote areas where the population may be classified as vulnerable and the surveillance structures are weak. This was expressed by one of the members. Health events occur everywhere among community members. However, those community members who are economically strong and are literate are able to handle their situation better. It is on this ground that researchers will come in conduct more with illiterate and poor people during their research activities. It is a challenge to judge the research process on the ground of justice. It requires wisdom and integrity by researchers to achieve justice in the

developing countries. Without handouts the general view by the community is that they are being misused (munatutumia) and yet there exists events that require research activities within the community.

6. CONCLUSION

Researchers are knowledgeable about the principle of justice in ethical research process. However they may fail to apply the principle of justice in HIV research due to challenges associated with low income in the communities, lack of practical skills and researchers' attitudes. Learning virtue ethics supports researchers in upholding personal integrity in research activities.

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