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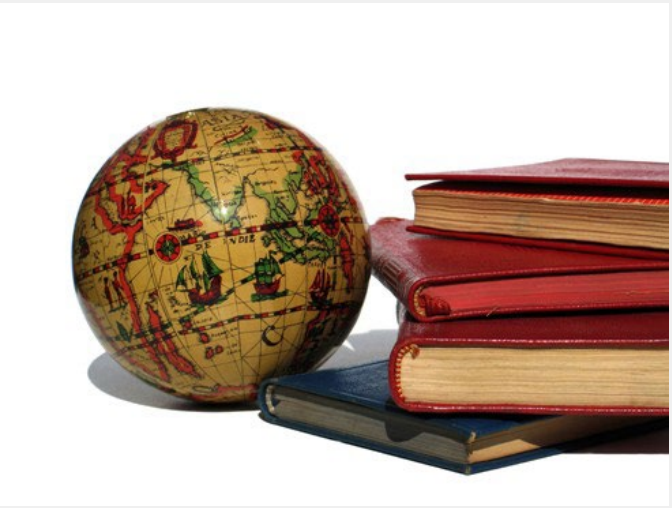

I am pleased to present to you the third issue, volume 3 of KEMRI Bioethics Review, in this issue we focus on the theme of ***Ethics in Social Science research***. When research involving human participants is mentioned, areas of biomedicine and health care are the foremost areas that come to mind, however, researchers in KEMRI conduct a great deal of human research within the discipline of Social Science. Social science research has long been concerned with ethical issues. Social scientists investigate many complex issues which involve cultural, legal, economic, and political phenomena. This complexity means that the scientist must work with "moral integrity" to ensure that research process and findings are "trustworthy" and valid and of even more concern that human subjects are not exposed to unnecessary discomfort.

In this issue we present articles by social scientists who have been conducting Social science research and provide an opportunity for them to discuss some of the challenges and opportunities in this field. The question often raised is "how can having discussions or simply talking to people cause any harm or be an ethical issue? There are no invasive procedures or specimen collection?" In the social science context, social harms may include violation of privacy or confidentiality, psychological or emotional harms and sometimes even financial harm resulting from participating in research. These risks of harm must be considered against the potential for benefit to individuals and society in all types of research. We hope this issue will provide some insights that will answer those questions for those who may have such questions, and also contribute to responsible conduct and protection of participants involved in social science research. We are also glad to introduce to you four new members joining the KEMRI ERC.

I encourage scientist to contribute by writing articles on bioethics or forwarding to the editorial team any challenges they encounter in implementing research as these may be valuable lessons that others within our large research family can learn from.

Wishing you all enjoyable reading.

Dr. Elizabeth Bukusi,
Deputy Director Research & Training
(DDRT), KEMRI

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Word from Director KEMRI

> “KEMRI has deployed social scientists to review committees to provide robust review of social science research”

Prof Solomon Mpoke, PhD
Director KEMRI

Welcome to yet another issue of *KEMRI Bioethics Review* under the theme: ***‘Ethics in Social Science Research’.*** Social science is an important field in research. It provides an avenue for scientists to use scientific methods to perform in-depth quantitative and qualitative studies and evaluation of human behavior. To be comprehensive in its research endeavors, KEMRI must be able to not only understand what health challenges are within our communities but to also address gaps as to why these challenges occur. This goes beyond documenting the numbers of those with a particular health challenge or concern, but understanding what else contributes to these challenges. Social science research enables us to understand these ‘soft’ aspects that are crucial to any eventual outcome for improving the health of communities.

Since inception, most of KEMRI’s research programmes have focused on infectious and parasitic diseases because of the huge burden of these diseases in a developing country like Kenya. However, there has been a growing concern for lifestyle diseases in the last few years. In addition there has been mounting interest in social science research in a quest for researchers to understand and interpret research results in order to improve on human health. For example, it has been observed in one study on HIV prevention that some participants did not use certain investigational products provided in that study. Social science research will be critical in trying to understand why the study participants did not use the products. Indeed, social science has a wealth to offer in terms of exploratory work, ranging from ethnographic surveys to in-depth evaluations of individual or community experiences. Scientists are therefore encouraged to incorporate social science research as an essential component of routine biomedical or clinical research in order to offer comprehensive solutions to the health challenges facing our nation.

Ethical issues in social science research are as crucial as those in biomedical research. Researchers must conduct this kind of research ethically and responsibly. Researchers must ensure that participants are respected, study subjects must be treated equally, benefits must be maximized and any harm minimized. To address the needs arising from diversification of research portfolio to include fields like social science, KEMRI has deployed social scientists to review committees to provide robust review of social science research. This measure is not only going to protect the well being of the research subjects but will also ensure that KEMRI remains an institution where research is carried out at the highest international standards possible.

I wish you enjoyable reading.

Update - New Ethical Review Committee Members

Amolo F. Okero MBA, MPH

Amolo Okero is a public health consultant with sixteen years of relevant experience in the health sector. She was appointed a member of the World Health Organization's Ethics Review Committee in July 2009 while working at the WHO in Geneva, a function she performed for three years before her return to Nairobi in August 2012. She attended several training sessions organized by the WHO ERC secretariat including their annual training and seminars on the ethics of bio-banks and research ethics systems. As an ERC member, she contributed to the development of the ERC's Online Research Ethics Training Course, developed to strengthen research ethics capacity across WHO, with special attention paid to the needs of WHO ethics committee members and to staff members who are often funders, sponsors or managers supporting health research.

Furthermore, Amolo worked as a technical officer in WHO's HIV department for 9 years, developing policy and guidance for various HIV intervention areas, and providing support to countries onpolicy development, budget management, program evaluation, fund-raising, proposal reviews, and adaptation of guidelines. She also has private sector experience where she has worked in sales and marketing of health commodities.Her interests are in governance and leadership, quality management, community mobilization and engagement and public-private partnership, particularly as pertains to the delivery of health services.

Amolo has graduate degrees in management and public health from both the Thunderbird School of Global Management and Johns Hopkins Bloomberg School of Public Health.

"Social science research has important contributions to improve the health of communities, and more support should be given to this research. From my experience working in HIV prevention, I believe there should be greater advocacy to increase efforts on health promotion and disease prevention to complement the work of treatment. Many behaviours impacting health take place outside of clinical facilities. Research that can more clearly demonstrate the links between these behaviours and health outcomes could lead to more effective health interventions."

Dr. Joan Wairimu Maluki, BVM, ALAT, RQAP-GLP

Dr. Joan W. Maluki is a Veterinary Doctor trained at the University of Nairobi. She also holds a Diploma in Computer Science from Strathmore University. Dr Maluki has attained a post-graduate certification in Laboratory Animal Technology and is a registered Quality Assurance Professional in Good Laboratory Practices (both certifications obtained in the USA). She is a member of the Society of Quality Assurance (SQA), the Mid-Atlantic Regional Society of Quality Assurance (MARSQA) and the Bioanalytical Speciality Section of SQA (all in the USA).

Her work experience since graduating from the university includes (but is not limited to) practising as a veterinarian, working as a veterinary aide in New Jersey (USA) and performing various roles in the pharmaceutical research industry, also in New Jersey. The bulk of her work experience is in the latter where she worked in the animal laboratory for approximately one year, followed by eight years as a Quality Assurance Auditor. Whereas she has vast experience in Good Laboratory Practices (GLPs), Dr Maluki also received extensive training in Good Clinical Practices (GCPs) and audited studies that were conducted in accordance with the same regulations. She has attended numerous seminars and training sessions on Quality Assurance related topics, and other topics as well.

Serving in the Ethical Review Committee (ERC) at the Kenya Medical Research Institute (KEMRI) is a great privilege and she looks forward to playing an active role in ensuring that the rights

and welfare of all human (and animal) subjects used in research are fully considered and addressed appropriately. Dr. Maluki is very excited at this opportunity. Her main aim is to ensure that she utilizes the education, experience and expertise that she has attained over the years in the USA, to assist Kenyan research institutions to achieve international standards.

"Briefly, I would like to offer my views on ethics and social science research. Social science research studies would in most cases be classified as minimal risk. However, an ERC must ensure that the subjects are not exposed to harm that is not considered physical in nature. There may, for example, be studies that create the possibility of subjects losing their privacy resulting in confidential information leaking out and the subject suffering emotional and/or psychological stress. It is therefore very important for an ERC to "think outside the box" during the review process and consider all aspects of a social science study protocol/proposal to ensure that the subjects' rights and welfare are not compromised."

Rev Philip. N. Owuor

Rev Philip Owuor studied Theology at the African International University. He is a member the organization of professional chaplains of East Africa (OPCEA) having studied Clinical Pastoral Education (C.P.E) which is a four unit course, 400hours each unit. This course is organized by the Servants of the Sick Training Centre. Rev Owuor is also currently the Chaplain at the Nairobi Hospital and also a Clergy with All Saints Cathedral responsible for Hospital Visitation. Dr Owuor has been a member of the Aga Khan University Hospital Research and Ethics committee since 2011.

Prior to joining the Holy orders he worked for the Reinsurance industry at Africa Re and Zepre for a total of 24 years as an Underwriter.

Prof. Christine Sekadde-Kigondu

Prof. Christine Sekadde-Kigondu is an Associate Professor in the Department of Human Pathology, School of Medicine University of Nairobi. She holds a PhD degree in Clinical Biochemistry from State University of New York at Buffalo, New York, USA. She has taught in many universities over the years. Her main interests are endocrinology and laboratory andrology. Prof Kigondu has been on international panels advancing research in reproductive health for the African region.

She has published very widely with over eighty publications in both local and international journals. She has supervised many students from different departments in the School of Medicine and other universities for their research in Kenya. Prof Kigondu has received extensive training in Bioethics. She is a member of both Kenyatta National Hospital – University of Nairobi Ethics and Research Committee and KEMRI ERC. Prof Kigondu also actively participates in various training programs in bioethics for university students, scientists, medical personnel and academic staff. She has served as a member on various committees in the university, regionally and internationally.

Protocol Deviation and Violation in Research

Protocol deviation

A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by an IRB (ERC in the case of KEMRI). Upon the discovery, the Principal Investigator should report the deviations to ERC using the standard reporting form.

Minor protocol deviations

Minor protocol deviation refers to any change , divergence, or departure from the study design or procedures of a research protocol that has not been approved by IRB and which DOES NOT have a major impact on the subjects rights, safety or well being, or the completeness, accuracy and reliability of study data.

Protocol violation

A protocol violation is a deviation from the IRB approved protocol that affects or has the potential to affect the subject's rights, safety, or wellbeing and/or completeness, accuracy and reliability of the study data. A protocol deviation is classified as a violation if but not limited to the following cases:-

I. **The deviation has harmed or posed a significant risk of harm to the research subject** e.g. When a research subject received the wrong treatment or incorrect dose of the treatment.
II. **The deviation compromises the scientific integrity of the data collected for the study** e.g. When a research subject was enrolled but does not meet the protocol's eligibility criteria.
III. **The deviation is a willful or knowing breach of human subject protection regulation, policies, or procedures on the part of the investigator** e.g. falsifying research or medical records.
IV. **The deviation involves a serious or continuing non-compliance with local or institutional subject protection regulations, policies or procedures** e.g. When a research study staff is working under an expired professional license or certification.
V. **The deviation is inconsistent with the international human research protection program's research, medical and ethical principal** e.g. A breach of confidentiality.

NB-Protocol violation must be reported to the IRB/ERC as soon as the investigators are aware. For violations/ deviations, investigators should indicate the measures taken to avoid any future similar events.

NIH IRB Professional Administrators Committee *Version5.1*
Regulatory process workgroup *11/18/2005*

Research Ethics in Social Science Research in Health

By Doris Wairimu Njomo,
PhD, Social Scientist, ESACIPAC, KEMRI, Nairobi

Introduction

Social science research refers to the academic disciplines concerned with the society and the relationships of individuals within a society, which primarily rely on empirical approaches. It is commonly used to refer to anthropology, economics, psychology and sociology. In this article, we discuss research ethics while conducting studies on sociology of health and illness in relation to social institutions such as family and community. Sociologists have demonstrated that the spread of diseases is heavily influenced by the socioeconomic status of individuals, ethnic traditions or beliefs, and other cultural factors [1]. Sociology of health and illness studies is conducted by social scientists, following a systematic plan and a conceptual framework.

Social science studies vary along quantitative and qualitative methods. Quantitative methods approach social phenomena through quantifiable evidence, relying on statistical analysis to create valid and reliable general claims which are related to quantity. Qualitative approaches however emphasize understanding of social phenomena through direct observation, communication with participants, or analysis of texts, may stress contextual and subjective accuracy over generality and are related to quality. Most sociology of health and illness studies however utilize both quantitative and qualitative methods for data collection, also known as mixed methods research and triangulation is then done in order to increase validity and credibility of results.

Privacy, Anonymity and Confidentiality

The World Medical Association (WMA) in 1964 developed the Declaration of Helsinki that laid down the guidelines of ethical principles to be followed when conducting medical research that involves human subjects, including research on identifiable human material and data. This was due to disregard for individual rights during clinical trials. These main ethical principles are: beneficence, non-maleficence, autonomy and justice and should be followed in all research involving human subjects.

The social sciences, broadly defined, have promulgated codes of ethics that require social scientists to ensure privacy during data collection and anonymity and confidentiality of the data collected for research purposes. Privacy, anonymity and confidentiality are essential for all participants. Both the rights of respondents and their continued willingness to voluntarily provide answers to scientific inquiries underlie this professional ethic. Where it is anticipated that there will be possible breach of privacy, confidentiality and anonymity, this should be addressed and explained to the participants. Appropriate methods should be devised to ensure privacy at the time of data collection as well as the validity of data. All research should guarantee the participants confidentiality -- they are assured that identifying information will not be made available to anyone who is not directly involved in the study. The stricter standard is the principle of anonymity which essentially means that the participant will remain anonymous throughout the study even to the researchers themselves. Clearly, the anonymity standard is a stronger guarantee of privacy, but it is sometimes difficult to accomplish, especially in situations where participants have to be measured at multiple time points (e.g., a pre-post study). In research projects dealing with stigmatized, sensitive or personal issues and information, anonymity is very important.

The obligation to maintain privacy, anonymity and confidentiality extend to the entire research team and all those who may possibly have access to the information. Researchers should maintain appropriate anonymity and confidentiality of information in creating, storing, accessing, transferring and disposing of records under their control. The records include written and tape recorded information as well as photographs/graphics.

Informed Consent

Essentially, informed consent should protect the research participants and be given without any direct/indirect coercion and inducement. It should be based on adequate briefing given to the participants about the details of the study. This means that prospective research participants must be fully informed about the procedures, benefits and risks involved in research and must give their consent to participate. Participation of individuals or communities in research should be voluntary and it must be clarified that participants have a right to refuse orwithdraw from the study without any penalty. Some social science studies in health such as those dealing with diseases relating to personal behavior may have great risks to participants due to psychological harm.

In any case, it should be clarified that the participants are not expected to give their names or disclose the identity of the person that they give information about. The information should be given both verbally and in writing in a manner and language that the participants know and understand. Essentially, the participants should be furnished with written information giving adequate details of the research. It is the duty of the researchers to ensure that the participants comprehend the information given.In rural areas of Kenya such as in villages of Malindi and Kwale districts, often it is not possible to obtain signed informed consent from the participants due to low literacy levels.

Challenges occur in cases where there is no equivalent of an English word in local languages such as Kigiriama or Kiduruma of coastal Kenya. Where a participant cannot write and is taken through informed consenting process and wishes to take part in the study, a thumb print using ink and ink pad should suffice. Importantly, the consenting process should bedone in the presence of a witness who can read and write and who should sign the informed consent form (ICF). The ICF should be produced in duplicate and one copy left behind with the participant.

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Assent for minors

Informed consent in the case of research with children should be sought from the parents/guardians as well as the children themselves. In Kenya, the legal age of assent is 13 – 17 years old, where the parents/guardians consent to participate, and the children have declined, the rights of the children should be respected. The consent from parents/guardians should be waived only in special cases such as child abuse. Peer review is indispensable and the protection of children especially from the immediate consequences of research gains is of prime importance.

Verbal consent from community gatekeepers.

In most situations, there is a need to obtain permission of the 'community gatekeeper' (chiefs, village elders, etc.) to access the participants for research. It is important however to bear in mind that permission obtained from the gatekeeper cannot be substituted for the need to take separate and full informed consent from the participants. The rights of participants in such situations are the same as in all other cases and need determined protection.For obtaining permission of the gatekeeper, no pre-condition demanding sharing of information or data obtained should be accepted.In the process of research or data collection, adequate care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardized.

Research methods- ethics and situations

Social Science in health research is usually designed as mixed methods study. There are four major ways of conducting mixed methods studies:

- The Convergent Parallel Design where both qualitative and quantitative data are collected concurrently, the two data sets are analyzed separately and data mixed by merging the results during interpretation.
- The Explanatory Sequential Design where the researcher starts by collecting and analyzing the quantitative data and then collects qualitative data as a follow up to the quantitative results. The quantitative results are used to shape the qualitative research questions, sampling and data collection. Challenges of this approach include difficulty in securing ethical review approval when the second phase cannot be specified before the first phase is complete.
- The Exploratory Sequential Design where the researcher starts by collecting and analyzing the qualitative data and then shapes the quantitative phase by specifying research questions and variables, developing an instrument, and/or generating a type of classification.
- The Embedded Design where the researcher collects and analyzes quantitative and qualitative data within a quantitative research design, qualitative research design, or research procedure.

Others- stories from the field and pictures/graphics

Time management is one of the major challenges experienced in the field during the implementation of social science research studies. To begin with, the research tools (quantitative and qualitative) require clear understanding by the persons who administer them. In most cases, the researchers have to rely on field assistants/enumerators who they recruit from the study sites based on an agreed criterion and then train. Training consumes a lot of time as there is need to come to a consensus on the intended meaning of each part of the ICF and the data collection tool in English, Swahili and local languages (Kigiriama and Kiduruma).The field assistants are expected to interpret all the questions as intended as well as pose each question without leading the respondent to give a certain answer. It is easier to train the field assistants to conduct quantitative data collection but much more difficult to train them to collect qualitative data. To enhance understanding of the process of qualitative data collection, the field assistants usually go through role-playing sessions during training.

Conducting quantitative data collection through household surveys requires a lot of movement from house-to-house which in rural villages of Coastal Kenya can prove to be very time consuming and tiring especially because the populations are sparsely distributed and the climatic conditions are unfavorable due to high temperatures. Collecting qualitative data for example using Focus Group Discussions (FGDs) and In-depth Interviews (IDIs) requires a lot of patience on the part of the enumerator, normally a moderator who moderates the discussion and a note-taker who not only takes the notes but also manages the tape-recording in the case of FGDs and an interviewer who interviews and takes notes in the case of IDIs.

For an FGD to take off, it is a requirement that there be a group of 8-12 participants and in some cases a lot of time is spent while waiting for the group to arrive and settle down so as to adhere to the requirements [2]. Qualitative tools seek to understand the how and the why and therefore call for probing in order to get in-depth information about a phenomenon. The field assistants/enumerators have to be very keen so as not to miss out on any information.Qualitative studies can be very expensive especially because the note-taker and moderator need to transcribe the recorded information back and forth from local language to English and compare with handwritten notes ensuring that no information is lost and data quality is maintained.

Transport Reimbursement, Refreshments and FGD Venues

While conducting social science research especially through FGDs, the participants are expected to assemble at a pre-agreed upon venue for the discussion to take place. The research team is expected to meet the cost of travel by reimbursing each participant with funds. In rural areas where there may be no public means of transport, the participants have to walk to the discussion venue but still claim for transport reimbursement.

Due to poverty levels of some communities, it is hard to determine if the participants consent to take part in the discussion because of the funds given to cater for transport or because they willingly want to provide information for the study. In a qualitative study conducted to determine factors that influence compliance with mass drug administration for lymphatic filariasis elimination in

Kinango District, Kwale County, more than 20 members of a women's group presented themselves for an FGD session. It appeared that even though prior to the date, instructions had clearly been given to the group leader that only 8-12 members were required, all members wanted to take part because they got word that transport costs would be reimbursed. This research team had to incur extra costs because all (more than 20) group members had to be given the transport funds while only a few (8-12) members took part in the group discussion.

Furthermore, as a way of keeping the discussion lively, the research team has to provide refreshments for the participants and sometimes it appears as if the participants consent to take part in the discussion because they are assured of the refreshments especially in areas where there is hunger or food shortage.Sometimes the women who participate in FGDs have requested that the research team provide a meal or provide them with some flour to take back home.

Moreover, in the same rural areas, finding a suitable venue for FGDs such as a room with a roof and walls to minimize the recording of noise made by animals and children playing outside is usually difficult. Often, venues for discussions are found at Shopping Centres and draw lots of attention from passers by. On one occasion at a village in Malindi district, an FGD was interrupted by a drunkard who walked into the room demanding to know what was going on. In such circumstances the moderator of the discussion is advised to pause and continue only after finding a solution of keeping such an intruder away.

Photo 1: Training of field assistants in Kilifi District.

Photo 2: Household survey in Sabaki, Malindi District

Photo 3: FGD in Kinango district, Kwale County

Photo 4: In-depth Interview in Sabaki, Malindi

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Conducting Ethical Social Science Research with Women who are Vulnerable to Gender-Based Violence

Janet M. Turan and Abigail M. Hatcher

For the past several years, our team, composed of researchers from KEMRI, the University of California, San Francisco (UCSF), and the University of Alabama at Birmingham (UAB), has been conducting social science research to understand and reduce HIV-related stigma and discrimination experienced by pregnant women in Nyanza Province. Our methods have been largely questionnaires and qualitative research methods (in-depth interviews, focus groups, non-participant observation), along with social and behavioral interventions. In our first qualitative exploratory studies of the effects of HIV on uptake and quality of maternity services in Kisumu, we began to realize that some pregnant women were at risk of negative social consequences—including abandonment and gender-based violence—as a result of disclosure of HIV-positive status. In further analysis, we learned that women feared taking up key health services, such as getting tested for HIV, without first obtaining partner consent.

[1]This early realization led us to include questionnaire items on fears and experiences of gender-based violence in our subsequent quantitative Maternity in Migori and AIDS Stigma (MAMAS) Study.[2] Our findings from MAMAS about the high rates of anticipated violence from a male partner at baseline (26%) and the high rates of women in MAMAS who reported actually experiencing intimate partner violence in pregnancy or after the birth (27%), led us to initiate the Gender-Based Violence (GBV) Study. In the GBV Study, we explored the social context and realities of GBV in rural Nyanza;[3,4] and then developed and pilot-tested an antenatal clinic-based community-supported intervention to reduce gender-based violence in a rural Nyanza community.[5]

In the course of these studies, as well as others we have conducted related to prevention of mother-to-child transmission (PMTCT) and maternal health, we have learned the great importance of taking precautions to make sure participation in the research is safe for women and men, and does not result in putting them at even greater risk of negative social consequences. To ensure safety, we initially consulted guidelines on ethical conduct of research on violence against women,[6,7]and spoke with a number of Kenyan legal and ethical experts, including the KEMRI lawyer, Chairman of the KEMRI Ethical Review Committee, an Advocate of the High Court, the Secretary of the KEMRI Ethical Review Committee, and a Senior Legal Counsel for FIDA (the Kenyan Federation of Women Lawyers). We learned that special precautions to protect study participants need to start in the very beginning: from the way that the study is announced in the community; through the informed consent procedures;privacy and confidentiality maintained during data collection and intervention testing; provision of appropriate referrals, and; finally through monitoring of any adverse events related to participation in the research. The approaches we have taken in each of these areas are presented below.

- **Community announcements and recruitment:** When conducting community mobilization and/or general announcements regarding recruitment for the study, we do not announce that the study deals with HIV, stigma, or gender-based violence, but rather describe it as research on the "social barriers" to use of health services in the community. This helps to ensure that those who chose to participate are not stigmatized and do not suffer adverse consequences for participating in research on stigma and violence.

- **Informed consent:** As for any study, informed consent procedures had to be conducted in private and confidential location. A special consideration is that some women do not want to keep or take home a copy of the informed consent form, as this may disclose to others that they are participating in a research project on sensitive topics like HIV or gender-based violence. Thus, study staff are instructed that if the woman does not want to take the form, this is documented and both copies of the signed form are retained in the study files.

- **Questionnaires, interviews and focus groups:** Again, extra precautions to protect privacy and confidentiality are needed when interviews or focus groups contain topics that could put women at risk if others learned the information she provides about sexual behavior, HIV, gender-based violence, or other sensitive topics. This is especially challenging when interviews are conducted in the community and/or during home visits. In order to facilitate group discussion and minimize risks in our focus groups on gender-based violence in the community, we instructed participants not to talk directly about or disclose personal experiences of violence during the focus group or interview.

- **Referrals:** For our studies in rural Nyanza, we developed a referral sheet with contact information (address, directions, and telephone) for local resources for women experiencing or at risk of violence. These resources include one local women's organization in the nearest town that provided counseling services, and three additional

organizations located in Kisumu, the nearest city. Interviewers offered these referral sheets to all women participating in the studies, regardless of whether the woman reported fearing or experiencing violence, but women were free to take the sheet or not, as possession of the sheet might pose a risk for some women. Later, we conducted local stakeholder meetings which allowed us to broaden our potential referrals based on informal and formal community systems to address violence. Now, our team uses a robust locally adapted "referral tree" appropriate for the rural Nyanza setting.[8]

- **Monitoring of adverse events:** Social harm should be assessed at each home or clinic research visit. Participants can be provided with an information sheet and a special numeric code to text to the cell phones of research staff at any time to report such incidents as HIV-related disruption of families, acts of discrimination, and physical harm.Another special consideration is the need to monitor adverse events that may be experienced by research staff or health workers who are participating in data collection or intervention delivery. In the GBV Study, we found that health workers who were screening for GBV and assisting women experiencing violence were seen as a threat by some members of the community, and experienced negative social consequences. For health workers addressing these challenging issues at the clinic, or lay health workers doing so in the community, it is crucial to provide ongoing mentorship to allay potential social harms.

Ethical considerations are paramount when doing any research that touches on issues of stigma, discrimination, and violence with vulnerable populations. However, it should be noted that social science research directly addressing these issues may be subject to greater scrutiny by institutional research boards (IRBs), than biomedical research, which may carry many of the same risks9. This may be because the research is less familiar, the issues are seen as intractable, or because social science tends to address more complex (messy) aspects of patients' lives. Similar to other studies globally,10,11 our experience indicates that it is possible to do safe and ethical research on HIV-related stigma, discrimination, and violence with pregnant women, and that these studies can be invaluable in developing culturally sensitive interventions to reduce stigma and violence, with resultant benefits for the health and well-being of women, men, and children.

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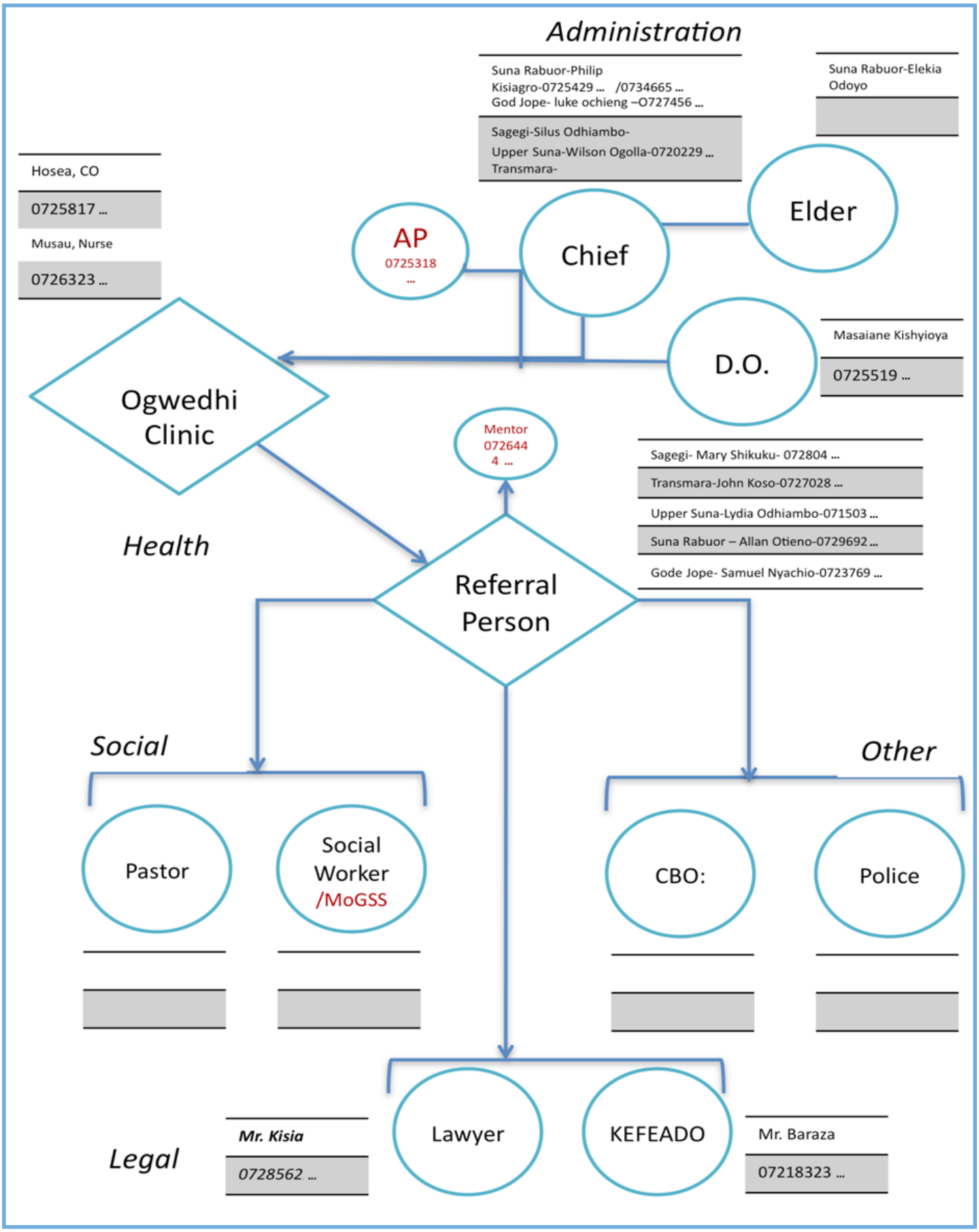

An example of a local referral tree.

Ethical Dilemmas of Social Science Research on PLWHAs in Migori County

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Abstract
This article is based on the experiences drawn from a one-year social science research programme on the impacts of an agricultural intervention on health outcomes of people living with HIV/AIDS in Migori County, Kenya. It discusses the ethical dilemma of maintaining a delicate balance between research ethics, the expectations of the study population and negotiating the community's vested interests in a health-related research project in a low-income society. Informed consent and the intended benefits of the study to the participants continue to be major challenges facing the justification of social science research among people affected by or living with HIV/AIDS in low-income societies.

The discussion in this article will add to the existing ethical debate concerning justification for research among vulnerable persons affected by AIDS by arguing that research is inseparable from epistemological concerns of knowledge production; thus, researchers should enhance efforts to innovatively design action-oriented research projects that foster data collection and address ethical challenges arising from carrying out research on vulnerable groups.

Introduction
HIV/AIDS and food insecurity are two of the leading causes of morbidity and mortality in sub-Saharan Africa. There are an estimated 33 million people living with HIV/AIDS (PLWHA) worldwide, 67% of whom live in sub-Saharan Africa. In Kenya, the prevalence of HIV is estimated to be 4.3% among men aged 14-49 years and 8.0% among women. In Nyanza Province, the site where the study was conducted, the prevalence of HIV is 15.3%; which is more than double the national prevalence of 6.3%. In Kenya, high levels of socio-economic vulnerability among people affected by or living with HIV/AIDS, such as orphans and widows, pose significant challenges to social science research(GOK/UNDP, 1999; Kenya NASCOP, 1998; Nyambedha,2000;).

This vulnerability is aggravated by the increasing levels of poverty and the inability of the extended family to support vulnerable people affected by or living with HIV/AIDS (Ankrah, 1993; Ntozi, 1997; Nyambedha&Aagaard-Hansen,2003;). The Shamba Maisha study sought to find a sustainable solution to the two major causes of vulnerability among people living with HIV/AIDS: household financial and food insecurity. This article highlights the ethical dilemmas that the field study team faced regarding informed consent,participants' heightened expectations and decisions regarding whether to intervene in participants' affairs.

Informed Consent and participants' expectations
In human subjects research, informed consent refers to a process through which a mentally-competent individual who has received the necessary information and has adequately understood the information, voluntarily agrees to take part in a study, having arrived at the decision without any coercion, undue influence, inducement or intimidation. All participants in a given research are required to give consent of participation. Whether or not consent is given by all after a careful examination of the same is the topic of discussion. In the 'Shamba Maisha'study, a multi-sectoral agriculture and microfinance intervention for health, all the participants were consented in the language that they understood best.

As the study progressed, several questions pertaining to the participants' expectations emerged from the research. For instance, a health caregiver who was effectively consented asked the study team, ''what are you going to give my children after studying them for one year?'' She wanted to know if we would "take" her orphaned child like a certain NGO did in their neighborhood. "Taking the orphans" ("kawonyithindkiye") is a phrase used to refer to a long-term commitment that an NGO or a financially capable member of an extended family undertakes to shape the entire childhood of an orphaned child mostly by educating the orphan and not just helping irregularly with immediate material assistance.

In as much as the study outlined mechanisms to strengthen household economic status and build the capacity of the participants to produce enough food to meet their dietary requirement, such expectations, requests and the living conditions faced by orphans and widows affected by or living with HIV/AIDS in a poverty-stricken community forms the wider context within which I write this article. According to the American Anthropological Association (AAA, 1998) guidelines, researchers are expected to explain to the research participants the purpose of the research. This is done in order to inform and protect the participants who

are expected to understand the reasons for the research and the consequences of taking part in it.

It is felt that genuine consent can only be obtained after the purpose of research has been carefully explained to prospective participants (CIOMS, 2002;Nuffield Council on Bioethics, 2004). This process of obtaining informed consent should be, in my view, a continuous exercise that enables research participants to understand the aims and consequences of participating in the research. However, because of the living conditions of people affected by HIV/AIDS, many people in the study area did not believe that somebody working closely with KEMRI and frequently supervised by lots of white people from the West could just come all the way to ask PLWHAs and their families' questions regarding their lives without providing direct assistance to them. Despite Shamba Maisha's trainings on sustainable, market oriented agriculture and issuance of a start up agricultural loan, many participants still believed that our intention in the long run was to 'take' the orphans and give grants the participants. There were rumours in the villages that the Shamba Maisha team in the area had been given a lot of money to help the orphans and widows and all they did was 'eat all that money' themselves. They frequently asked the research assistants why we were not doing the same as other donor-funded organisations in the neighbouring localities that were 'taking' orphans.

To intervene or not to intervene

Research involving human participants continually emphasizes the need to ensure that the researcher strictly adheres to the interview session and questions in order to ensure consistency in the way data are collected. Research participants undergoing repeated study visits often develop a certain level of trust in the research staff and may volunteer information about their day-to-day lives or practices that is not part of the questions asked in the interview. The research staff has to make a decision whether they need to act on the information or not, and to what extent they may act on that information. Myths or rumours in the participants' community may be a source of information that influences a participant's decision-making process or practices as illustrated in the case below.

John's* family;

During one of the regular home visits carried out in the Shamba Maisha study, one of the participants narrated to the research assistant that she and her husband had resolved to be sharing the husband's drugs between them while keeping the wife's supply to be used at a time when the country would supposedly run out of ARVs after the March2013 general election,depending on who was elected the president of the Republic of Kenya, , The mandate of the research assistant at this point was to carry out pill counts and not to advice and she did just that. She, however, shared with me the information she had received from the participant on her return from the field. The research assistant was, however, greatly concerned that she had missed an opportunity to advise the participant on the right thing and was persistently worried of what would happen to the female participants' health given that she was now taking a different ARV regimen from what had been prescribed by the healthcare provider.

The district's social science department was informed of the couple's decision after the realization the female participant's viral load was rising in the subsequent clinic visit. The social science department professionally took up the matter with the couple, with disastrous results. The female participant decided to withdraw from the study citing intimidation and intrusion in her family affairs by the research assistant. As fate would have it, her husband passed on just a week after his wife's decision to withdraw from the study, and the participant immediately informed the research staff. Although at this point it was too late to reverse the consequences of the couple's decision, we were left with critical questions for which there were no immediate answers: firstly, had the research assistant advised the couple on what to do in the first instance they reported their decision to share their drugs, would the situation have turned out differently? Secondly, would the couple have taken the research staff's advice not to share their drugs given their apprehension and their belief that they could not be guaranteed of ARV supply after the March 2013 general elections?

Food for thought.

The name has been changed for confidentiality purposes.

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CASE CHALLENGE:

Investigation of Vaginal Microbicides

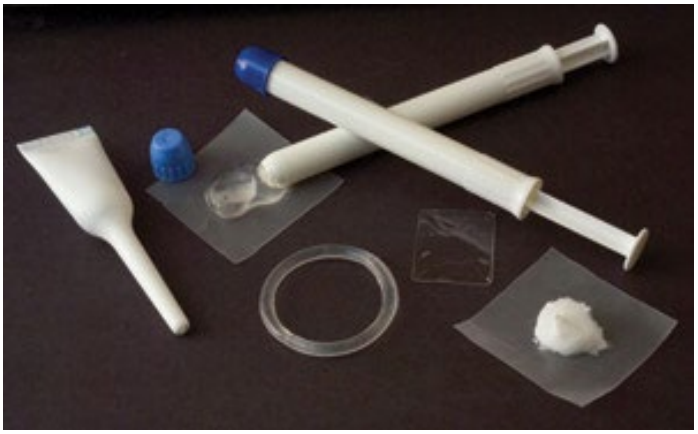
Adapted from the case study titled "Standard of Care HIV Prevention Trials" Provided by Katherine Shapiro

An East African Country has scattered network of community family-planning clinics that provide free access to family planning methods, maternity related services and some diagnosis and care for sexually transmitted infections (STIs): however patients must pay for any medications and physicians at these clinics often write prescriptions for drugs that patients cannot afford. The clinics also do not offer papanicolaou (Pap) smears1 for cervical cancer, since they do not have equipment or personnel to perform them.

A group of researchers have received a grant from a foreign health agency to carry out a multi-site, randomized controlled trial at some of the country's family-planning clinics to test for effectiveness of a vaginal microbicide2 for prevention of HIV transmission in women. Study participants will be routinely tested and treated for viral and bacterial STIs. They will also get annual Pap Smears, and appropriate medications for most disorders (including STIs) will be provided free of charge. Women who present with problems unrelated to the study, such as diarrhea and malaria, will be referred to a clinician on the study team and will receive necessary treatment without charge.

The researchers say that funders have provided support at this level in previous trials, on the basis that research participants owed the "standard of care" that they would receive in the sponsor's country. The study protocol does not specify whether, and if so how, access to this level of care would be provided after completion of the 3 year trial.

The information material that will be provided to potential participants explains the possible benefits and harms in detail; before giving informed consent the women must demonstrate, through their answers to a short question, that they comprehend basic facts about the study. Nonetheless, a member of the research ethics committee has expressed concern that women might not carefully weigh the risks and benefits but instead will join the study simply to get health services not otherwise available to them, this concern about unfair inducement is echoed in reverse in a report from the community advisory board for family-planning network, which states that women served by the clinics who were not eligible to join similar studies in the past have voiced frustration that this kept them from having access to the same quality of health services



Questions:

1. **How would you define "unfair inducement"? Does the provision of this level of care present an "unfair inducement" to participate in the research?**
2. **How would you address the concerns of the women who have not been chosen to participate in the study?**
3. **Given background level of care, should the study be conducted in this country?**

[1]A routine screening test used for detection of early cervical abnormalities, namely precancerous dysplastic changes of the uterine cervix, together with viral, bacterial and fungal infections of the cervix and vagina. Cervical screening is a relatively simple, low cost and non-invasive method. Regular screening for cervical cancer reduces both the mortality and incidence of cervical carcinoma.

[2] Vaginal microbicides are chemical agents used by women within the vagina in order to prevent infection by HIV and potentially by other enveloped viruses and sexually transmitted pathogens. Prototype microbicides are designed to be inserted prior to sexual intercourse and could also be contraceptive, although most current potential microbicides are not. The development of vaginal microbicides assumes a great significance in the context of HIV epidemic, because an effective microbicide would be an effective women controlled method. Condoms, though very effective against the transmission of HIV remain under control of the male partners.

The first responses sent in will receive a prize. The first correct response will also receive a prize.
Answers should be submitted to DDRT@kemri.org

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Partners: