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Ethics of conducting Research on vulnerable Groups

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CALL FOR ARTICLES

The KEMRI Bioethics Review is eager to relay information about Ethics in Research within KEMRI and elsewhere on a regular basis. The Chief Editor encourages articles submission from all members of staff at the Institute.

Next theme: Ethics of conducting Clinical Trials Research

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From the Editor In Chief

PROF ELIZABETH BUKUSI
DEPUTY DIRECTOR, RESEARCH AND TRAINING

Welcome to the third issue of this year with a focus on research among vulnerable population. The Belmont Report defines vulnerable populations as those groups that might "bear unequal burdens in research" because of their "ready availability in settings where research is conducted". This reminds of my earliest contact with research as a medical student. A lecturer came to class and asked us to test a particular product. We all consented, at least by participation though we were not asked to sign anywhere. The topic this lecturer taught was a difficult subject (not sure which subject in medicine is easy) and no one wanted to offend the senior colleague. We all participated, indicated our response to the product we tested. The next week or so, the lecturer brought us all sodas. We appreciated it and felt very privileged. We did not realize our vulnerability as students doing research with a lecturer. This was before some of the advances made in the field of research regulation worldwide and before the structures that NACOSTI has worked hard to create.

In this issue we feature articles on vulnerable subjects who include: People who inject drugs, men who have sex with men, and sex workers. These are just few examples of vulnerable population that we hope offer insight on the ethical challenges of vulnerable populations and give guidance on the extra safeguard measures required to ensure that the autonomy of such groups are always protected. It is our responsibility as researchers to conduct research, but we MUST do so carefully, respectfully and ethically. This duty is further magnified when undertaking research on any groups of people who are perceived to have less autonomy in any particular circumstance.

The concept of autonomy is very important in research involving vulnerable subjects. Individuals should be treated as autonomous agents, and when that autonomy is affected or diminished as in the case of vulnerable populations, then those individuals are entitled to increased protection. Before granting approval for research, ethical committees must consider if adequate information and options are provided and if indeed informed consent can be obtained in such circumstances without coercion or undue influence. Any researcher seeking ethical approval either from the KEMRI ERC or any other accredited ethical review committee should be aware of the need to adequately justify the inclusion of vulnerable subjects such as prisoners, students, children e.t.c in their research.

Of note however that the principle of justice demands that vulnerable populations should not be automatically excluded from research or treated as if their health or other concerns do not merit scientific study or intervention. It is however important that they be included in research that can respond to their specific needs and circumstances as well and that they are not used as an easy target or available populations to respond to research that will benefit other population groups. Typically, the clear justification for inclusion of a vulnerable group in research is when there is sufficient evidence that a problem disproportionately or otherwise directly also affects such a group.

Researchers must be cautious when dealing with vulnerable populations as misconduct within such groups is more likely to attract unwarranted attention in ways that may adversely affect the reputation of researchers or the institutions they are part of. This may make it more difficult for future researchers to gain access to particular groups or communities or conduct research in some regions. I hope you will find this issue informative.

Prof Elizabeth Bukusi

The Chief Editor

A word from the Director KEMRI

PROF SOLOMON MPOKE, PhD, MBS DIRECTOR KEMRI



Telcome to this issue on Vulnerable Subjects in Research. Biomedical research plays a crucial role in improving health and quality of life of all human populations, including those who may be vulnerable or marginalized in one way or another. Good quality research studies offer accurate

and objective representation of wide-ranging circumstances and helps to bring to light the existing health gaps within a population. However, some pockets of a population may be easily left out, or have their concerns not easily attended to. KEM-RI's core mandate is not only limited to conducting high quality research for health but also guaranteeing that such research is done with integrity that meets the highest possible ethical standards- and that all relevant populations are duly attended to.

We live in a diverse society with differing social, economic and health status, and also where existing health problems vary across populations. Targeted interventions are needed to provide solutions to the prevailing health problems afflicting different groups of people in our communities. Good scientific ethics demands that research must include groups in the population that may be considered vulnerable e.g. prisoners, students, subordinates, sex workers, and other marginalized groups. These groups of people may be considered to have reduced autonomy and would therefore need additional attention and protection when research that involves them is being reviewed by ethical review committees.

Another common challenge while conducting research is that, despite relevant safeguards, some participants in research may often feel they are being used (common word is as "guinea pigs") and that the researchers do not care about their wellbeing. Such periences discourage antagonism this reinforces the sense of vulnerability of the

a perception therefore 46 It is critical that all **KEMRI** researchers exercise due diligence to ensure that vulnerable research in that they subjects are protected lead to lack of trust and empowered to have towards a full understanding of researchers among the their participation in a community or groups proposed study, and any involved. If research is limitations of the study as not conducted because a strategy to effectively of this perception, then manage the expectations the study subjects"

groups that such research is supposed to be helping. However, there is a solution to this, and this is found in the informed consent forms. With adequate informed consent, such participants have an opportunity to inform the Ethics Research Committees of any concerns they may have concerning the study. The information provided on the consent is therefore more than just a routine requirement; it is a critical part of empowering those engaged in research by allowing them an avenue through which they can voice their concerns as part of protecting their rights.

It is critical that all KEMRI researchers exercise due diligence to ensure that vulnerable subjects are protected and empowered to have a full understanding of their participation in a proposed study, and any limitations of the study as a strategy to effectively manage the expectations of the study subjects. It remains important that vulnerable groups are not excluded from research to ensure that their well being and research needs are taken care of. I hope this issue on vulnerable subjects will be informative to you.

> Prof Solomon Mpoke Director KEMRI

TIPS ON CONDUCTING RESEARCH WITH PEOPLE WHO INJECT DRUGS

Prof Kawango Agot, Director, Impact Research & Development Organization

have asked myself many times why most of us researchers like to locate our studies in or recruit our participants from relatively deprived communities – we seem to have unwritten affinity to sites in and around informal settlements, such as Kibera, Majengo, Kariobangi, Mathare, Korogocho and Mukuruin Nairobi; Obunga, Manyatta, Nyalenda and Bandani in Kisumu; or in hospitals serving poor rural communities. I ask myself: Why aren't our clinical trials conducted in Runda, Kileleshwa, Westlands, Muthaiga (Nairobi) or Milimani, Tom Mboya, Grace Ogot (Kisumu), or Nyali (Mombasa) or other affluent neighborhoods in our cities? What propor-



Kibera informal settlement

Nairobi, Aga Khan, MM Shah and Avenue,? And this is not just when we study conditions assumed to be of the "poor" such as diarrheal diseases, skin infections, malnutrition, and the like. Is it because individuals from these settings are likely to refuse to participate in a study on HIV, for example, yet they equally benefit from drugs and other interventions resulting from such studies? Or is it too expensive or cumbersome to conduct studies in such neighborhoods that researchers purposefully keep a wide berth between them and these neighborhoods or hospitals? I do not have an answer, and neither do I regard research among poor populations as wrong or unethical.

Inclusion of the poor in research work makes it relevant to them, I attempt a discussion on the ethical implications researchers need to consider while conducting research among poor and vulnerable populations. The Belmont Report[1] and the Common Rule[2] set forth three principles which guide all research with human subjects, (I prefer to call them human participants). These include justice, respect for persons, and beneficence. Institutional Review Boards (IRBs) or Ethics and Research Committees (ERCs) responsible for protecting the rights and welfare of human research participants are guided by these principles, as are study funders, sponsors and investigators. While these principles guide research with all human participants, special attention needs to be paid to studies involving certain categories of people, termed as 'vulnerable population'. These include children, pregnant women, prisoners, minority populations, economically disadvantaged groups, people with various disabilities - mostly mental and physical, patients, and so on. These groups may, for various reasons, be mentally incapable of understanding the study well enough to provide informed consent. They may also be compelled to participate in a study because of the anticipated gain or their inability to decline, especially if the researcher holds power over them (e.g., in doctor-patient, employer-employee or teacher-student relationship - see scale where one person is "heavy" enough to call the shots). This piece presents a few tips on how to conduct research with people who inject drugs (PWID): how to recruit them, how to obtain consent, and how to compensate them. The Principle of Justice requires that vulnerable groups participate in research so as



Railway tracks in Kibera informal settlement



to receive their share of benefits from research findings. However, they must be protected from having more than their fair share of burdens

arising from participating in research. Similarly, the Principle of Beneficence calls on investigators to do no harm. This includes avoiding undue influence and being keen to ensure that vulnerable participants fully understand the risks of research and the voluntariness of participation before they join. Respect for Persons entails that investigators ensure potential participants have the capacity to make informed decision to participate in a study, without direct or indirect influence. This responsibility extends to protecting those with limited or compromised autonomy. How then do we enroll PWID in studies while providing additional precautions to protect them, knowing as we do that drug use can reduce autonomy and compromise capacity for decision-making?

However, when all is said and done about the three principles and how they apply to vulnerable populations, more still remains to be done. The Australian National Health and Medical Research Council [3] aptly states: "The responsibility for maintaining trust and ethical standards cannot depend solely on rules or guidelines. Trustworthiness of both research and researchers is a product of engagement between people. It involves transparent and honest dealing with values and principles....and a subtlety of judgment required to eliminate prejudice and maintain respect and human dignity." Thus, researchers should not only obtain IRB/ ERC approval of study protocol or signed con-



sent from study participants; they should also ensure they build a solid relationship with participants based on trust and mutual respect.

Recruitment of participants



Criminalization of injecting drug use in many countries make PWID arguably the most stigmatized – hence the most hidden – population of all vulnerable populations. In fact, except for literature from Australia, PWID are hardly listed among vulnerable populations in most literature on the ethics of conducting research with human participants. Because PWID are highly vulnerable and face extreme social isolation, the effort to contact them for research purposes poses a number of questions concerning privacy and confidentiality. A key question that arises is whether participants would be publicly identified as people who use drugs because of their association with the study once word gets out that the study is recruiting such participants.

There are a number ways to address this concern. One is to meaningfully engage PWID in the protocol-making process; for example, by including their representatives in community advisory board or groups, running sensitive topics by them (such as title of the study), asking them to review the consent documents, discussing with them how and where to conduct recruitment and where to locate the study, getting their views on who should conduct recruitment, and so on. Two is to include in the protocol, for IRB/ERC review and concurrence, how potential participants will be identified, where participant recruitment will take place, and how the recruitment



process will be conducted in order to protect the privacy of participants. Three is to select a neutral study name, as that is what gets known by the public. For example, instead of having a study named "Substance Abuse Study" or "Injecting Drug Use Study, one could name it "PWID Study" or "Key Population Study". In a recent study conducted by Impact Research and Development Organization in collaboration with Kenya Medical Research Institute and University of California at Davis, we named the study "XXX [name of study location] Health Study". A name such as this can be written anywhere and the public would not know what the study is about. Then in the consent document, the actual descriptive title, eligible population and purpose of the study are discussed so potential participants are not misled into joining a study where full disclosure has not been made; however,



because the document is seen only by the study staff and each participant individually, the details are unlikely to spill out unless a participant or a study staff discloses the details to the public. Investigators should be aware that like most vulnerable populations, PWID may have a group advocating for their rights, and you do not want to be in collision path with them!

Once the name of the study is not obvious to the public regarding the population targeted, a site should be selected, with consultation with representatives from PWID, that is neither too secluded (as this may raise suspicion of the public) nor too open (as this may lead to involuntary disclosure of the target population). Ideally,

recruiters and tracers should be their peers who know where to find them and whom they trust well enough not to disclose their identity to the wrong people (read: the police). Our study is located at a Drop-in Center (DiCE) serving different Key

Populations (female sex workers, men who have sex with men, and PWID). When participants come in, it is not obvious whether they come for the study or for routine services at the DiCE. This way, and working with peer educators as recruiters/tracers, we are able to conceal the identities of the participants from the public and other DiCE users. In addition, some participants prefer to be interviewed in their safe spaces, and the study makes this provision.

Consenting:

Investigators are called upon to evaluate the ability of their participants to independently enter into informed-consent agreement and protect their own interests throughout the study. Drug (mis) use has the potential to impair the ability of potential or actual participants to make rational decision about joining or remaining in a study (often referred to as decisional impairment). However, depending on the extent of addiction, investigators should train study staff on how to assess whether the participant is cognitively competent to understand the study and make an informed decision to participate or not. Most PWID have what



is known as situational impairment, in which they move in and out of stupor or just being high. The study staff should take advantage of windows of soberness to administer consent, and importantly, assess comprehension of the consent by asking questions after each paragraph, giving quizzes to document understanding, asking them to state in their own words key areas such as purpose of the study, study procedures, risks and benefits, asking for

their understanding of technical terms and phrases, and so on. Additionally, it should become clear to the participants what the study can and cannot provide as many expect additional benefits, such as clean needles and syringes, Hepatitis B and C testing, Methadone....and even job opportunities. While administering enrolment consent may appear difficult, it is relatively easier compared to ensuring participants turn up sober for follow up visits. The tendency is for PWID to come when intoxicated, and in studies where the window for follow-up visits is narrow, participants may easily make the study fail when they miss their visits or come too intoxicated to understand the study procedures so cannot give consent for continued participation. PWID should provide written consent, even more so than non-vulnerable participants. This is because of the temptation to justify oral consent because of their compromised status, and shortchange them in the process. That said, extra care must be taken not to disclose their participation to family members or the public, because in the state of being intoxicated they may leave the consent documents where it can be accessed by unauthorized persons. Study staff should ask participants if it is safe for them to carry the document home or if they prefer to have it kept at the clinic; alternatively, investigators should con-

sider requesting for a waiver from the IRBs/ERCs to exclude the names of participants and only have their study numbers, signature and date included, which would make it relatively more difficult to link the document with any individual.

For participation in research,

Compensation:

studies often refund fare for coming to the study site and compensate participants for time spent at the study venue, including time taken to travel to and from the venue. Setting an appropriate compensation for time pose challenges in terms of setting the amounts or types of compensation that would not be deemed by IRBs/ERCs or the participants as coercive. It is reasonable to factor in a full day for a study

where procedures and waiting time take at least 4

hours, excluding travel time to and from the study site. This is because even when total time spent travelling and at the clinic is, say, 6 hours, the disruption of going for a study visit would not allow the participant to engage in other income-generating activities for the remaining time. For instance, a participant cannot go to the farm or sell her merchandise on the day of her/his study visit, and investigators should consider compensating for one full day of lost wages. Even when a visit takes only 2 hours, a participant is unlikely to go to the shamba (farm)unless she/ he visits the study site in the afternoon, a practice study staff often discourage. The point I am making is that if compensation for time is being considered, it should be based on actual time taken to participate in the study procedures, time taken to travel to and from the study venue, and the disruption of routine work simply by the fact that the participant needs to set everything aside to go for the visit. That said, compensation should be based on some justifiable basis, and daily wage for a typical participant has been used in many studies to set the rate. All factors constant, investigators should avoid incremental compensation or a larger compensation at the final visit as this will influence participants' decision to continue coming for study appointments even if they would otherwise withdraw. Where finan-

cial compensation is likely to lead to social harm, for example in settings where intimate partner violence is common, a female participant being compensated with money may face violence if she does not surrender it to her partner. In such instances – and investigators are encouraged to be well versed with the social milieu of

their study communities ahead of finalizing the protocol non-monetary compensation is recommended. What about compensating a participant who injects drugs? The principle of justice posits that study participants should not be treated differently just because they are vulnerable. On the other hand, there is genuine concern that compensation might influence the voluntariness of participation. While compensation for time might not be of big concern in the

case of people who use drugs occasionally, it might be a challenge in the case of people who have a drug addiction. In addition, the type of compensation should be cognizant of the principle of do no harm (if you suspect that they will use the money to buy drugs or if the compensation is so high that it acts as undue inducement to trial participation); however, this does not mean that some participants should be compensated more than others, but rather, that the level of addiction of participants may justify providing cash compensation in some cases and not in others. Another option is to withhold payment in circumstances where risk of harm to certain participants is elevated, and providing it at a later time where these concerns have subsided. Whatever the decision, the type and value/amount of compensation must be identical to all participants in a given site, because providing different types of compensation to different participants depending on their level of addiction is both unethical and could bias the data or create unnecessary friction between study staff and participants who feel shortchanged if they do not get the type of compensation they prefer. Importantly, investigators should be aware that when enrolling PWID as participants, especially in a prospective study, chances are high that study staff may learn of some criminal behavior a participant may have engaged in or where they obtain their drugs. The staff should be trained to remember that they are not working for the police, and should NOT under any circumstances divulge any confi-



dential information entrusted to them by the participants or which they bump on to in the course of interacting with these participants – this would make participants lose trust in the study completely.

Conclusions:

Hidden, yes; socially excluded, yes; less informed, at times; but PWID have a right to be included in studies if researchers expect results to be significant to them. However, they must be accorded extra protection. To do so, investigators must collect views from representatives of PWID groups to inform protocol development, including recruitment, wording of consent documents, locating study sites, hiring of recruiters/tracers, and so on.

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Collaborating with Gay Men, Other Men Who Have Sex with Men, and Transgender Individuals (GMT) Organizations on HIV Prevention, and Care Research in Coastal Kenya

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n September 2005, scientists at the KEMRI-Wellcome Trust Research Programme (KWTRP) in Kilifi sought permission from KEMRI's Ethical Review Committee (ERC) to enrol adult volunteers who reported recent anal sex, with a view of studying HIV and sexually transmitted infections (STI) acquisition risks in men who have sex with men (MSM) and other at-risk populations. While MSM had long been recognized to exist in Kenya (1, 2), KEMRI's ERC was the first ethics review board in Kenya to grant scientists permission to enrol MSM in research. Since then, over 1,400 MSM have been mobilized and screened for HIV-1 infections, and over 1,000 MSM have enrolled in biomedical research studies at the KEMRI research clinic in Mtwapa.

Gay men, other men who have sex with men, and transgender individuals (GMT) were neglected in

the early HIV epidemic in Africa, due to stigma, discrimination, and even denial of their existence (1). In the past 5-6 years, however, increasing attention has been paid to the high risk of male-male sex globally, including in sub-Saharan Africa (3, 4). In 2011, the World Health Organization (WHO) published its first guidelines on prevention and treatment of HIV and other STI among MSM and transgender people (5). This was a critical step towards the recognition of this population's special needs. Respect for and protection of human rights is a key principle of this document, which made two important recommendations on human rights and non-discrimination in health care settings that bear repeating here:

- 1. "Legislators and other government authorities should establish antidiscrimination and protective laws, derived from international human rights standards, in order to eliminate discrimination and violence faced by MSM and transgender people, and reduce their vulnerability to infection with HIV, and the impacts of HIV and AIDS.
- 2. Health services should be made inclusive of MSM and transgender people, based on the principles of medical ethics and the right to health (5)."

These principles are carried forward into the new

WHO guidelines on HIV prevention, diagnosis, treatment and care for key populations (6), and are supported by the Kenya Ministry of Health's National AIDS and STI Control Programme (7).

KWTRP has established a strategy for community engagement (CE) to address and minimize social risks for GMT research participants. This strategy was developed after an attack on the KEMRI research clinic in February 2010 which specifically targeted this group (8). Before the attack, a community advisory board (CAB) with representation from at-risk populations and their advocates had been in place, but this CAB did not represent the broader community. The current CE strategy involves not only working with GMT representatives and their advocates, but also mobilising and educating various stakeholders of the broader Mtwapa community, including religious leaders, health care workers, tra-

ditional chiefs, village elders, and government representatives. Another important component of the current CE strategy is the involvement of other at risk populations such as female sex workers (FSW) and injection drug users (IDU), in our research, in order to avoid the impression Photo by freedigital photos.net

that KEMRI is singling out GMT

as a risk group. Ongoing CE efforts aim to ensure an accurate understanding of our research mission and our goals of preventing HIV and improving care for at risk populations in and around Mtwapa.

In light of this mission, KEMRI researchers recently consulted relevant GMT organizations in the Coast, including 'G-10', a recently established national LGBT coordinating research liaison group under the umbrella of the Gay and Lesbian Coalition of Kenya (GALCK), and Nelion, a coastal coordinating organization for GMT, about the need to plan and discuss new research together. An outcome of this consultation was the formation of a new GMT committee on research in the Coast, called "Utafiti Pwani" (UP). Because of the stigma and discrimination faced by these groups, research involving GMT individuals presents unique challenges in order to

ensure participant safety and benefit. With the formation of Utafiti Pwani, KEMRI researchers saw an opportunity to learn more about the views of GMT leadership concerning ethical principles and the research KEMRI has conducted with GMT individuals over the past 9 years. We therefore invited the newly formed Utafiti Pwani committee to a meeting to discuss the ethical principles of research.

We chose as the focus of our discussion the general principles of autonomy, beneficence, non-malevolence, and justice, as outlined in the Belmont Report and in a recent publication "Respect, Protect and Fulfil" on best practices for conducting research with GMT groups in rights-constrained environments (9, 10). During a first meeting between Utafiti Pwani members and KEMRI researchers, these four ethical principles were presented. The five GMT representatives present were asked to share

their views and understandings of these principles in an open discussion. Group consent was obtained prior to the meeting, and notes were taken by the four researchers present (MM, EvdE, EG, and EJS). Notes were compiled and edited after the meeting, and the draft manuscript was then presented back to GMT

representatives for critical review and comment.

Autonomy was the first principle discussed. Autonomy is not a univocal concept, but for the purpose of the discussion, the concept of personal autonomy was discussed and defined as individual self-rule or decision-making that is free from controlling interference by others and free from limitation, such as a limited understanding that prevents meaningful choice. In connection with this definition, the following elements or conditions were discussed:

1. Competence (the ability to understand) and voluntariness in deciding about research participation. An example was given of persons who are under the influence of drugs or alcohol. This would cause a researcher to determine that the individual lacks (at least temporarily) decision-making capacity. With respect to low education

levels and literacy rates in the GMT community on the coast, empowerment was mentioned ("We have the passion to learn"), as well as providing sufficient time – "no rush" – to decide participation.

2. Accurate information and the right to refuse. GMT representatives referred to the actual information-giving procedures at KEMRI, including information provided in the reception area, at the drop-in centre, in an informed consent video describing ongoing research, and in counselling and clinical sessions. GMT representatives unanimously felt that autonomy is respected during these processes, although they thought professional behaviour from research staff was important: "The way you handle participants/patients...First impressions matter." GMT representatives felt that decisions to refuse research participation were well respected by the research team. In contrast, it was felt that peer workers who provide information in the field were sometimes "under pressure to recruit" or under "pressure to meet research objectives." It was felt that these peer mobilizers need additional training in providing information.

3. Informed consent and balancing risks and benefits. After current informed consent procedures at the KEMRI clinic, it was felt that potential participants were sufficiently informed about the potential benefits and risks of their choice of participation, however, "there are sometimes risks you are not thinking about, they are not in the consent form..." "Risks can come in at a later stage..." It was recognized that participants are allowed to withdraw from research at any time, although some benefits of research could be lost by doing so: "You (as a participant) can pull out of the research anytime, but whoever pulls out of the research, doesn't realize the free service...[will no longer be provided]." It was stressed that investigators would do well to solicit and incorporate the suggestions of the GMT community and potential participants in designing research protocols, consent forms, and recruitment strategies.

4. Collaboration, dialogue, and interpersonal trust. Dialogue between researchers and GMT individuals was identified as the most important component needed to address the issue of autonomy. The importance and value of communication was mentioned throughout the discus-



GMT, KEMRI, IAVI, GALCK Consultation meeting on research in coastal Kenya.

sion, and was closely intertwined with truth telling and transparency. In the words of one GMT representative, "It all depends on how open [staff members] are in a given facility..." Communication breakdowns between participants and the research team may be traced back to a lack of clarity about expectations, which can lead to strong emotional reactions and disagreements. These breakdowns should be remedied by maintaining open lines of communication and by ensuring that expectations of the research team are realistic.

5. Ethical conflicts and coercion. As much as an individual's voluntary decision of research participation should not be influenced by others or be based on monetary incentives, GMT individuals may consent to research participation in large part due to medical or financial need. Medical care was frequently mentioned as a benefit of the KEMRI research clinic: "The treatment given professionally when one presents with a medical problem..." or "I presented myself because I needed medical care..."Another challenge that was brought up as possibly coercive was the transport reimbursement provided to participants after attending study visits. This reimbursement is perceived by some in the GMT community as "getting money for participation." In the words of a GMT representative: "GMT are financially restricted, and if you need treatment and you don't have money, it helps when you get 350 shillings..." Another reflected "I see transport reimbursement as a way of taking care of your participants..." It was thought that the needs of GMT indi-



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viduals may sometimes interfere with the autonomy of their decision making.

Recommendations of the GMT representatives about protecting autonomy were therefore to allow adequate time for decision-making, ensure accurate information from all levels of staff, obtain input from the GMT community to improve understanding, clarify expectations regarding services, and provide options for medical care outside of research protocols.

The next principle discussed was beneficence. The principle of beneficence refers to a moral obligation to act for the benefit of others. This was presented as a promotion of well-being, with the notion that individual risks should be acceptable only if overall benefits of the research were prevailing. This led to a lively discussion of both direct and indirect

benefits of research. GMT representatives considered a number of research clinic procedures beneficial, including medical care, treatment, and counselling sessions. transport reimbursement (currently 350 shillings per scheduled visit) was also considered a benefit. In contrast, attending the KEMRI clinic, which is known by the community to serve GMT individuals, was considered an important risk by one GMT representative: "The risk is shame - being insulted, ridiculed and called shoga..." by people in the neighbourhood. Another perceived risk was loss of confidentiality when particular procedures are performed that could potentially identify individuals as HIV infected. The large blood draw for patients enrolled in the acute HIV infection protocol was mentioned as a drawback of research participation. However, most GMT representatives felt that risks and benefits were well balanced. Receiving quality medical care, including STI treatment, was a benefit outweighing the risks of being recognized for entering a "gay" clinic. GMT representatives also reflected on the empowerment that many of their members had gained over the years that KEMRI's research with GMT communities has taken place. In addition, GMT representatives felt that an indirect benefit came from the public health impact of KEMRI's work to reduce HIV and STI transmission, as well as from sharing research findings that can promote the public good. Finally, GMT representatives felt that training peer educators to provide accurate information on ongoing or new research would help promote accurate knowledge of the risks and benefits of potential research participation.

The ethical principle of non-malevolence was described as the researchers' mandate to cause no wilful harm, and to ensure the safety of participants at all times. Discussion of this principle highlighted the difficulty of distinguishing intentional malevolent harm from harm that may occur as an unintended but potential risk of research participation. The idea that most research carries some degree of risk, albeit for which necessary contingency measures are in place, was in itself seen as harmful. The example of large blood draws required for some research protocols was again given. These blood draws were felt to be distressing and unhealthy, and the harm therein improper. Another example concerned the participation of GMT in a recently KEMRI-made CE film called Facing our Fears (11). Some participants felt that public release of the film could identify GMT individuals and potentially cause harm, even though participants in the film provided informed consent. One GMT representative who had been filmed was uncomfortable with the scene he was in, and requested that it be edited. However, the GMT representatives also felt that facilitated viewing of this film with community stakeholders had contributed to a greater perceived safety of the KEMRI clinic and its environs. Overall, the discussion of non-malevolence was reassuring, with its emphasis on protection by the ethical review process, by emphasizing patient autonomy in decisions about participation, and by data protection and confidentiality procedures in ongoing research protocols. The GMT representatives felt that providing accurate information to all potential research participants, detailing potential risks and benefits, and allowing potential participants adequate time to process and fully understand the implications of their involvement would create a more trustful relationship between researchers and GMT individuals.

Justice was the final ethical principle discussed. The principle of justice was presented as one of fairness: research should be impartial, should ensure equitable treatment, and should provide benefit to

communities. For research to be just, recruitment and inclusion of participants should follow clear and transparent procedures that derive from clear scientific objectives. Risks and benefits should be made clear, and should not be unfairly distributed between participants. For example, some GMT representatives felt that the provision of the same transportation reimbursement, regardless of primary residence, was inequitable. Others complained that individuals perceived to have a social connection with clinic staff would sometimes jump the queue. Some felt that staff could be indifferent, unfriendly, or even rude to certain individuals who were more stigmatized than others (for example, transgender individuals). A non-research example was the provision of food aid in some local clinics to HIVpositive individuals only. GMT representatives felt that justice went beyond fair treatment of participants or patients, extending to the community from which participants are recruited. To them, justice includes a moral obligation to ensure fair adjudication between competing claims, not only as they relate to research participation, but also in terms of hiring and retention of community members in research-related jobs. In general, the GMT representatives felt that justice could best be served by:

 Promoting policies that advance fairness and safety for the GMT community, including access to research benefits, formal recognition and/or employment of those contributing to research efforts, non-discrimination for all individuals, and protection from violence, harassment and mistreatment;

Expanding the base of support for GMT

health rights by forging alliances with other advocacy and human rights groups; and
• Implementing and monitoring research procedures to ensure that protocols are closely followed and staff are trained in fair and equitable treatment of participants.

Overall, this discussion of ethical principles proved enlightening for both researchers and the GMT representatives who participated. There was considerable appreciation of the need to adequately balance the risks and benefits of research. In addition, we identified a clear need to ensure the provision of accurate information about research, both in the community and at the clinic. We found that there is great value in promoting open communication between GMT organizations and researchers, with an ongoing exchange of ideas on ethical principles, policies, and human rights. The new Utafiti Pwani committee on GMT research has identified a potential role for itself in conveying research information to the community during outreach sessions. In addition, the GMT representatives serving on this committee expressed interest in further training on research and ethics, and a desire to be included in protocol development from the early stages, in order to help inform recruitment, consenting, and monitoring procedures.

This exploration of ethical principles by researchers and GMT representatives was an important opportunity to exchange views and learn from each other. Although it was not an in-depth assessment of the GMT representatives' understanding of research ethics, this meeting and its summary have provided a valuable learning opportunity, both for a newly formed GMT research liaison committee and an experienced research team. In the words of a GMT representative who participated, "GMT are not special, but we have special needs. Although not yet accepted by the community, we are of the community...We also have our rights." Researchers should make every effort to keep an open line of communication with communities affected by their research, particularly communities that are vulnerable or stigmatized. In addition, representatives of such communities should be empowered to make their voices heard and provide their own unique contributions to improving health and other outcomes. We believe that such efforts will result in greater inclusion, acceptance and respect for GMT people — and indeed for all people.

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SEX WORKERS AS VULNERABLE SUBJECTS IN RESEARCH

Mariga Wang'ombe Martin Communication student Moi University

ovember 16th 1972 saw the hurried end and closure in Macon County, Alabama of a syphilis research program more famously known as The Tuskegee Experiment. Researchers had intentionally not treated 600 participants who had syphilis despite the fact that penicillin had been discovered as a cure and was available. They also withheld information about penicillin and prevented them from accessing syphilis treatments available for the purpose of monitoring and documenting the progression of syphilis in human subjects, all under the guise that they were receiving free health care from the national government. The experiments went on for 40 years before a leak to the media eventually resulted in study closure. This may be arguably the most infamous biomedical experiment in US history[1].



Sex Workers

While researching the Tuskegee Experiment in 2005, Professor Susan Mokotoff found documents detailing yet another unethical experiment cloaked as research known as the Guatamala experiment. This experiment involved intentionally infecting unknowing subjects with syphilis to test the effect of penicillin in curing syphilis. The records were incomplete but extrapolated data suggests that complete treatments were administered to only about 26% of the 1500 study subjects[2]. Dr. John Cutler was involved in both these studies. The research-

ers paid sex workers infected with syphilis to have sex with prisoners and some prison guards. Some subjects were infected by directly injecting them with the bacterium and led to believe that it was medicine being injected. The study appears to have ended in 1948 partly due to rumours of the experiment going round medical circles and the cost and scarcity of penicillin during the Second World War. This was a dark era in medical research.

Both these experiments did not involve sex workers *per se* but took advantage of vulnerable subjects for the 'greater good of medical research'. I focused on sex workers as vulnerable subjects in research as shown by these two experiments, their vulnerability and the ethical considerations that should be taken when conducting research on sex workers.

Vulnerability

What is vulnerability and what constitutes vulnerability in subjects (sex workers)? It is a distinctive precariousness in the condition of the subject: a state of being laid open or especially exposed to something injurious or otherwise undesirable. A vulnerability is, so to speak, an avenue of attack and in this context, an avenue of attack through poorly thought out, planned or malicious research. Kenneth Kipnis of the University of Hawaii seperates vulnerability into six general classes under which everything else would fall [3]:

Cognitive:

Does the subject have the capacity to deliberate about and decide whether or not to participate in the study? Capacity here can take many forms. There have been cases of sex workers signing consent forms though they are illiterate or semi-illiterate thus have no idea what they are consenting to. There are also those that have some level of education but yet not knowledgeable enough to understand the, the risks and the benefits of research and so though literacy would be an advantage, they might still not fully be capable of grasping the research concept.

Juridic:

Is the subject liable to the authority of others who may have an independent interest in that par-

ticipation? The authority in this case could be the sex worker's "madams" or "Pimps", who would have a potential monetary benefit from the allowances given to the sex workers. The authority could also come with parental authorities or guardians for young sex workers who still live at home or are under the influence of their guardians.

Deferential:

Is the subject given to patterns of deferential behavior that may mask an underlying unwillingness to participate? Deference to authority may not be an openly visible cultural diversification trait but

in some communities for example, directness is looked down upon so the subject will not decline directly. There are communities that women see men as figures of authority to be obeyed and even out of their cultural context, still remain as they are and thus would never outrightly reveal their hesitance or unwillingness to participate. See



participate. Sex workers arrested by authorities in Nairobi

Medical:

Has the subject been selected, in part, because he or she has a serious health-related condition for which there are no satisfactory remedies? An example is the research team studying commercial sex workers' immunity to HIV through possession of 'T-Cells.' They concluded that they could not use less vulnerable subjects to carry out the same research after looking at the alternatives as some of the subjects were infected with HIV which has no known cure.

Allocational:

Is the subject seriously lacking in important social goods that will be provided as a consequence of his or her participation in research? Poverty makes people particularly vulnerable. Desperation caused by poverty could possibly make participants sign off without asking too many questions or sign off on research that they know will most probably harm them because they don't feel like they have anything to lose.

Infrastructural:

Does the political, organizational, economic, and social context of the research setting possess the integrity and resources needed to manage the study? Studies carried out on commercial sex workers operate within a context. Sex workers are in a particularly sensitive position seeing as the oldest trade in the world is also illegal. Sex workers face a hydra-headed composition of adversities in their day to day lives and thus the study needs to be socially and culturally welcoming and stable. Studies that are poorly funded and which are not well supervised or held responsible tend to be, by history, a disiaster in the making.

ETHICAL CONSIDERA-TIONS IN RESEARCH ON SEX WORKERS

Benefits

This is perhaps the most visible and spoken of ethical factor that stands out when performing research. UNESCO's Declaration on Bioethics and Human Rights

notes that "Benefits should not constitute improper inducements to participate in research."[4] Poverty can be a great factor in inhibiting voluntary consent. It has long been agreed that a reasonable monetary benefit is not payment for or an inducement to research but acts as compensation for the time, effort and comfort that the participant sacrifices to participate in research. On recognizing this comes the challenge of determining what the benefits will be, who can meaningfully share in the benefits, what motivates participants to take part in research and do monetary benefits play a role in their motivation and if so to what extent. Sex workers in Kenya and in other developing countries, are primarily in that position because of poverty or other extenuating circumstances and thus if their primary motivation is money, research on them would be unethical as they would be unable to make an objective decision on their participation in research.

Legal environment and requirements

Researchers and the research sponsors should

comply with the relevant national and international laws and regulation regarding research and if possible, specifically regarding HIV-AIDS research. Research involving human subjects is bound by the Declaration of Helsinki, 28 and the CIOMS Guidelines.29 These do not have independent legal stand- Beneficence ing, but comprehensively touch on medical ethics, influencing the formulation of international, regional and national legislation.

UNESCO has issued a variety of Declarations relating to bioethics and human rights, which seem to be written with particular concern to developing countries where a lot of medical research has moved to because of less stringent research regulations. They provide guidelines in the formulation of relevant policies. The Human Genome Organisation (HUGO) Ethics Committee acknowledges benefit sharing as a research principle and apart from promoting benefits to the participating community, they also propose that benefits should not be limited to the communities that participated in the research[5]. Kenya has also developed National Guidelines for Research and Development of HIV/AIDS Vaccines to provide a framework for evaluating and developing HIV/AIDS vaccines in the country. The Guidelines provide a collaborative blueprint that enables government and non-governmental organizations to participate in research and development of the HIV vaccine[6].

Ethical review approval and process

Ethics Review Boards (ERB)



hoto by freedigitalphotos.net

are necessary to ensure supervision of research to ensure that it is carried out within the set out bounds. The committees carry out approval of planned research, can review the research as it is going on and can intervene if ethical regulations are being flouted. For organizations carrying out international research, international guidelines dictate that approval should be sought from the ERB in the country where the researcher is based and the country where the research is going to take place. The ERBs must clearly be identified by the researchers in their documentation and if approval will not be given by both boards then a satisfactory reason must be provided.

Informed consent / assent

Emerging economies have started acknowledging the particular vulnerability that their citizens have due to their current1. informed consent must be strictly^{tee.}

tonomy, justice and beneficence should be documented in written form and followed for accountability. In the case of sex workers, it should be clearly acknowledged and outlined that they are a vulnerable population and the necessary steps taken to ensure adher-Justice ence to the principles of informed consent e.g. Interviewing them to ascertain their motivation for participation in the research process. The potential benefits should be presented in a balanced and objective manner. The sex workers should be made aware of the actual and potential risks that they face, whether short-term or long-term.

> The sex workers should also be provided with alternatives in case they don't want to participate in the research e.g. other research programs or other treatments that they could pursue.

> Sex work is an ethical discussion that reverberates internationally but the recognition of sex work as an occupation would help researchers carry out research in an ethical and responsible manner. The Hippocratic Oath would also help when facing conundrums- Do No Harm - seems to succinctly sum up how to run biomedical research.

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Case challenge- Impact of civil war on health systems

Adapted from THE CASE BOOK ON ETHICAL ISSUES IN INTERNATIONAL HEALTH RESEARCH, Case 41, pg 133

Effective control of malaria is heavily dependent on a functioning health care system (i.e. drug distribution, information systems, and preventive, curative, and referral systems). In some of the countries in greatest need of malaria control, however, armed conflict has severely disrupted the structure of their health systems by putting strain on resources and increasing the burden of disease.

A group of researchers from the health ministry of a sub- Saharan African country decide to study the impact of armed conflict on their country's health system, in the hope of identifying interventions that can strengthen health systems in time of war. They decide to collect data from two groups. One group will include those who are most likely to be vulnerable to disease outbreaks during armed conflict, namely, internally displaced people (IDPs) and members of the host communities in which they live. The second group includes key leaders and stakeholders responsible to and for these host communities, such as policymakers, representatives of aid agencies, and officials in charge of health care and of IDP camps. Data from the first group (i.e. vulnerable people) will be collected through focus group discussions while data from the second group (i.e. leaders and stakeholders) will be obtained through semi structured interviews. In order to "purposively select ID camps and communities that best reflect the reality of

the district conflict setting", the IDP camps and communities will be selected by district officials. Focus group participants will be recruited by self-appointed community leaders.

At the end of the study, the researchers plan to hold a 2-dayworkshop for leaders and officials in charge of health care in each community to present the results. These officials will then be responsible for disseminating the findings to study participants and other members of each community through public meetings. No compensation will be provided to the research participants.

Questions

- 1. Is it appropriate for community leaders to be responsible for recruitment of participants from a vulnerable population, in this case an internally displaced population?
- 2. How much is owed to the participants in terms of dissemination of results? If the researchers do not directly convey the findings to participants, is it their responsibility to ensure that health care leader-saccurately convey them to participants?
- 3. Should there be ethical concerns about including both IDPs and members of the host community in the same group? Why or why not?

The first three respondents in will receive a prize. The first correct response will also receive a prize.

Answers should be submitted to ddrt@kemri.org



ANNOUNCEMENT

Transition to S.E.R.U Review

The Kenya Medical Research Institute wishes to inform all researchers that Scientific Ethics Review Unit (SERU) will initiate multiple committees for a joint science and ethics review beginning 1ST NOVEMBER 2014

Consequently you are advised to submit five copies of the following documents directly to S.E.R.U and not SSC or ERC from 1st November:

- Amendments
- Notifications
- Protocol deviations or violations
- Severe Adverse Events (SAE)
- Submission of investigators brochures
- Continuing review requests(CRR)
- Study closeout reports

Note that all <u>new protocols</u> must be submitted to <u>SSC</u> for review and subsequent forwarding to ERC upon approval

All new protocols with animal use must be submitted to Both SSC and ACUC as was previously done

Template documents to be used for submission will be uploaded on the KEMRI website at www.kemri.org/index.php/research-commitees/research-commitees/seru

CALL FOR LOGO SUGGESTION

The new KEMRI Science and Ethics Reviw Unit (SERU)

The ADILI Task force is requesting logo suggestion for the KEMRI Scientific and Ethics Review Unit (SERU). Submission is open to all KEMRI staff members.

Please consider the unit functions in creating the logo.

The staff member with the winning logo will be acknowledged and rewarded for the innovation

Kindly submit your logo in suitable format(JPEG) to Office of the Deputy Director Research and Training through ddrt@kemri.org by 10th November 2014.