Vulnerability: Sex Workers in Nairobi's Majengo Slum

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Researchers from the Universities of Oxford, Nairobi, and Manitoba are collaborating on a project to develop an HIV vaccine based on the immunological protection mechanisms found in commercial sex workers from the Majengo slum in Nairobi. This group consists of educationally and economically disadvantaged women who resort to commercial sex work for a living. A clinic was established in the slum to study sexually transmitted diseases, which now includes HIV/AIDS. The clinic serves as a research facility for the collaborating researchers who have been using the women's blood, cervical, vaginal, and saliva samples for the ongoing studies. The clinic runs two HIV-integrated activities: HIV research and HIV care and treatment. For HIV negative participants, samples are collected and used for research and care after they give informed consent. HIV positive participants are involved in research, HIV antiretroviral treatment (ART), and the receipt of care support services after giving informed consent. No more than four blood samples (20 ml each) are collected per year. Notably, the timing of research samples' collection is usually planned to coincide with ART and care monitoring to minimize costs. This article asks what makes these women vulnerable as research participants. The first part contextualizes the definition of vulnerability. The indicators of vulnerability are discussed in the second part, focusing in particular on informed consent and access to the benefits of research. The discussions in this article are based on information obtained from interviews with Kenyan stakeholders and current literature on ethical issues related to vulnerability.[1]

Vulnerability in the Context of the Definition

> To be vulnerable means to face a significant probability of incurring an identifiable harm while substantially lacking ability and/or means to protect oneself.[2]

This definition captures the key points relating to vulnerability in the Kenyan case. Majengo women are poor and have little education. One woman who was interviewed said: ''They [the researchers] help me even more than I can be helped

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elsewhere."[3] Another asked for help to abandon prostitution: "If there is any way you can help us to fend for ourselves and get on in life like others; that would be good."[4] Because concerns have been raised about considering all poor people as inherently vulnerable,[5] it is important to discuss the context of these women's vulnerability. Contextualization is vital because "vulnerability cannot be defined independent of ... the relationships, power dynamics, and social and political circumstances of the particular protocol."[6]

Majengo women are likely to *incur an identifiable harm* (e.g., invalid consent, lack of access to the benefits of research), *and they substantially lack the means to protect themselves* (due to illiteracy/lack of knowledge in medical research).

It has been argued "that persons who are educationally and economically disadvantaged remain the *invisible vulnerable*" and they have not been accorded sufficient protection in research guidelines.[7] Majengo women certainly fit within this description insofar as they *lack the means to reduce either the probability or the magnitude of the identifiable harm in question.*

The tendency to consider economically disadvantaged groups as categorically vulnerable has generated a lot of debate. One interesting argument is "that under-representation of vulnerable groups ... in clinical research makes scientific findings needlessly less generalisable."[8] Other strategies have been suggested to "reduce economically disadvantaged vulnerability owing to low education levels" instead of "blanket exclusions that can weaken the scientific validity of study results."[9] These strategies are: provision of study information in the appropriate language and reading level, clarification of study questions by field staff, and use of the "Teach Back" method of informed consent,[10] where the participants are asked to repeat what they have understood from the explanation.

Prospects of obtaining meaningful consent from potential participants in Majengo given the difficulties of translating complex concepts into languages that may not (yet) have the linguistic resources is a great concern. "The moment you begin translating into a language that the participant understands, you find that most words do not exist here."[11]

It is evident that Majengo women have multiple vulnerabilities as educationally and economically disadvantaged women participating in research.

Main Features of Vulnerability

Schroeder and Gefenas suggested identifying those deserving special protection in the research context through identifiable possible harms they face.[12] They noted four main indicators: unfavorable risk/benefit ratio, breach of confidentiality, invalid consent, and lack of access to the benefits of research. The first factor is not a real concern in the Majengo case due to the minimal risk involved.

Confidentiality

Possible breach of confidentiality is a concern. As noted in the Joint United Nations/World Health Organization Program on HIV/AIDS (UNAIDS/WHO) *Ethical Considerations in Biomedical HIV Prevention Trials*, participants who engage in illegal or socially stigmatized activities such as sex work should be given extra consideration.[13] Fear of stigmatization among participants such as Majengo

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women is well founded, as prostitution is illegal in Kenya. Participants in similar circumstances reported that, in the face of a breach of confidentiality, "they grew to distrust the provider system and faced physical, emotional, mental and financial suffering and loss."[14] No literature exists on the ramifications of breaches, but there is a clear indication that a "risk of harm following a breach of confidentiality varies with the national or local context."[15]

Informed Consent

The issue of informed consent is very challenging for the women in Majengo, according to a representative from the Kenya Medical Research Institute's (KEMRI) national ethics review committee. The women are unlikely to understand the nature of the research as they lack the capacity to distinguish between activities related to research and their treatment in the event they fall sick in the course of participation.[16] The situation raises the following fundamental questions: What led the women to start participating in this research? Has there been open communication between the researchers and the women? Have the women been given all the information relating to the research and its results on an ongoing basis?

These are challenging questions, but the Nairobi university researcher's explanation confirms that consent was technically properly obtained: "We would explain to the women that we want to do A, B, C, D. . . . This is what we require. If you agree then sign here."[17] The level of these women's understanding is, however, questionable in view of the conceptual issues that were raised by KEMRI: the stigmatized environment that makes prostitution illegal and the fact that the researchers demand that the women must acknowledge that they are sex workers before they can join the clinic. Technical compliance in procuring consent may not be open to the type of communication that these women may need.

Lack of knowledge about research can lead to invalid consent. It has been correctly argued that "vulnerable people are those who cannot refuse to participate, lacking knowledge, means, or any element necessary to decide in full capacity."[18] Some Majengo women who were interviewed seemed unable to appreciate the meaning of research; they did not question what it entails because they are likely to be content with the information given by the researchers. One woman responded that she agreed to participate because of the work she does (sex work).[19]

The second issue that leads to invalid consent is coercion or undue inducement: "What makes something coercive is not just the perceived way out of the situation but the situation prior to the offer of a way out."[20] Consequently, "money or good healthcare or whatever the subject is lacking become potentially coercive instruments in the hands of the researchers."[21] One Majengo woman confirmed that she is totally dependent on the clinic: "I don't know what I will do if they close down."[22] The representative from KEMRI's ethics committee equally confirmed that "poverty is a great factor and sometimes militates against voluntary consent."[23]

The women do not have an alternative option for the services offered at the clinic. Yet, lack of alternative choices per se does not lead to coercion or undue inducement. This point has been succinctly explained by Hawkins and Emanuel:

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> When bleak situations are no one's fault ... the situation does not by itself present a moral problem. There is at least this much similarity between bleak choice situations and coercion: in both the agent faces a narrow set of options that she might reasonably prefer not to face. We often say that such people have "no choice" about what to do; but this does not mean that they are being coerced.[24]

As Arnason and van Niekerk have convincingly argued in this issue, research that only involves minimal risk will not be made unethical through the provision of benefits (i.e., inducement).[25] On the contrary, they argue that the fact that an offer is made either in terms of monetary compensation or medical treatment tends to enhance peoples' options rather than limit them. In view of this argument, it can be concluded that free medical treatment and minor expenses that are given to Majengo women do not undermine informed consent but expand their options.

Lack of Access to the Benefits of Research

Are the Majengo women likely to share in the benefits derived from the research undertaken with their samples? Currently recognized benefit sharing modes in the literature are financial compensation, posttrial access, and healthcare.[26] This section discusses how these modes would work in the Majengo case.

An international consensus is emerging that collaborating researchers should share the benefits from human genetic resources that are obtained from research participants in developing countries.[27] In Kenya, the best that KEMRI can do is to advise the parties in such collaborative research projects to address issues related to intellectual property rights, which directly affect benefit sharing. In response to the question of whether the researchers ever heed the committee's advice, a representative from KEMRI's ethics committee revealed this:

> They are mostly half-hearted. In the end they would say we have addressed it or we have done some agreements, because we never see the agreements ourselves. If you want them to talk about it you do not know how deeply they have gone into it. ... We do not begin to probe in to see ... the intellectual property agreement. They would just say we have addressed it this way.[28]

KEMRI also reiterated that "ethics committees ought to be involved in the intellectual property issues to see [that there] are benefits even for the researchers, the community or the individuals in the final product."

What is clear from the foregoing is that there is a need to set standards in terms of benefit sharing modes as voluntary compliance is not forthcoming.

Financial Compensation?

In Majengo the initial trial vaccine based on the research undertaken on the women's samples proved unsuccessful. However, the researchers and their institutions have gained considerably from the ongoing studies in terms of techniques for developing DNA-based vaccines, lessons in immunology, technology transfer, and patents for vaccine development processes. Kenyan

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researchers have confirmed having benefited personally and professionally from their involvement in such research.[29] Others, however, have indicated that benefits in terms of technology transfer and so forth have been disappointingly limited.[30]

How can sample donors be compensated? Three practical problems are identified in creating a rule at the outset for financial compensation to participants during research: First, university scientists would be prohibited from participating in drug discovery due to lack of ability to advance funds; second, ''the idea of benefit sharing presupposes that there are some benefits and becomes void if no benefit accrues''; and third, ''fewer projects would move to actual clinical testing if projects taken over from academic groups had significant financial commitments attached.''[31]

An interesting proposal for compensating sample donors indirectly once benefits have emerged is the case of Pseudoxanthoma Elasticum (PXE) International, a nonprofit support organization for families of children with PXE (a rare and incurable genetic disorder). The organization provides tissue and blood samples from the tissue bank to researchers under specified conditions, for example, that the organization must share in any intellectual property and profits resulting from the research.[32] In return, any money raised this way can be reinvested through the organization in activities to further the interests of the families involved.

Likewise, developments in the Canadian province of Newfoundland and Labrador have set a useful precedent, which requires inclusion of benefit sharing in protocols. Legislation was introduced to establish a Provincial Health Research Ethics Board (PHREB) to review all genetic studies conducted in the province. The recommended benefit-sharing protocol requires the establishment of a Standing Committee on Human Genetic Research (SCHGR), ''that would operate at arms-length from, but parallel to, the PHREB.'' The model requires ''all research projects utilizing the Newfoundland genome ... to submit a benefit-sharing proposal with supporting rationale to the SCHRG.'' The proposal should indicate how the economic benefits derived from the study will be shared. This may take the form of ''an agreement in principle to bring forward a detailed plan if and when commercial opportunities arise.''[33] This model ensures that communities do not ''relinquish a claim to future economic benefits at the outset either because the project is initiated in the public sector, or because the possibility of commercialization seems remote.''[34] The precedent could be used in other jurisdictions that are considering introducing similar measures.

A third innovative proposal is the following. Because upfront compensation of participants may make research more expensive and sharing potential profits with individuals may not be practical, a middle ground has been suggested: ''to distribute ... a single share of stock in any biotechnology business venture associated with the research, because it might be worth very little unless the research is successful.''[35]

A general framework that is yet to be explored exists in Kenya's Guidelines.[36] The Biological Material Transfer Agreement, which the Guidelines recommend, can be used for blood samples that are donated by study populations and from which genetic information is extracted and shared by the collaborating researchers.[37] The agreement would be legally binding, and the terms for benefit sharing can be included in such agreements. A representative from KEMRI's ethics

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committee indicated that one of the roles that ethics committees can play in this regard would be to guide the parties on the acceptable terms, which should be included in such agreements.

An enabling environment that facilitates financial compensation is, however, vital. Such an environment would foster the enforcement of favorable intellectual property rights arrangements and give effect to the benefit sharing agreements. This in turn calls for the harmonization of the underlying regulations that govern intellectual property rights in the collaborating developed countries that carry out research in developing countries among vulnerable populations. Failure to ensure harmonization has led to breaches of conventional research ethics standards in Kenya.[38] An arrangement between the parties such as that which is recommended above would be helpful in filling the regulatory oversight gap that seems to exist currently in Kenya as confirmed by a representative from KEMRI's ethics committee:

> In most cases ... when these materials are gone we never get to know what happened. ... As an ethics committee we deal with these issues here. And once we have given them the approval, that is the end of it; we never hear about the research ever again. We might hear about its publication.[39]

The above situation is not peculiar to Kenya. Two areas that have been identified in the literature as requiring attention are expert ethical review procedures and allocation of benefits following commercial exploitation. Consequently, it has been argued that "governing structures in these areas require great political sophistication as human genetics moves from individuals to groups."[40] It is therefore an open question, which cannot be resolved within the space of a journal article, whether financial compensation is the best way forward to compensate vulnerable research participants in genetic research in developing countries. It is equally an open question how women should be empowered to join the negotiation table if individually negotiated benefit sharing agreements were shown to be the way forward.[41]

Posttrial Access?

Paragraph 30 of the Declaration of Helsinki provides that every patient entered into a study "should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study." Guideline 21 of the Council for International Organizations of Medical Sciences (CIOMS) reinforces this requirement by obliging external sponsors of research to ensure the availability of "services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned."[42]

The above guidelines seem to be very clear on benefit sharing for those taking part in research. However, the Declaration only refers to studies undertaken on patients presumably at the clinical trial level and does not apply to the donation of samples by the Majengo women. And it is further unclear how guidelines such as the ones issued by CIOMS could be operationalized in the Majengo case. It has therefore been suggested that the existing frameworks be reevaluated and replaced with realistic alternatives.[43] A realistic alternative in the Majengo case

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could be a properly negotiated benefit sharing agreement with the women in terms of Kenya's HIV/AIDS Research Guidelines. Ethics committees may thus find it useful to ensure that benefit sharing arrangements that cater to such participants' interests are included in the memoranda of understanding, which are used in collaborative research.[44] This can be done when the protocol is considered by an ethics committee, which can play an important role "by declining to approve any proposed clinical research ... that may breach ethical requirements."[45]

Healthcare?

Sample donors in developed countries are not normally compensated for their samples or do not receive a share in intellectual property rights. Medical research leads to benefits for humankind in terms of new treatments, and hence the altruistic donor model is prevalent in such countries. However, this is not altruism of its purest kind. By contrast to many donors in developing countries, those in the West normally have guaranteed poststudy access. For instance, a participant in a trial in the United Kingdom is assured of subsequently receiving benefits from any trial through the National Health Service because poststudy access is built into the social welfare system. This is not the case in, for instance, Kenya. Majengo women will not automatically gain access to the fruits of research undertaken on their samples. Ideally, one could argue that equal access to essential healthcare should be the prime goal in benefit sharing for medical research.[46] Complicated, bureaucratic regulations that make individually negotiated benefit sharing agreements compulsory could lead to even less research beneficial to the poor. Instead, from an idealistic and highly ambitious point of view, a strategy of making essential healthcare available to all should be established. Only then will the exploitation of research participants in developing countries be stopped. Such proposals exist, for example, the Incentives for Global Health Plans of Pogge.[47]

At the same time, these ambitious proposals align with some of the intuitions expressed by Majengo women. "I expected treatment, free of charge," is how one woman answered the question of which benefits she expected before enrolling in the study. Another said: "No, I did not expect money or such things, just treatment." A third: "For me I see that the benefits I would expect is treatment because whatever kind of sickness I get I am treated. So this Clinic has a lot of benefits." And a fourth noted: "I don't think there should be any other kind of benefits we are given free medicine, free treatment."

Conclusions

The Majengo case raises ethical issues that can significantly inform the process of developing an appropriate framework for the use of human samples, both in Kenya and on the wider international stage insofar as the concerns that are highlighted are not unique to Kenya and Majengo. The markers of vulnerability can be helpful for ethics review committees who review protocols for studies that intend to use vulnerable participants. Most importantly, the rationale for benefit sharing for human biological samples that has emerged in the context of this case

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needs to be explored further to develop a model for benefit sharing with communities such as the Majengo women.

Notes

1. Clearance for conducting these interviews was granted by the University of the Witwatersrand's Human Research Ethics Committee (Non-medical) Protocol Number 61110 and the Kenya Medical Research Institute's National Ethical Review Committee reference number KEMRI/RES/7/3/1.
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11. Interview with a representative from KEMRI's ethics committee, GenBenefit April 2007.
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28. See note 11, Representative from KEMRI's ethics committee.
29. See note 17.
30. See note 11.

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