

# Views of providers and clients on feedback and benefit sharing in studies using biological materials in Eldoret Kenya

Violet Naanyu<sup>1</sup> Eunice Kamaara<sup>2</sup> Alfred Kirui<sup>3</sup> Hillary Koros<sup>3</sup>  
Daniel Lagat Singh Ilina Edith Kamaru Kwobah<sup>4</sup> Lukoye Atwoli<sup>2</sup>

<sup>1</sup>Moi University, Eldoret Kenya, <sup>2</sup>Moi University, Eldoret, Kenya,

<sup>3</sup>Academic Model Providing Access to Healthcare Research Program, Eldoret,

<sup>4</sup>Moi Teaching and Referral Hospital, Eldoret, Kenya

The Global Health Network

Published on: Jul 26, 2023

URL: <https://tghncollections.pubpub.org/pub/uk0on75e>

License: [Creative Commons Attribution 4.0 International License \(CC-BY 4.0\)](https://creativecommons.org/licenses/by/4.0/)

**DOI: [10.58177/ajb230002](https://doi.org/10.58177/ajb230002)**

## **Abstract**

### **Title of the article**

Views of providers and clients on feedback and benefit sharing in studies using biological materials in Eldoret Kenya

### **Abstract**

**Context:** The use of biological materials raises diverse ethical concerns and there is insufficient research into the views of stakeholders on these concerns.

**Aims:** This study investigated healthcare providers' (HCPs) and clients' perspectives on giving feedback about biological samples that are used in research and sharing of subsequent benefits.

**Settings and Design:** Using a qualitative in-depth interviewing approach, this study investigated perspectives on feedback and benefit sharing in studies using biological materials. We engaged HCPs (doctors, clinical officers, nurses, and laboratory technicians) and clients from the Moi Teaching and Referral Hospital, Kenya.

**Methods and Material:** Vignettes and open-ended questions were used, and all sessions were audio recorded, transcribed, then coded and summarized thematically.

**Results:** We found no substantive differences between the perspectives of HCPs and clients. Participants desired that sample donors were provided with feedback and support for their healthcare. Community-level feedback and initiation of health development projects were viewed as valuable. Participants lauded the global dissemination of findings and sharing of benefits ensuing from the research.

**Conclusions:** Healthcare providers and clients in Eldoret Kenya appreciate the use of biological materials in research. They believe in feedback and benefit sharing at individual and community levels, and in broad dissemination of the research findings. All research stakeholders should be encouraged to plan and implement contextualized dissemination of research findings. In addition, feedback on research findings and equitable benefit sharing should be strengthened.

**Key-words:** Biological material, research ethics, research benefits, in-depth interviews, Kenya

## **Background**

Human biological materials such as tissues, cells, and blood are a key resource for research toward identifying biological mechanisms of individual diseases [1]. As biobanks collect, preserve, and provide access to these

resources, they become essential research platforms in support of biomedical research that seeks to improve interventions for health and increase understanding of the complex relationship between genes and the environment in the development of diseases [2]. Biobanking in Africa is characterized by a lack of clear guidelines to regulate the sharing and use of biological samples for research purposes, and there is also little specific guidance available for ethics committees and researchers [3-4]. Among the many ethical issues noted in research using biological samples, benefit sharing and feedback to donors and communities of research are frequently expressed concerns in African research populations.

Benefit sharing in research remains controversial and continues to change in meaning [5-8]. Schroeder [9] defined benefit sharing in the context of human genetic resources as the action of giving a portion of advantages/profits derived from the use of human genetic materials to the resource providers, with particular emphasis on the provision of benefits to those who may lack reasonable access to resulting products and services. Bege and Kris [10] add a communal element by defining benefit sharing as the fair benefits that research communities should accrue in exchange for participating in research. This suggests individuals and local communities that contribute to research should receive access to the knowledge and other study outputs [11-12]. Giving feedback to research participants can be defined as the provision of health information to sample donors and sharing of aggregate research findings with the broader community engaged in a study. This is an ethical obligation founded on beneficence, reciprocity, respect, and full recognition of study participants [13]. Where research engages donors and utilizes the samples in numerous future analyses, the donor and their local communities ought to get feedback on findings and any resultant products [14,15]. Trial participants wish to receive research findings and understand the potential effects and implications of such results [16,17]. What remains unknown is the most effective way to give feedback without causing harm [13,17].

The literature presents critical debates in Africa concerning the exportation of biological samples, potential exploitation of participants, benefit-sharing, secondary use of samples and data over time, and return of results, among others [18-20]. This article emanates from a larger study that broadly investigated general knowledge, beliefs, and attitudes about biobanking and research use of stored biological materials. The study was not based on any given research that was ongoing at that point in time. In this article, we focus particularly on views on obtaining feedback and benefit sharing in research involving biological materials.

## **Methodology**

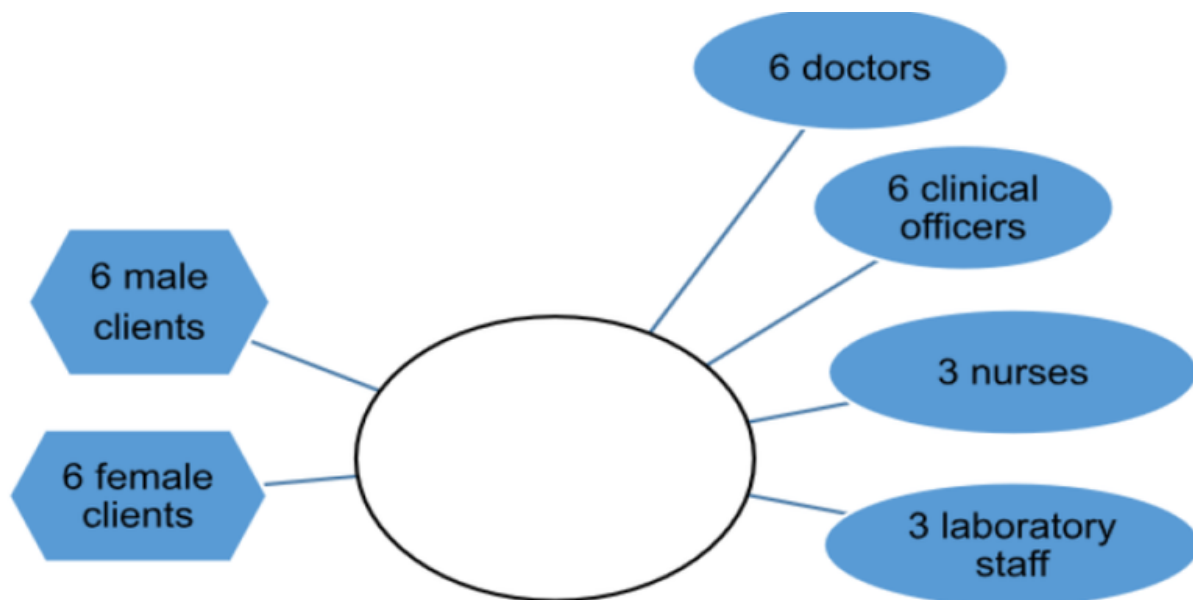
### ***Study Design and Setting***

This was a cross-sectional qualitative study utilizing vignettes and open-ended questions. A vignette is a short, generalized description that focuses on a given personality, idea, or location [21]. The assumption is that respondents get to understand the vignette description, capture a particular image/idea from it that guides the study, and then use their understanding of the matter to answer related questions. Three vignettes capturing the use of saliva, blood, and breast tissue were developed by the investigators and used in this study

(Supplementary File 1). The vignettes prompted respondents to reflect upon their knowledge, beliefs, and attitudes on biobanks and biobanking. This study was conducted among healthcare providers (HCPs) and clients at the Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya. The MTRH offers diverse health services ranging from basic to specialized care and largely serves the western part of Kenya. It is also a hub of research involving human participants in the region.

### **Study Participants**

This study engaged 30 participants from two main categories: HCPs and health facility clients from outpatient departments of MTRH as they waited to be served or as they completed their hospital visits (Figure 1). This number was considered adequate because data from in-depth interviews are reported to adequately allow saturation between 9 and 17 interviews [22].



**Figure 1. Study Participants**

The study did not require any of the participants to have earlier experiences in research or any activities involving biological materials. The sample included six doctors, six clinical officers, three nurses, and three laboratory staff working at the MTRH. The inclusion of multiple cadres of healthcare providers was to ensure diversity of viewpoints from individuals working in different sectors of the national teaching hospital. Doctors interviewed included two from each of the following three specializations: adult medicine, mental health, and pediatrics. Similarly, the nurses were recruited from different specializations/departments of MTRH. One nurse was recruited from each of the following departments: maternal and child health, mental health, and adult medicine. In addition, six male and six female clients seeking care at the MTRH were invited to participate.

Using convenience sampling, the MTRH clients were randomly recruited from outpatient departments of MTRH as they waited in line to be served by diverse healthcare providers or as they completed their hospital visits. On any one waiting bay, every second individual in the queue, who was comfortable conversing in English and/or Kiswahili, was invited to participate. Trained research assistants recruited healthcare providers in their MTRH workstations and arranged for a suitable time and venue for interviews.

### ***Interview Materials***

Using three vignettes (Supplementary File 1), and a question guide, we used two main question domains. The first explored participant knowledge about biobanks and included questions on their earlier experiences as researchers or participants engaged in any study involving biological materials. The second domain covered beliefs and attitudes toward research involving the collection and storage of biological materials. There were specific questions on participant beliefs and views on consent information that should be provided in such studies, handling and storage of samples, use of stored biological material, sharing of benefits emanating from research, and willingness to donate biological samples. This article specifically reports on study findings on giving feedback and benefits sharing.

### ***Data Collection***

Healthcare providers and clients who accepted the invitation were taken to a private space where research assistants sought their consent and engaged them in one-hour face-to-face open-ended interviews on knowledge, beliefs, and attitude towards biobanking and research use of stored biological materials. A private interview room was provided in MTRH. After introductions, the vignettes were used as a tool to increase comprehension of the subject matter and facilitate the discussion on the biological specimens used in research. The three vignettes captured the use of saliva, blood, and breast tissue (Supplementary File 1) and were easily understood by all study participants.

At the beginning of each interview, and soon after consenting, the interviewer read one of the vignettes aloud in the language preferred by the participant. Most (29) of them chose English while one participant opted for Kiswahili. The interviewer would address and clarify questions paused by the participant. The vignette session took on average 3-5 minutes and mainly created a rapport preceding the main interview questions, and a shared understanding of the meaning of biobanks and biobanking. We had 30 participants (12 clients and 18 HCPs) and each of the three vignettes was used with 10 participants (4 clients and 6 HCPs). Nonetheless, the same interview guide was used for all participants. The vignettes prompted respondents to reflect generally on their personal knowledge, beliefs, and attitudes on biobanks and biobanking. The assumption was that respondents would get to understand the vignette description, capture a particular image/idea from it about biological materials that were being discussed, and then use their understanding of the matter to answer related questions. Most (10 clients and 16 HCPs) had heard about biobanks before our interviews and therefore easily flowed with the vignette content. In addition, none of the interviewers observed a need to revisit the vignette after the

interview sessions had begun. All interview sessions were audio recorded and captured through field notes. All audio recordings were transcribed verbatim and translated as necessary for analysis.

### ***Data Management and Analysis***

The audio recordings were transcribed verbatim and translated into English where necessary. Transcripts were managed in NVivo (v. 12) and coded by two coders using a continuous iterative process of applying codes and then integrating emerging findings into logical thematic categories in line with study questions. Any discrepancies in coding were re-examined as coders checked the transcripts and discussed all possible meanings associated with the text in question until the analysts reached a consensus. The current analysis relied on the participants' perspectives on giving feedback about biological samples used in research, and sharing of subsequent benefits. The coded segments and identification of key themes are presented in Figure 2 below.

Ethics review and approval for this study were granted by the Moi Teaching and Referral Hospital/Moi University College of Health Sciences Ethics Committee (Ref FAN: IREC 3161).

### **Results**

Table 1 summarizes the demographic characteristics of the study participants. A total of 18 HCPs (9 female, 9 male) with a mean age of 32.1 were interviewed. Most (12) held post-diploma education. Post-diploma education includes undergraduate, master's, and postgraduate studies. Two clients and six healthcare providers held undergraduate degrees, respectively. Only healthcare providers held master's (3) and postgraduate level of training (3). There were 6 female and 6 male clients with a mean age of 33.5. Three held post-diploma education, four had certificate-level training, four held secondary-level education, and one had completed primary school. Seven clients and 8 HCPs had earlier experience with biobanking, however, only one client and 7 HCPs had experience with biobank-related research.

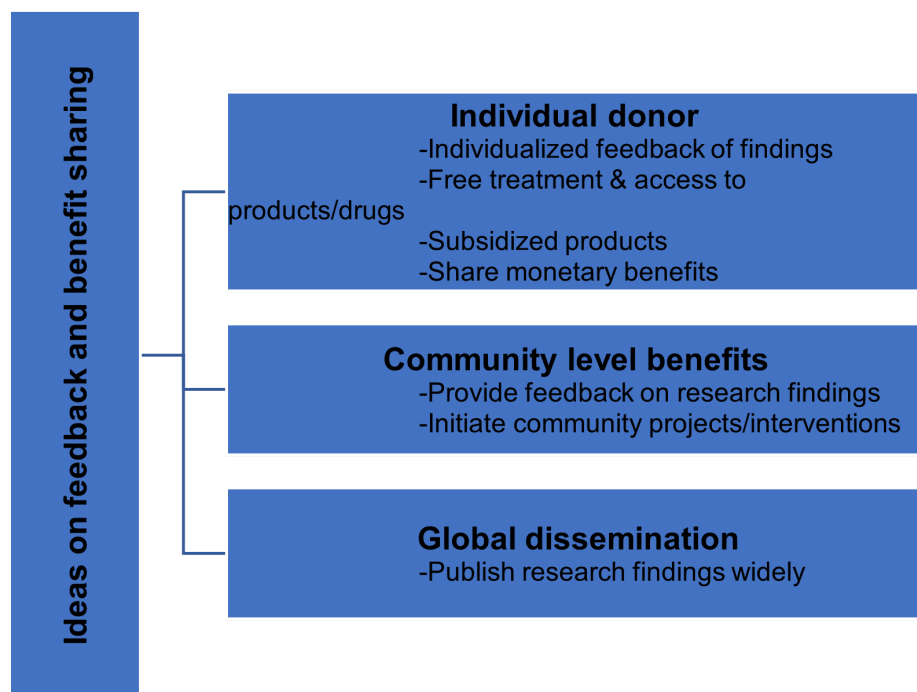
**Table 1. Demographic Characteristics of Study Participants**

Category	Mean Age	Sex		Level of education					Total
		Male	Female	Primary	Secondary	Certificate	Diploma	Post Diploma	
<b>Healthcare Providers</b>	32.1	9	9	0	0	2	4	12	<b>18</b>
<b>Clients</b>	33.5	6	6	1	4	4	0	3	<b>12</b>
<b>Total</b>		15	15	1	4	6	4	15	<b>30</b>

Healthcare providers and clients presented a range of views on feedback and benefit sharing. Both groups discussed similar ideas, which we have grouped into three categories (Figure 2). They are individual, community, and global level considerations of research benefits.

### ***Individual level considerations***

At the individual level, four sub-themes were noted: 1) provision of individualized feedback of findings; 2) provision of free treatment and arrangements for access to associated research products/drugs; 3) provisions of subsidized research products; and 4) sharing of monetary benefits.



**Figure 2. Views among Healthcare Providers and Clients on Feedback and Benefit Sharing in Studies Using Biological Materials in Eldoret, Kenya**

Firstly, clients and healthcare providers thought that the donors of biological materials should get individualized feedback on findings. They wanted the donors to be given relevant findings emerging from diverse analyses on their biological samples. Participants said that donors (or their caregivers) could be sensitized on the characteristics of their sample and any relevant health implications. They felt that, in this way, donors could have important knowledge about their health. Such knowledge could be used to facilitate individuals' treatment plans or to address specific health issues in the donors' communities.

*“If it is to benefit the research participant - they should get back the feedback...if the researcher could assist this research participant as a way of appreciating them, I think that is even better.”* (Female Nursing Officer, 01)

*“The donor should be aware of what is recorded as per their sample...and maybe their caregivers. From there... researchers can seek consent to share [the findings] with the [broader] community for purposes of improving other people’s health issues.” (Male client, 09)*

Participants also reported awareness of situations where, at the time of donating, the donor was unaware of having any ailment. S/he would give their sample and later the researchers might find information showing either the risk of disease or evidence of current disease. Participants felt such donors would greatly benefit from feedback so that they could consider the management of the identified condition.

*“I think the benefits come when you take these biological materials and do research...if you see there is a benefit, you come back to that person and say, ‘From our results, we see this will help you’...” (Female Clinical Officer, 03)*

*“I could be having a certain problem and this [feedback] could help me get treatment...you could advise me on better living, and I would have gained knowledge...” (Female client, 06)*

The second and third sub-themes were closely related. In the case of research leading to a breakthrough such as finding a type of drug for a particular ailment, healthcare providers suggested that the donor of the sample should be given priority in terms of drug supply and treatment. Furthermore, some participants suggested that the donor could be given the drugs free of charge.

*“In Kenya, most of these samples have never resulted in any beneficial product to the people. You realize somebody gives his sample, a new product is developed, and that person does not benefit. In fact, they are not given priority when it comes to a new product like drugs developed out of those samples or out of that research. I think priority should be given to those people who gave their samples and their families. (Male Clinical Officer, 06)*

*“Looking at the benefits from the research, I think it is important for the researcher to benefit, it’s also important for the one who has given the sample to also benefit.” (Male client, 10)*

On the contrary, some participants thought free products were unrealistic. They wished instead to have the donor subsidize rates of any resultant products such as drugs.

Fourthly, where the benefits of research outcome were in the form of monetary gain, clients and healthcare providers thought it would be good to share the money with the donors of the biological samples. However, they noted that it would be difficult to determine what share to give sample donors. They further raised concerns about the feasibility of tracing donors after the study closure. Some providers expressed a contrary opinion that sharing of monetary benefits could make future research ‘money oriented.’ They argued that it would make some people donate samples for monetary gains. Some participants opined that, instead of paying



out to donors, it was better to focus on interventions that would support care for the donor, their relatives, or other people ailing in their broader community.

### ***Community level considerations***

At the community level, there were two sub-themes: 1) Provision of feedback on research findings; and 2) Initiation of community level health interventions.

Firstly, clients and healthcare providers encouraged sharing of knowledge emanating from research findings at the general community level. They believed such study findings could be beneficial to local communities where the studies were conducted. Such knowledge could be used to address relevant community problems.

*“If the knowledge that has been created from this research can benefit the community, then it should go ahead, trickle down even to the community so that we can see the essence of the research.”* (Male client, 10)

*“For researches, for example, that are done in other countries, the results should be disseminated back to that country...so these results should be disseminated back as a benefit to the person who gave out the sample or the country so that it will help some other person.”* (Female Nursing Officer, 01)

Secondly, they suggested the establishment of community projects as a way of giving back to local communities from which sample donors were recruited. This they indicated would ensure that the benefits emanating from the research were shared beyond individual participants. This was viewed to have a higher impact beyond the donor and reaching many community members. Furthermore, participants noted that some researchers routinely build health interventions around earlier investigative research activities. Communities, where donors live or lived, ought to be prioritized when such interventions occur.

*“I think benefits should definitely come back home and if this patient can't benefit in person, at least people from that surrounding should benefit from it. If it's a new intervention, it should be implemented ...in places where these samples were taken.”* (Female Clinical Officer, 05)

Clients and healthcare providers also asserted that local institutions that participate in study implementation, particularly sample collection, should also be given feedback on any new knowledge arising from the study; and that health workers in such institutions should assist the research team in communicating such information to sample donors.

At the more universal global level, wider dissemination to national and global audiences was recommended. Participants suggested the dissemination of findings through scientific publications and media to reach a wider global audience. By so doing, their findings would be used to inform health and healthcare for the good of humankind – especially in the countries where the samples were collected.

*“...Results should be disseminated back to that country [where samples are collected]...it can be done maybe through a publication.” (Female Nursing Officer, 01)*

*“If it [findings] is something useful, you should share it in the media or anywhere else.” (Male client, 12)*

*“I think somebody can come up and write a book when he has done research on those tissues.....I think that....on writing and publishing alone, it can help everyone, everyone who wants the knowledge of that particular specimen can get from there.” (Female Laboratory Technician, 02)*

## **Discussion**

This study explored views on giving feedback and sharing of benefits amassed from the use of human biological materials in research. Participants wished to get feedback that they could use to improve their health and access to healthcare. They also valued the initiation of health development projects at the community level, global dissemination of research findings, and fair sharing of resultant study benefits. There was a lack of differences in the findings by category of participants and by socio-demographics. This can be due to the study design (small qualitative exploration of perspectives on the subject matter) and inclusion of participants who were not necessarily currently involved in biobank related research.

Earlier research has been done on giving feedback and benefit sharing in Kenya, [6,20,23-24] however, it only reported views from the coastal region of the country. Our study which was carried out in Eldoret Kenya echoes those findings and therefore adds to scholarly dialogue on the topic. Concerns about benefits and feedback to research participants stem from the three basic principles in research: respect for persons, beneficence, and justice [25]. A study could potentially discover beneficial information – sometimes outside the objectives of the research project - that could be useful to participants in managing their health conditions [13,26] or averting imminent ill-health danger [27]. Feedback on results ought to be encouraged because there is evidence that biobanks and research teams can return individual research findings to donors who give their material/s to the biobanks [13,28]. Participants wish to receive results when the study findings have direct relevance to their health or that of their close relations [29]. Sharing results with the study participants demonstrates respect and appreciation of their integral role in the research and provides research participants the opportunity to use emergent information for personal decisions [13,1]. Lack of information about a disease can lead to inaccurate diagnosis, use of ineffective treatments, economic, and social losses [30]. Failure to give feedback may result in harm to research subjects especially where the incidental findings could have helped research participants make important health decisions such as seeking healthcare to evade looming danger. Researchers ought to notify participants when study results suggest imminent ill-health danger [27]. Moreover, past research shows participants wish to receive results when the study findings have direct relevance to their health or that of their close relations [29,31]. Lack of information about a disease can lead to the use of ineffective treatments and economic losses. Awareness of what causes ailments can enhance more accurate

diagnosis, strengthen clinic visits, reduce use of ineffective interventions, and prepare families to deal with socio-cultural consequences of ailments [24].

Researchers may fail to share study results with participants due to participants' low health literacy, participants' lack of desire for results, optimal timing to give results, the nature of informed consent applied, and logistical barriers [24,30]. Nonetheless, many research ethics guidelines now oblige researchers to offer research participants the results of research in which they participated but there is wide variation in opinion regarding what should be disclosed and under what circumstances [26,32]. Health information feedback ought to be weighed against potential repercussions to the donor and their family for feedback on unfavourable health conditions can also cause anxiety, worry, hopelessness, stigmatization, suicide, and even prompt unwarranted medical intervention [16,33]. Like many researchers, Kenyan investigators and ethics committees show minimal awareness of what benefit sharing entails [12]. All research stakeholders need to educate patients about their health, voluntariness of participation, and realistic potential benefits from research [34,35]. Creating more awareness about healthcare and associated research remains important in Kenya. Where patients are enrolled in research, providers, the research team, and caregivers need to play their role as healthcare educators by empowering the patients with information about their health, the voluntariness of participation, and realistic potential benefits from the research [34-35].

It is also important to consider the welfare of the researchers, especially when demanding the return of results where researchers lack direct funding and/or when the timing and tracking of the sample donors is challenging. It should also be clarified what role is played by specific people (researchers, sponsors) in implementing efficient feedback of results [8,30]. Furthermore, as we reflect on guidelines to support the release of individual results in any research, we must be cognizant of blurred aspects noted in the process of returning results [36-38]. For every new research project, each research team needs to make informed ethical and societal considerations for the return of individual results. There is a need for contextualized decision-making frameworks for the return of individual research results – beginning earlier on with participant expectations that are made in the consent process. The results that are returned also require thorough analytic and clinical validity, and an effective communication plan to ensure all individual participants are reached and informed well. For many nations, there is a need to restructure the legal and regulatory landscape to support these efforts to return individual research results [8,36-38].

Benefits to the wider research community have been well categorized based on recipients. There are benefits to researchers and participating local institutions, benefits to the wider community in which research is located, and societal benefits [5,8,12,39]. Such benefits include access to investigational products and care, compensation for time and effort, technology transfer and solutions to common ailments, employment and retention of qualified healthcare personnel, infrastructural development, provision of social amenities, and community health education [40-42]. Benefit sharing in Kenya and beyond is complex and various forms have been suggested, however, most scholars posit that benefit sharing needs to account for the broader socio-

political structures that make individuals vulnerable to fundamental causes of ill health [39,41,43]. Kingori [34] reflects on the Kenyan scenario and similar contexts and notes that macro-level structural factors, such as poverty and lack of access to healthcare, imply that many people do not have a real 'choice' or power when it comes to decision-making to participate in research. Structural factors cannot be uncoupled from the choice presented to individuals; they permeate the options and decisions involved in research participation. Furthermore, she argues that possessing knowledge and agency does not mitigate the weight of these structural factors acting on individuals. So even well-intentioned propositions such as informed consent and benefit sharing, are structured by a power imbalance between researcher and participant. The only way to manage this injustice, from which risk of exploitation emanates, is at the macro-level [34].

It is also important for studies that entail donation of samples to capture community reservations and associated cultural and structural reasons for such hesitancy. Perceptions of participation in such studies vary, and need pre-evaluation to determine what can be done on a case-by-case basis, especially in international clinical trials in Africa where study participants may feel their participation indicates a potential violation of cultural boundaries. It is therefore important to contextualize and understand all perceptions and their potential importance during recruitment, consenting, data collection, and future information sharing [44-45].

Addressing the specific issue of feedback to communities, Marsh and colleagues [24] emphasize the need for international collaborative researchers to share genetic findings with local communities of research. Determining what kind of communal benefits are appropriate (and when), and how much the research team should invest can be complicated [46]. Public sharing of research findings and benefits can be designed in alignment with local traditions. For instance, Baylor and colleagues [47] modelled their dissemination of research findings after a typical local wedding to create a familiar and comfortable setting. Furthermore, participating in research and getting feedback (including incidental findings) is crucial because such feedback can stimulate immediate attention (at individual or communal level) to healthcare needs. Researchers ought to evaluate and fully disclose incidental findings of potential clinical importance to research participants. Research associated with such studies ensures that there is a future solution common to noted ailments and that other community members get remedies [12,48].

Research teams can purposively commit to channel monetary or non-monetary payments to individuals and groups involved in their research undertakings (Hayden 2007). This requires some emphasis on localized agreements on expected benefits and what grounds to use in laying down benefit sharing terms. For instance, Millum [49] suggests fair sharing of benefits, however, he is cognizant of the need for context-specific considerations in determining what is fair. We must therefore recognize social realities and local judgment, and then determine the best way to fairly share benefits, particularly safeguarding the most vulnerable [50].

Non-research-related assistance to communities and their health facilities has been highly appreciated in resource-limited settings such as Kenya. Provision of care supplies to primary health facilities and initiation of health interventions to alleviate pressing communal needs (e.g. digging boreholes, provision of school fees for

orphans, and provision of farming inputs) are noteworthy [5,41-42]. An example of a study in Kenya that is using biological materials and engaging local stakeholders is the NeuroGAP study [51], a multisite international case control study, where saliva is being collected for DNA extraction to establish genes that are associated with psychosis. The extracted DNA is being shipped to the Broad Institute in the US for genetic analysis. NeuroGAP sample collections are being undertaken primarily in pursuit of an international goal, to ensure that genetic advances in psychosis diagnostics and treatments include data from Africa. Another rationale for the NeuroGAP collections is to build capacity among African researchers to conduct similar work without over-reliance on external support. These types of studies and their approach to beneficence and justice should be emulated [5]

Benefits to society at large include the development and global sharing of any useful tools, interventions, and discoveries. Research projects often develop beneficial interventions, as well as medical and public health tools that are applicable in resource-limited environments. These benefits ought to be utilized in improving local health systems to help address existing gaps. This implies ethical health research aligns with the health priorities of host countries - it engages realities as defined by the settings in which the studies are undertaken [40]

In this study, participants wished to see research findings disseminated widely on scientific platforms and through the media. Dissemination of research findings locally and across the globe is considered obligatory and is a way of expanding the benefits of research beyond the communities directly involved in the study. Failure to share research findings globally denies other investigators useful information that could inform other interventions, improve healthcare, and provide guidance for relevant policies [52]. By having a dedicated allocation of budget for dissemination activities, researchers can ensure their findings are shared globally through scientific conferences, workshops, publications, and directly to research participants [42,53]. Researchers need to shift to a more comprehensive view of phases of scientific studies – that includes stakeholder feedback. Indeed, they have a duty to report to researchers and diverse stakeholders who are beyond academia and their reports should cover all study findings, societal trends, and power relations therein [54].

Dissemination of research findings locally and across the globe is considered obligatory and is a way of expanding the benefits of research beyond communities of research. The useful information informs other interventions, improves healthcare, and provides guidance for relevant policies [52]. It is clear that, despite limited structures to guide individuals and institutions on benefit sharing processes, researchers and all other stakeholders should make considerations regarding forms of research benefits, and situations in which they can be justified. Key stakeholders beyond the community of study include physicians, ethics committees, citizens, public health officials, and international actors in the promotion and control of genetic research [55]. While researchers and other stakeholders have a responsibility to provide feedback and to share the benefits of genetic research with the research community, national governments and citizens too have a responsibility to take

action to ensure feedback and fair sharing of resources [7]. Indeed, national governments across the world ought to establish and ensure continuous updating of frameworks for governing feedback and sharing of benefits.

### ***Strengths and Limitations***

This study has several strengths and limitations. The qualitative sample, distributed across two main categories of key stakeholders allowed us to get their perspectives. Therefore, this study provides useful emic views on giving feedback about biological samples and sharing benefits accruing from the future use of any stored materials. The lack of differences in the findings between the two main groups, or on other demographic variables suggests a need for a larger mixed methods study that may allow a robust analysis to reveal differences in perspectives.

A second limitation of this study is that it was carried out at a national teaching hospital where research and health interventions are common. As such there is potential for biased answers in the hope of research benefits. Moreover, community members often look up to researchers and try to provide “correct answers” whenever engaged in health research. Given the qualitative face-to-face micro-interactions in this study, our research team had to apply reflexivity to avoid influencing the interview process in terms of content and direction. The interviewers’ objective and non-judgmental attitude helped facilitate a warm environment within which respondents freely responded to study questions. Thus, the limitations noted do not disparage the quality of the findings reported herein.

### **Conclusion**

This study explored views on giving feedback about biological samples and sharing benefits accruing from future use of the stored materials. Findings show healthcare providers and health facility clients value research and wish for feedback to donors and support for their ailments. They also value community level feedback and health development projects, dissemination of research findings globally, and fair sharing of study benefits. This study is valuable because it reminds key stakeholders including sponsors, investigators, ethics committees, and communities participating in research, about the importance of paying attention to feedback and benefit-sharing concerns. Local research communities and governments can develop guidelines for sharing benefits emanating from the use of biological materials. Researchers can also make purposive commitments to channel monetary or non-monetary payments to individuals and groups involved in research [7].

In Kenya, the National Commission for Science, Technology, and Innovation (NACOSTI) facilitates the promotion, coordination, and regulation of science, technology, and innovation, which includes serving as the national body for regulating research, accrediting research institutions, and governing institutional review boards across Kenya. There are no specific regulations on biobanking research in Kenya and the existing ones are silent on data sharing, ownership of samples collected as part of research, and return of genetic results [7].

There are no clear Kenyan guidelines for the provision of individual participants with feedback on significant findings. Nonetheless, NACOSTI has recently highlighted the importance of informed consent in any research undertaken in Kenya and also developed material transfer agreements for use in studies using biological specimens. In 2020, NACOSTI revised the guidelines for the conduct of biomedical research involving human participants in Kenya, and included a finite section on the use of secondary data and stored samples [56]. NACOSTI can intentionally address this concern about feedback and benefit sharing by engaging stakeholders and coming up with a specific guideline to provide a framework for benefit sharing. NACOSTI can spearhead decisive steps toward the establishment of feedback and benefit sharing practices. Our study results suggest areas that require enhancement within the Kenyan guidelines for research. For instance, there ought to be specific guidelines to cater for the provision of free treatment and/or subsidized research products, sharing of monetary benefits, requirements for feedback on research findings, and post-study community-level benefits among researched populations. In addition, it is critical to review and where necessary craft new guidelines on the provision of individual participants with feedback that may impact their health.

The NACOSTI should consider initiating regulation to require researchers and sponsors to pay a percentage of profits made from products emanating from biological materials from Kenya. They should also determine and immediately roll out a criterion to be used in making such payments to sample donors, and to their local communities. The money allocated to the community should be used for capacity building, civic and health education, and projects aimed at improving the standards of living for underprivileged community members. Such projects should be identified in a consultative manner that should involve community representatives, civil society, sub-county, and county officials. Furthermore, non-monetary benefits such as enhancement and furnishing of local laboratories/biobanks ought to be encouraged. All materials imported to facilitate the research activities should be left in the local institutions and absorbed for health care and future research. Lastly, studies that entail the donation of samples require education initiatives to address false assumptions and beliefs held by localized communities [44-45]. This is needed even after people have signed consent forms and enrolled in studies.

Furthermore, legally binding frameworks that address human genetic resources are needed [8]. Local research communities should work with their national governments to generate legally binding frameworks for sharing the benefits of biobanking in a way that ensures mutual values of equity and justice. Such guidelines ought to be clearly stated in relevant languages and should require researchers and sponsors to provide a comprehensive list of all possible benefits to participants and their communities [57]. Like many resource-limited contexts, individuals and communities in Kenya have limited information and knowledge on their rights, and could therefore end up getting exploited through research. Research in such communities should put into consideration the role of gatekeepers for they can facilitate conscientious communication and highlight ethical obligations needed in conducting appropriate stakeholder engagement during research design, implementation, and feedback [58].

The key notions from this article include 1) giving feedback to research participants; 2) sharing monetary and other products of research; 3) building local capacities and infrastructure in researched communities; and 4) disseminating study findings broadly. It is recommended that these ideas are extensively discussed in research ethics and related workshops/educational forums where research sponsors, policy makers, investigators, ethics committee members and staff, and students can reflect on these matters extensively. Future research should explore benefit-sharing by nature of research projects, dissimilar socio-cultural contexts, and types of research sponsors and investigators. It should also look at how to package feedback in different settings. Although study participants seem to appreciate receiving their results, they sometimes report the negative psychological impact of getting these findings. Further research should therefore examine the social and emotional burdens of receiving research-associated feedback

## References

1. Zatloukal K, Stumptner C, Kungl P, Mueller H. Biobanks in personalized medicine. *Expert Review of Precision Medicine and Drug Development*. Taylor and Francis Ltd 2018;3:265-273
2. Doucet M, Yuille M, Georghiou L, Dagher G. Biobank sustainability: current status and future prospects. *J Biorepository Sci Appl Med* 2017;5:1-7
3. de Vries J, Munung SN, Matimba A, et al. Regulation of genomic and biobanking research in Africa: a content analysis of ethics guidelines, policies and procedures from 22 African countries. *BMC Med Ethics* 2017;18:8.
4. Staunton C, Moodley K. Challenges in biobank governance in Sub-Saharan Africa. *BMC Med Ethics* 2013;14:35.
5. Aellah G, Chantler T, Geissler W. *Global Health Research in an Unequal World: Ethics Case Studies from Africa*. CABI; 2016. Available from: <https://books.google.co.ke/books?id=5rU3jwEACAAJ>. [Last accessed on 2023 Feb 23]
6. Kamuya D M, Marsh V, Njuguna P, Munywoki P, Parker M Molyneux S. "When they see us, it's like they have seen the benefits!": experiences of study benefits negotiations in community-based studies on the Kenyan Coast. *BMC Med Ethics* 2014;15:90
7. Hayden C. Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-sharing. *Social Studies of Science* 2007;37:729-758.
8. Sudoi A, De Vries J, Kamuya D. A scoping review of considerations and practices for benefit sharing in biobanking. *BMC Med Ethics*. 2021 Jul 27;22(1):102
9. Schroeder D. Benefit sharing: it's time for a definition. *J Med Ethics*, 2007;33:205-209
10. Bege D, & Kris D. An Ethically Accepted Concept but not well known: Research Ethics Committees in Nigeria on the Concept of Benefit Sharing. *J Clin Res Bioeth* 2015;6:1-9.
11. Lévesque E, Joly Y, Simard J. Return of research results: general principles and international perspectives. *J Law Med Ethics* 2011;39:583-592



12. Lairumbi GM, Michael P, Fitzpatrick R, English MC. Ethics in practice: the state of the debate on promoting the social value of global health research in resource poor settings particularly Africa. *BMC Med Ethics* 2011;12:22
13. Thorogood A, Joly Y, Knoppers BM, et al. An implementation framework for the feedback of individual research results and incidental findings in research. *BMC Med Ethics* 2014;15:88
14. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Available from: [http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines\\_nov\\_2002\\_blurb.htm](http://www.cioms.ch/images/stories/CIOMS/guidelines/guidelines_nov_2002_blurb.htm). Published 2002. [Last accessed on 2023 Feb 23]
15. MacNeil SD, Fernandez CV. Offering results to research participants. *BMJ* 2006;332:188-189
16. Cox K, Moghaddam N, Bird L, Elkan R. Feedback of trial results to participants: a survey of clinicians' and patients' attitudes and experiences. *Eur J Oncol Nurs* 2011;15:124-129
17. Shalowitz DI, Miller FG. Communicating the results of clinical research to participants: attitudes, practices, and future directions. *PLoS Med* 2008;5:5
18. Halkoaho A, Pietilä AM, Vesalainen M, Vähäkangas K. Ethical aspects in tissue research: thematic analysis of ethical statements to the research ethics committee *BMC Med Ethics* 2012;13:20
19. Igbe MA, Adebamowo CA. Qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria. *BMC Med Ethics* 2012;13:27
20. Tindana P, Molyneux CS, Bull S, Parker M. Ethical issues in the export, storage and reuse of human biological samples in biomedical research: perspectives of key stakeholders in Ghana and Kenya. *BMC Med Ethics* 2014;15:76
21. Naanyu, V. Social Context and Mental Illness Stigma in South Africa. Saarbrücken: Violet Naanyu & Verlag Dr. Müller Publishing House Ltd. 2010. ISBN: 978-3-639-26340-4
22. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Soc. sci. med* 2022; 292:114523.
23. Molyneux S, Mulupi S, Mbaabu L, Marsh V. Benefits and payments for research participants: experiences and views from a research centre on the Kenyan coast. *BMC medical ethics* 2012;13:1-5.
24. Marsh V, Kombe F, Fitzpatrick R, Williams TN, Parker M, Molyneux S. Consulting communities on feedback of genetic findings in international health research: sharing sickle cell disease and carrier information in coastal Kenya. *BMC Med Ethics* 2013;14:41
25. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Bethesda, MD: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; 1979. Available from: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>. [Last accessed on 2023 Feb 23]
26. Cadigan RJ, Michie M, Henderson G, Davis AM, Beskow LM. The meaning of genetic research results: reflections from individuals with and without a known genetic disorder. *J Empir Res Hum Res Ethics* 2011;6:30-40

27. Beskow LM, Burke W. Offering individual genetic research results: context matters. *Sci Transl Med* 2010;2:38
28. Vermeulen E, Boeckhout M, Zielhuis GA, Bakker R, Janssens AC, Schmidt MK. Biobanks and the return of results to donors. *Ned Tijdschr Geneesk* 2014;158:5
29. Long CR, Purvis RS, Flood-Grady E, et al. Health researchers' experiences, perceptions and barriers related to sharing study results with participants. *Health Res Policy Syst* 2019;17:25
30. Alahmad G, Alzahrany H, Almutairi AF. Returning Results of Stored Biological Samples and Biobanks: Perspectives of Saudi Arabian Biomedical Researchers. *Biopreserv Biobank* 2020;18:395-402
31. Murphy, J., Scott, J., Kaufman, D., Geller, G., LeRoy, L., Hudson, K., Borchelt, R., & Williams, S. (2008). Public Expectations for Return of Results from Large-Cohort Genetic Research. *Am J Bioeth*, 8(11), 36–43.
32. Miller FA, Christensen R, Giacomini M, Robert JS. Duty to disclose what? Querying the putative obligation to return research results to participants. *J Med Ethic* 2008;34:210-213
33. Bemelmans SA, Tromp K, Bunnik EM, et al. Psychological, behavioral and social effects of disclosing Alzheimer's disease biomarkers to research participants: a systematic review. *Alzheimers Res Ther* 2016;8:46
34. Kingori P. The 'empty choice': A sociological examination of choosing medical research participation in resource-limited Sub-Saharan Africa. *Curr Sociol* 2015;63:763-778
35. Naanyu V., Some F.F., & Siika A.M. (2014). "I understood some parts...but some were confusing and hard to grasp": Patients' perception of informed consent forms and clinical trials in Eldoret, Kenya. *Perspect Clin Res* 5(1), 20-24.
36. Lang, M., Zawati, M.H. Returning individual research results in international direct-to-participant genomic research: results from a 31-country study. *Eur J Hum Genet* 30, 1132–1137 (2022)
37. Lázaro-Muñoz G, Torgerson L, Pereira S. Return of results in a global survey of psychiatric genetics researchers: practices, attitudes, and knowledge. *Genet Med*. 2021 Feb;23(2):298-305
38. National Academies of Sciences, Engineering, and Medicine. 2018. Returning individual research results to participants: Guidance for a new research paradigm. Washington, DC: The National Academies Press
39. Molyneux S, Geissler PW. Ethics and the ethnography of medical research in Africa. *Soc Sci Med* 2008;67:685-695
40. Ijsselmuiden CB, Kass NE, Sewankambo KN, Lavery JV. Evolving values in ethics and global health research. *Glob Public Health* 2010;5:154-163
41. Lairumbi GM, Parker M, Fitzpatrick R, English MC. Forms of benefit sharing in global health research undertaken in resource poor settings: a qualitative study of stakeholders' views in Kenya. *Philos Ethics Humanit Med* 2012;7:7
42. Mfutso-Bengo J, Ndebele P, Masiye F. Disseminating research results to research participants and their communities. *Malawi Med J* 2008;20:64-66
43. Geissler PW, Pool R. Editorial: Popular concerns about medical research projects in sub-Saharan Africa - A critical voice in debates about medical research ethics. *Trop Med Int Heal*. 2006;11(7):975–82

44. Kutalek R, Baingana F, Sevalie S, Broutet N, Thorson A (2020) Perceptions on the collection of body fluids for research on persistence of Ebola virus: A qualitative study. *PLoS Negl Trop Dis* 14(5)
45. Fairhead J, Leach M, Small M. Where techno-science meets poverty: medical research and the economy of blood in The Gambia, West Africa. *Soc Sci Med*. 2006 Aug;63(4):1109-20
46. Gupta, C., & Kelly, A. B. (2014). The social relations of fieldwork: Giving back in a research setting. *J. Res. Pract.*, 10(2), 1–11
47. Baylor, C., Yorkston, K., Eadie, T., Kim, J., Chung, H., & Amtmann, D. (2013). The Communicative Participation Item Bank (CPIB): Item Bank Calibration and Development of a Disorder-Generic Short Form. *J. Speech Lang. Hear. Res.*, 56(4), 1190–1208
48. Wolf SM, Paradise J, Caga-anan C. The law of incidental findings in human subjects research: establishing researchers' duties. *J Law Med Ethics*. 2008 Summer;36(2):361-83, 214
49. Millum J. How should the benefits of bioprospecting be shared? *Hastings Cent Rep*. 2010 Jan-Feb;40(1):24-33
50. Njue M, Kombe F, Mwalukore S, Molyneux S, Marsh V (2014) What Are Fair Study Benefits in International Health Research? Consulting Community Members in Kenya. *PLoS ONE* 9(12)
51. Stevenson A, Akena D, Stroud RE, Atwoli L, Campbell MM, Chibnik LB, et al. Neuropsychiatric Genetics of African Populations-Psychosis (NeuroGAP-Psychosis): A case-control study protocol and GWAS in Ethiopia, Kenya, South Africa and Uganda. *BMJ Open*. 2019;9(2).
52. Dobbins M, DeCorby K, Twiddy T. A knowledge transfer strategy for public health decision makers. *Worldviews Evid Based Nurs* 2004;1:120-128
53. Wilson, P. M., Petticrew, M., Calnan, M. W., & Nazareth, I. (2015). Does dissemination extend beyond publication: a survey of a cross section of public funded research in the UK. 1–8.
54. Tubaro P. Whose results are these anyway? Reciprocity and the ethics of “giving back” after social network research. *Soc Networks [Internet]*. 2021;67:65–73.
55. Fedeli P, Casella C, Buccelli C, Cannovo N, Graziano V. Genetic Research: The Role of Citizens, Public Health and International Stakeholders. *Open Public Health J*. 2019;12(1):106–13
56. NCST (2020). National Guidelines for Ethical Conduct of Biomedical Research Involving Human Participants in Kenya. Second edition
57. Dauda B, Dierickx K. Benefit sharing: an exploration on the contextual discourse of a changing concept. *BMC Med Ethics*. 2013 Sep 12;14:36
58. Singh S, Wassenaar D. Contextualising the role of the gatekeeper in social science research. *South African J Bioeth Law*. 2016;9(1):42

### **Acknowledgment**

Authors wish to acknowledge support from The Africa Ethics Working Group (AEWG) which is part of the NeuroGenE project, ([www.neurogene.org](http://www.neurogene.org)) and is funded by the Stanley Centre at the Broad Institute of Harvard and MIT [HQR01031].

### **Declaration of Interest statement**

No potential conflict of interest was reported by the authors.

### **Data availability statement**

The data used in this research are available upon reasonable request from the corresponding author.



[Supplementary File 1.pdf](#)

51 KB