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International Perspectives on the Collection, Storage, and Testing of Human Biospecimens in HIV Research

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Biomedical research that seeks to advance health knowledge and medical practice is an overall social good. However, there is a wide range of professional and lay perspectives regarding the distribution of benefit from research involving human biospecimens. The questions surrounding such research are generally described in terms of property and ownership based on North[1] concepts of selfhood and the collective good.[2] But with the increasing globalization of biomedical research, the framing of such debates must also expand. Ethnographic research indicates that people in many cultures and societies invest human biospecimens with value and meaning.[3]

Understanding societal norms and cultural beliefs concerning research with human biospecimens is important for ensuring ethical obligations are met and the benefits of scientific advancement are mutually received. Anecdotal reports suggest that collecting blood and other biospecimens (e.g., breast milk, placental tissue, saliva, semen, urine, and vaginal swabs) have sometimes resulted in controversy in a wide range of cultural settings. Examples include concerns that collected blood will be used for satanic purposes, that confidential and identifiable information will be disclosed, and that biospecimens from poor people in the South will be used in treatments for patients in wealthy countries or to create new drugs that will enrich pharmaceutical companies with no benefit to those donating the material.

The extent to which these and other concerns are prevalent among diverse populations participating in research is currently unknown. As an initial exploration of how international communities view the collection, storage, and testing of human biospecimens, a structured discussion session on this topic was held at the annual meeting of a global HIV prevention research network. The storage and future testing of biospecimens collected as part of the network studies is important because laboratory tests as well as knowledge about HIV and the way the virus interacts with the body are continually evolving. Stored biospecimens obtained from globally diverse at-risk and infected populations support basic research that can contribute to the development of effective interventions such as vaccines.

Method for Tabletop Sessions

The HIV Prevention Trials Network (HPTN) is a global research network funded by the U.S. National Institutes of Health (NIH). Prior to the 2006 HPTN annual meeting in Washington, DC, attendees were invited to sign up for a 90-minute structured discussion

about the collection and storage of human biospecimens for research. Approximately 90 conference attendees joined the session, including community advisory board members, community educators, research team members, and NIH staff. Session participants represented all three regional working groups of the network (Africa, Asia, and the Americas), and all had experience with the collection, use, and/or storage of biospecimens, though this experience varied widely. Biospecimen collection, use and storage are part of almost every HPTN research protocol. The session participants who were likely to have the least knowledge about the topic were the community representatives, though they were far from naïve. The large number of participants in the session (90+) is an indication of the level of interest in and knowledge about the topic among all HPTN stakeholders. This session competed with others at the annual meeting, yet almost 20% of meeting attendees attended the session. Ethics review was not required for this conference activity under U.S. human subjects protections regulations. This activity was reviewed by the FHI Institutional Review Board (IRB) administrator and determined not to be human subjects research as defined by 45 CFR 46.

Session participants were divided into tabletop groups of about 12 people, with a facilitator and at least one note-taker assigned to each table. Where appropriate, participants were grouped by language to ensure inclusion of viewpoints from those with limited or no English fluency. Translators ensured that non-English speaking participants were able to contribute to the discussions. Each tabletop group was asked to discuss the following four questions with regard to the extent of concerns in their communities around the collection, storage, and use of biospecimens, and to describe how these concerns have been or can be addressed. Participants received the questions prior to the meeting so they could solicit input from other stakeholders in their communities:

1. What has been your community's experience with the collection of biospecimens for research purposes?
2. How do people in your community feel about leftover biospecimens being stored after the original research is over?
3. What is known in your community about the decision-making process in regard to biospecimens left after the research is over (i.e., testing and disposal of biospecimens)?
4. Overall, should there be any constraints or conditions placed on future use of leftover biospecimens after the original research is over?

Each table included representatives from each of the major stakeholder groups. Many of the individuals attending (and especially the community advisory board members and community educators) actively solicited input from their constituencies before coming to the meeting; thus, they actively represented the broader perspectives of their constituencies rather than voicing only their personal experience and views.

Notes from each of the small group discussions were aggregated, and the authors systematically categorized the responses and identified major themes. This was done by jointly reading the notes from each tabletop discussion, developing a list of themes based on

that reading, linking themes with specific text in the notes, and refining the themes to identify major and minor themes. A draft session report summarizing the major and minor themes was compiled and distributed in hard copy at the HPTN meeting one day after the session with a request for comments. The draft session report was also distributed via email to all session participants who were asked to provide feedback and comments to ensure accuracy and representative voice in the final session report. Appeals for additional comments and suggestions to the draft report were requested as part of four HPTN conference calls in March 2006 with members of the global Community Working Group, the Africa Regional Working Group, the Asia Regional Working Group, and the Americas Regional Working Group. These efforts resulted in corrections and comments from 18 reviewers of the draft report, mostly session participants.

What the Sessions Revealed

At the request of session participants, particular comments were not identified with specific countries or sites in order to avoid stereotyping or stigmatization. There was no clear geographic pattern with regard to the types of issues identified by participants, which fell into four broad categories (described in detail below). Many solutions were also proposed, and these are summarized along with examples of specific concerns.

Sensitivity to Local Culture, Context, and History

The pervasive importance of local culture, context, and history for biospecimen collection and storage was evident in wide-ranging references to the implications of beliefs (e.g., about the significance of specific types of biospecimens), relationships (e.g., family interests in biological “remains” following death), and experiences (e.g., previous history of medical or research exploitation). Many session participants felt that U.S. values and beliefs about human biologic material cannot easily be used as a guide for policy development that is appropriate in all global research settings. For example, in some places the expression of breast milk and the collection of placentas may be viewed as unacceptable for use in research testing. In some cultural settings it is believed that all parts of the body must be buried once a person dies or the soul will not find peace; therefore, long-term storage of biologic material has raised concerns among potential research participants about whether the material can be retrieved for burial when a current or former research participant dies. Research policies and practices need to reflect awareness of and sensitivity to such cultural values, otherwise concerns about exploitation could prevent important research from moving forward.

In some settings partners and spouses of research participants may want to know where biospecimens will be stored and to be included in decision-making about the disposal process. In such contexts confidentiality may need to be addressed as a family issue, rather than participant-specific. The discussions around this topic highlighted broader challenges related to balancing respect for cultural values with principles of autonomous decision-making in research.[4] Most session participants did not see these as insurmountable obstacles for important research, but stressed the need for cultural sensitivity and community dialogue for finding an acceptable way forward.

Transparency and Trust

From the tabletop discussions it was clear that rumors tended to emerge within communities when people did not understand the scientific reasons for collecting biospecimens. In the absence of trust those rumors tended to be negative. Thus, transparency with regard to scientific motivations and requirements appeared to be a key component of trust-building. The collection of what were viewed to be large quantities of blood, either at one point in time or as a result of multiple blood draws over time, were the source of many negative perceptions. Session participants explained that some people recruited for research worried about potential illness that could result, such as anemia, or had expressed concerns about the need to drink to replenish one's fluids after a blood draw. These concerns were heightened with regard to blood draws for research with infants. It was noted that people generally have a poor understanding of the amount of blood in their bodies and the body's ability to replenish the blood supply. A recommended approach for addressing this concern was to visually demonstrate how much blood is in the body compared to how much is taken, e.g., with appropriately sized containers.

In some settings community leaders' lack of confidence in the local health system extended to clinical trials. Some session participants noted that previous research experiences can impact community views and either undermine or enhance trust of local and international researchers. Many examples of this distrust were given. Session participants reported rumors that people got HIV from free condoms that researchers provided and that the blood collected by the researchers would be sterilized and used to manufacture tablets that caused HIV. In one setting researchers were rumored to be responsible for the abduction of a two-year-old girl who was murdered and mutilated.

There were several reports of concerns that biospecimens would be used for satanic purposes, with one site reporting that such rumors were promulgated by some churches. Stories about vampires drinking the collected blood were also described. At one site concerns were raised that vaginal biospecimens may be used for infertility treatments in the United States. Others reported situations where reimbursement to research participants was greater than actual study-related costs such as transportation, leading some research participants to suspect that the extra payment was for the use of their blood for negative purposes elsewhere. Some research participants were reported to believe there was a direct relationship between the quantity of blood taken for research protocols and the amount of money gained by the researchers as a result of perceived commercial uses of the blood. In general, it seemed that whenever there was uncertainty about how biospecimens were to be used, people would reach their own conclusions based on knowledge about similar situations, media reports, and cultural beliefs. One way to dispel these kinds of uncertainties is to hold an open house at laboratory facilities and demonstrate laboratory and material collection procedures.

Some session participants suggested that negative rumors about research in a community may have been started by those ineligible to enroll in studies as a way to avoid being stigmatized based on the assumption that they could not participate because they were HIV positive. For populations experiencing discrimination such as racial and ethnic minorities, men who have sex with men, or injection drug users, there were concerns about the kinds of

testing that might be done in the future and whether the results could lead to harm of persons. Fears were also expressed that identifiable information from a biospecimen, especially HIV status, would be disclosed.

As concerning as these fears were, most session participants nonetheless felt that once researchers won the trust of a research participant, the collection and future use of biospecimens was generally not an issue. Therefore, the main challenge was viewed as one of building trust between the research participant, his or her community, and the research staff. Considerable debate emerged as to whether it was necessary to address the issue of future testing in detail, or whether the trust built with participants as part of the informed consent process is enough. Some were concerned that placing undue emphasis on something that people were not concerned about could in fact create suspicion if research participants are already trusting or indifferent about the issue.

Many session participants mentioned that research participants and community members want to know the research results from testing done on their biospecimens, including future testing. Returning the test results to participants and their communities was thus viewed as an important issue for consideration when biospecimens are collected and stored.

Informed Consent Challenges

Session participants from all sites reported a general lack of community understanding about long-term storage of human biospecimens, why biospecimens are taken out of the country where they were collected, and what kinds of testing may be done in the future. Future testing of biospecimens was viewed as a distinct issue within the informed consent process about which researchers needed to provide more awareness, as the usual assumption is that biospecimens are used only for the current study. It was reported that at one site some research participants refused to agree to storage of their biospecimens when they were told the biospecimens would be kept for 12–18 months, indicating the importance of individual choice in determining whether their biospecimens could be stored for future research.

Overall, there was strong consensus among session participants that research participants should be informed about their rights with regard to long-term storage and future use of biospecimens. It was repeatedly stated that researchers should obtain separate consent for current and future research use and that individuals should be given the opportunity to opt out of future studies. Some argued that it is a form of coercion when biospecimen storage is not required to meet current study objectives, but individuals must nonetheless consent to storage in order to be allowed in the study. There was general agreement that researchers who gained the people’s trust through an appropriate informed consent process would see that trust expressed in positive decisions concerning future use of biospecimens.

Session participants recognized that researchers cannot always specify how biospecimens will be used in the future. This was viewed as a major challenge with regard to the need to strike a balance between burdensome consent requirements and the educational needs of research participants. The difficulty in finding a balance that does not impede science while protecting participants’ rights was evident in the amount of discussion devoted to this issue. Session participants differed in their opinions about the feasibility of strategies such as

reconsent; however, there was general agreement with regard to the scientific importance of biospecimen storage and the ability to access biospecimens for unanticipated research purposes.

Most session participants felt that a lengthy informed consent process was problematic, despite the need for full disclosure, as it could make some people suspicious. Many also explained that when a person gives consent to participate in a study, that does not always mean that she or he fully understands the study; it might simply mean that the person is tired and wants to get the informed consent process over with. Others noted that people often do not know that they have the right to ask about things such as storage of biospecimens, and that attention to body language or nonverbal communication is often needed to identify unstated concerns or fears.

Increasing reliance on community advisory boards for advice on achieving an appropriate balance in the informed consent process was noted, but some session participants stated that board members do not always understand how informed consent is administered in practice and therefore may not be empowered to effectively advise researchers. There was general agreement that there is a need to train members of community advisory boards and all research team members about individuals' decision-making processes regarding the storage of their biospecimens.

International Biorepositories

In the context of international research, the issues described above take on added complexity. Session participants reported many concerns in their communities around the issue of blood being transported from African, Asian, and South American countries to the United States for unknown use. Some session participants wanted to know if their respective Ministries of Health were aware that human biospecimens were being stored outside the country. Some also reported that in their countries regulations existed that restricted the transfer of biospecimens elsewhere. In other countries local regulatory agencies were reported to monitor the storage of biospecimens. These agencies request information on and justification for studies that include the collection of biospecimens, including specific time periods for storage. Once this time period has expired, researchers are responsible for reapplication to the local regulatory authority to extend the storage period, or the material must be discarded. Session participants were often divided with regard to the acceptability of indefinite long term storage. Many communities viewed community advisory board members as appropriate representatives to make decisions about future testing when such storage was planned.

According to meeting participants, research participants in some settings feel that if biospecimens are stored in their own country, they are more likely to find out the results of future testing. However, other research participants felt that storage outside the host country is safer because it may be more confidential, and because well-regulated repositories in more developed countries may have better quality control of biospecimens. Another important issue centered on how biospecimens would be destroyed if they are not to be stored. Many session participants felt research participants would want to be informed once their biospecimens were destroyed. There were strong feelings that destruction needed to be

observed either by the participants or by a community advisory board member. In settings with high levels of distrust, however, it was stated that even with direct observation there may be lingering doubts or concerns over the destruction process.

A special concern was often raised over possible use of blood for genetic testing. It was reported that one local ethics committee was very concerned about the issue of storage and opposed biospecimens being sent overseas for fear that genetic testing would be done without consent and that results could lead to the publication of negative and stigmatizing information about the population.

For session participants outside the United States, the ability of host country researchers to have future access to biospecimens collected as part of U.S.-sponsored research was an important issue. Concerns were expressed that if research protocols did not explicitly state that host country researchers would have such access then they could lose all rights to the biospecimens. There was also concern that the future research benefits would accrue outside the country, and that the research participants would therefore carry the burden of the research, but not gain the benefits. Others expressed the need for multicountry research teams to work together with regard to accessing biospecimens for testing and assuring benefit to communities where the biospecimens were collected. Many session participants said there is a need for host-country capacity building so that biospecimens can be stored and analyzed without having to send samples to the United States.

Discussion

Structured tabletop discussions with a broad cross-section of stakeholders in the global HIV prevention research network revealed that research participants have a wide array of concerns about the collection and storage of human biospecimens. The limited generalizability of U.S.-based principles and experience for international settings was repeatedly noted, along with the corollary need for sensitivity to local culture, context, and history. Transparency emerged as a critical issue for a wide range of topics: the reasons for collecting biospecimens; where they will be stored; who will have access to them and for what purposes; how confidentiality will be maintained; whether future testing results will be shared with research participants or their communities; who will benefit from future research and how; who will provide oversight of stored biospecimens; and how the destruction of biospecimens will take place. Viewpoints varied with regard to how much information research participants needed to have to make an informed decision about storage of the biospecimens. Considerations included the background level of trust between research participants and researchers, the need to avoid overly burdensome consent procedures, and the potential for generating rather than alleviating distrust. However, there was broad agreement that participants should not be required to consent to the collection or storage of biospecimens that are not needed to meet current research protocol objectives as a condition of participation in that study. The involvement of community advisory boards and local ethics committees and the development of governmental oversight mechanisms were generally viewed as positive means for addressing the concerns identified. In this regard, it is important to note that guidance from community advisory boards in addition to local ethics committee oversight was viewed as critical by many of the session participants. This

contradicts the findings from recent empirical studies in Kenya and Uganda suggesting that local ethics committees can provide sufficient oversight.[5] Whether this reflects sampling bias related to cultural variability, a bias toward greater community participation among the HPTN stakeholders, or biases in the design of the empirical studies is unclear. However, as indicated by Upshur and colleagues in a review of these and other studies "there have been no studies that look specifically at the perceived relationship between donors and their tissues and the significance of the relationship for communities. … To get at the root of these interests it will be necessary to go beyond survey designs, which pose questions from the perspective of the researchers, to more naturalistic modes of enquiry, which can help to reveal insights and meaning that survey methods can't reach."[6]

Importantly, the session participants were geographically diverse and represented a wide range of perspectives on the topic. Their comments highlight the need to address policy development for human biospecimens from the perspectives of scientific advancement, socio-cultural beliefs, ethical obligations, regulatory guidelines, and political realities. Despite this complexity, there was much agreement on the benefits of biomedical research using human biospecimens. The challenge is in balancing the logistical and often ambiguous demands of science with the perceived and actual threats to effective protection of the research participants and communities.

The results of this report are limited in that they are derived from a 90-minute discussion on a complex topic, albeit with a range of global stakeholders. The involvement of the session participants in a research network meant that they were likely to be proresearch; thus, their specific viewpoints should not be generalized more broadly without considering this bias. The tabletop sessions differed from traditional focus groups in that at least some participants in each group knew each other. This was a participatory exploration of a focused topic, not a classic qualitative data collection effort. The approach reflects the dialogic, participatory research model explicitly developed within and promoted by the HPTN. The tabletop grouping strategy was intentional and reflects the recommendations of members of the HPTN Community Working Group who provided input on how to most effectively structure the session to promote active dialogue among all stakeholders. Anecdotal reports derived from previous discussions within the HPTN Community Working Group served as initial probes for the tabletop discussions. In this sense, many of the findings reported here are confirmatory. While the broad types of findings were therefore not surprising, the specific examples that emerged from the discussion help to inform specific recommendations for addressing the issues identified here and in other reports. Even though these concerns were raised in the context of the experience of an HIV prevention research network, they are likely to be of interest to and relevant for other contexts.

In order to fully understand the implications of cultural beliefs and social reality for the collection and storage of human biospecimens, there is a need for more in-depth discussions with communities in the environments where research is being conducted. Potential follow-up steps include an assessment of the laws and regulations concerning the collection and long-term storage of human biospecimens within host countries and further discussions with local researchers and communities regarding ownership of biospecimens and ways to enhance the benefits that accrue from future research within their countries.[7]

There is also a need for observations of the informed consent process in order to form a better understanding of how individuals are being told about the risks and benefits of participating in research with human biospecimens. Further observations are also needed of how biospecimens are collected, what type are collected, where they are stored and for how long, and how biorepositories are accessed for new research questions. The verification processes of biorepositories should be reviewed with regard to the destruction of biospecimens. Finally, alternative models should be researched and evaluated in order to develop more culturally and socially appropriate trainings and processes for informed consent and research literacy.

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