

Stakeholder Input and Recommendations for Good Participatory Practices (GPP) in Biomedical HIV Prevention Trials in Thailand



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Executive Summary

Stakeholder Input and Recommendations for Good Participatory Practices (GPP) in Biomedical HIV Prevention Trials in Thailand gathers and analyzes qualitative data from a diverse array of Thai stakeholders using key informant interviews and focus group discussions. The goal is to identify successes, issues and recommendations to guide the implementation and adoption of the Good Participatory Practice Guidelines in Thai research contexts.

Three categories of stakeholders were involved in this project:

- i) researchers and research site staff,
- ii) staff of non-governmental organizations (NGOs) and community-based organizations (CBOs)
- iii) community members, among whom were past and present participants of biomedical HIV prevention trials.

The interview schedules were designed to explore and elicit recommendations for community engagement and participatory practices including community advisory boards (CABs) and community advisory mechanisms (CAMs), standards of HIV prevention and informed consent, and recommendations for communication for researchers, communities, participants, policy makers and sponsors.

Interviews were audio recorded, transcribed, translated as necessary and thematically analyzed. In relation to key issues, fifteen themes and recommendations emerged from these stakeholder conversations.

1. Good participatory practice engages with potential research participants and their communities. It encourages communities to learn and share trial-related information and knowledge.
2. Representatives of key stakeholder groups such as injecting drug users (IDU) and sex workers have invaluable knowledge and experience. Their expertise can help guide recruitment and retention and the development and delivery of a standard of prevention.

3. Sponsor-mandated community advisory mechanisms can grow beyond simply a requirement of funding, to be a successful part of a trial.
4. Policy makers, sponsors and prevention trial implementers should consider the creation of local or national community advisory mechanisms, which are not necessarily trial specific but ongoing beyond the length of an individual trial.
5. Genuine engagement will not be possible in the presence of prejudice, whether from research teams toward community members or from community members toward research teams.
6. Sensitivity training for trial implementers and trial site staff strengthens the quality of community engagement. It helps facilitate the meaningful involvement of marginalized groups. It will strengthen the attainment of the overall objective of the research also.
7. Meaningful engagement requires seeking, accepting and/or responding to the input from all types of stakeholders. This means soliciting and acting on input from people who are low in social status or have low levels of education, income or literacy.
8. Early community involvement is essential. Community should be involved at the initiation of the study design stage or at the initiation of the design of operational plans.
9. Community engagement is effective when research protocols, the researchers and teams implementing those protocols have clear plans for creating and sustaining that engagement before, during and after a specific trial.
10. Effective community engagement requires that trial entities support the means for participants to reduce the risk of HIV as well as support their overall health and well-being. This will help participants to safely and routinely engage in trial activities while protecting themselves from HIV and its transmission. Trial sponsors and policy makers need to work to amend national policy to enable the distribution of the full range of HIV prevention tools, like clean injecting equipment for IDU, without exception or discrimination.

11. Training for people involved in community advisory mechanisms helps them to be effective advisors to researchers and trial staff. This training may require dedicated funding, sufficient time on the part of research teams and others, and a commitment for ongoing training. Ongoing training is necessary because the knowledge needs may change during the course of a trial.
12. Community advisory boards are not the only effective form of community engagement. There is need to explore other forms of community advice. The exploration of other forms of community advice could be done on a local basis. One example would be to link advisory mechanisms and to form a network of such mechanisms.
13. Evaluation is vital. Policy makers, sponsors and trial implementers should work with communities to develop and make a set of tools available to assist researchers to conduct and evaluate the community engagement of a trial.
14. Community education and the shared knowledge that it promotes does not end when a trial ends. Community knowledge has benefits over the long-term. It should be encouraged and supported during and between trials.
15. Social and power dynamics often prevent genuine community participation. Effective and genuine participation requires recognition and attention to these dynamics.

BACKGROUND TO THE PROJECT

After ethical concerns led to premature closures of biomedical HIV prevention trials in several countries, UNAIDS (the Joint United Nations Programme on HIV/AIDS) and AVAC (Global Advocacy for HIV Prevention) developed Guidelines for Good Participatory Practice for biomedical HIV clinical trials (GPP). The first edition of the GPP Guidelines was published in 2007,¹ and the second edition in 2011.² The Thai-language translation of the second edition of GPP appeared in 2012.³ The GPP Guidelines include guidance related to various ethical principles. The guidelines offer advice to trial practitioners in order to promote participatory practice. The intent of participatory practice is to address some of the concerns that led to premature trial closures.

The present Project—*Stakeholder-based Input and Recommendations for Good Participatory Practices (GPP) in Biomedical HIV Prevention Trials in Thailand*—gathered and analyzed qualitative data from a diverse array of Thai stakeholder groups. These stakeholder groups included researchers, research site staff, non-governmental organizations, trial participants and local community members. The goal was to articulate and better understand stakeholder input on and recommendations for the implementation of community engagement. Key issues of focus include communication between stakeholders, informed consent, and standards of HIV prevention. In a 2009 consultation with Thai community stakeholders conducted by the Thai AIDS Treatment Action Group (TTAG), these particular topics were selected to be the focus of this project because they were identified as crucial areas for improvement.

¹ Joint United Nations Programme on HIV / AIDS (UNAIDS), Global Advocacy for HIV Prevention (AVAC). UNAIDS / 07.30E / JC1364E. Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials, 1st Edition. Geneva: UNAIDS, 2007. URL: http://whqlibdoc.who.int/un aids/2007/9789291736348_eng.pdf

² Joint United Nations Programme on HIV / AIDS (UNAIDS), Global Advocacy for HIV Prevention (AVAC). Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials, English Language 2nd Edition. Geneva: UNAIDS, 2011. URL: <http://www.avac.org/ht/a/GetDocumentAction/i/35219>

³ Joint United Nations Programme on HIV / AIDS (UNAIDS), Global Advocacy for HIV Prevention (AVAC). Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials, Thai Language 2nd Edition. Geneva: UNAIDS, 2011. URL: <http://www.avac.org/ht/a/GetDocumentAction/i/41693>

METHODS AND SAMPLE

This qualitative research project collected recommendations using key informant interviews and focus group discussions (FGDs) with people involved at a variety of levels with HIV-related clinical trials in Thailand. Three categories of stakeholders were involved: i) researchers and research site staff, ii) staff of non-governmental organizations (NGOs) and community-based organizations (CBOs), and iii) community members, among whom were past and present participants of biomedical HIV prevention trials. Stakeholders participating in FGD and key informant interviewees were recruited directly or through word-of-mouth. Those participating in FGD received Thai Baht 500 as compensation for their time and Thai Baht 200 reimbursement for their travel expenses. All key informant interviews waived any compensation or reimbursement.

Interviews and FGDs were audio recorded and transcribed. Thai-language interviews were translated into English. Perspectives and recommendations were compared within and across stakeholder groups; analyzed for agreement and differences between stakeholder groups; and presented as reflections and recommendations for improving the implementation of GPP.

All participating stakeholders signed an informed consent form that was available in English and Thai. The study protocol was approved by the University of Toronto Research Ethics Board.

In total, 14 in-depth interviews and three FGDs were held in Bangkok, Chiang Mai and Pattaya, Thailand. Of the in-depth interviews, 10 were conducted with researchers and trial staff and four were conducted with representatives of Non-Governmental Organizations. FGDs included an average of seven people each.

PROJECT LIMITATIONS

The project has several limitations. The stakeholders participating in interviews and FGD were selected based on their knowledge or experience. However, the interviewees who participated in this study were not necessarily representative of all researchers, trial staff or NGOs. Similarly, those who participated in the FGDs were not necessarily representative of all people involved in HIV-related clinical trials in Thailand. This research recruited more researchers than trial staff or representatives of NGOs. In addition, the majority of questions focused on the research enterprise as opposed to community development or community advocacy work. This may make it difficult for this particular project to reflect on the full breadth of community experience. Finally, this project focused on how to improve future research and less on what worked well or what limited the success of past projects.

OUTLINE OF THE ANALYSIS

The outline of the analysis is as follows. First, it will describe definitions of community engagement provided by the research participants. It will then explore stakeholder experiences with good participatory practices, and challenges for community engagement. It will consider stakeholder input and recommendation for improving community engagement, community advisory boards and community capacity building. It will reflect on stakeholder input and recommendations for improving good participatory practices in relation to standards of HIV prevention, informed consent and communication. Finally, it will consider stakeholder's specific recommendations for researchers, communities, and policy makers and sponsors.

DEFINITIONS OF STAKEHOLDER AND COMMUNITY ENGAGEMENT

Individuals participating in this research were asked to provide definitions of stakeholder and community engagement. There was a consensus among all those that participated in this research project, that "stakeholders" of biomedical HIV prevention trials could include many different parties. For example, researchers and those who work

at NGOs, potential research subjects and also their families, neighbors and communities.

A stakeholder could be a person from the community or an individual from an organization within or outside of the catchment area of a trial site. Stakeholders might be people living in a community where the trial is taking place, or specific groups of people, such as youth, monks or housewives. Stakeholders do not necessarily have to be from a trial's target population; stakeholders could also include those who represented the interests of that population or could represent the interests of local government and authorities.

Community engagement included activities that targeted everyone involved in HIV interventions. This included doctors, nurses, communities, policy makers, local policy makers, organizations and centers, and people who may benefit from or be affected by the research, especially people living with HIV (PLWHA).

EXAMPLES OF EXPERIENCES WITH GOOD PARTICIPATORY PRACTICES

Stakeholders were asked to describe successful examples of trials working with research participants in the community as well as facilitators of success

One researcher stakeholder reflected on the experience of a large, well-established research team. The researcher said that the most useful and fulfilling activities from the perspective of the research team were those that genuinely engaged with research participants and their communities. One reason for this was that the trial team designed the engagement so that the community was encouraged and resourced to take ownership of the research and to both acquire and share trial-related information and knowledge. The researcher thought that community engagement activities created ties between potential research participants and study staff. Community engagement helped better inform stakeholders about aspects of the study. This was important because the study was lengthy, and would occur over a number of years. The informant suggested that participation that built research knowledge and capacity and that contributed to informing standards of prevention and the provision of prevention services, functioned to help reduce participant loss and attrition.

Research stakeholders noted also that representatives of key groups in the community such as IDU and sex workers have invaluable knowledge and experience. They indicated that this expertise could help guide recruitment and retention. They also said that this expertise could help with development and delivery of a standard of prevention. They felt that, despite challenges, there are many good reasons to involve community stakeholders more broadly. Meaningful involvement was contrasted with other forms of community engagement that might be tokenistic and as a result, less challenging or easier to include in a trial setting.

Some researchers suggested that incorporating representatives of marginalized groups like men who have sex with men (MSM), sex workers, IDU and migrants into collaborative, participatory processes could be challenging. They contrasted these challenges with the observation that in many instances civil society engagement in national policy-making was an important part of the Thai approach to HIV and AIDS.

Trial staff stakeholders indicated that enrolling marginalized groups such as sex workers or IDU could prove challenging because some of their requests go against national policies. One example of this has been the request from IDU and their advocates for clean injecting equipment to be provided as part of the standard of prevention in clinical trials enrolling IDU. Clean injecting equipment is not allowed in Thai government policy on health care for IDU, and as a result, it was not made available in communities where the trials were taking place. Nevertheless, the groups requested this equipment be provided because they wanted to protect the health of their communities, and because the provision of clean injecting equipment is recognized as part of international best practice for harm reduction with IDU.

Trial staff also reported that it takes time to develop good relationships and establish trust. Further, that it is not always easy to build time into the research process because the research process is often results-oriented. The tight timelines of trials may not promote strong community engagement.

Other trial staff stakeholders reported that they undertook community engagement at the insistence of trial funders or sponsors. For example, a sponsor might require that the research team form a CAB and consult with the CAB regarding protocol development. Several stakeholders noted that initially such advisory groups consisted mainly of government or academic stakeholders. They described how, over time, these groups could branch out to include people with religious affiliations like monks and people affiliated with temples, some of whom had offered care and support to people living with HIV. Later, community advisors expanded to include volunteers in the community who work as advocates for PLWHA, and then to representatives of marginalized groups themselves. In these instances, CABs or other CAMs began from a sponsor-mandated requirement, and then evolved to become a successful part of community engagement.

However, as individuals from all the stakeholder groups noted to varying degrees, engagement will not be possible in the presence of prejudice, be that prejudice experienced on the part of research teams towards community members or community members towards research teams.

CHALLENGES FOR COMMUNITY ENGAGEMENT

Stakeholder reflections on challenges to community engagement

Stakeholders reported a number of challenges on the part of the research community and others about working with communities, in particular marginalized communities.

One of these challenges related to language and literacy. Stakeholders noted that it could be difficult to retain scientific accuracy while seeking to communicate in language that can be understood by participants. They noted the need to address literacy levels while also retaining the scientific accuracy of numerous terms, particularly the terminology of informed consent documents.

Research staff also highlighted the challenge that came when some participants (or even an entire target group) engaged in criminalized behavior. The criminalization of

drug use and/or injecting equipment such as needles and syringes creates barriers to engaging with IDU in a trial context. Stakeholders felt that laws and legal frameworks often work against developing and sustaining adequate standards of prevention.

Several stakeholders from the NGO sector explained that a major challenge facing the involvement of community is that many researchers do not fully appreciate the benefits of community engagement. Therefore, researchers who do not value participation do not see the importance of putting mechanisms into place to support such engagement.

NGO stakeholders spoke from their experiences with trial-related CAMs. According to NGO stakeholders, researchers may not have enough resources, including financial resources, to sustain long-term consultation with community. NGO stakeholders also noted that research teams might identify a specific community as being a source of participants for a trial and yet not follow the advice of NGO and community sectors for engagement with that particular community. Some NGO stakeholders believed that recruitment activities that did not incorporate community involvement could result in it taking much longer than planned for the researchers to attain their enrollment numbers. These NGO stakeholders believed that enrollment was most efficient when researchers accepted the input from NGO and community advisors.

Trial staff stakeholders described a further challenge to greater community engagement. Within the area of biomedical HIV prevention trials, much of the community involvement work in Thailand is confined to a relatively small circle of stakeholders. This group is often made up of a small handful of knowledgeable NGO advocates. Trial staff believed successful community engagement in clinical trials requires discussion with a wider range of people.

STAKEHOLDER INPUT AND RECOMMENDATIONS

FOR COMMUNITY ENGAGEMENT

Stakeholder input and recommendations to ensure community engagement

Overall, it was suggested that community engagement could be most effective when research protocols and the research teams putting those protocols into practice had clear plans for creating and sustaining engagement. Plans and mechanisms for community engagement should begin prior to the commencement of a trial, in the trial design phase.

Stakeholders recognized that researchers and trial staff should work with community partners and advisory mechanisms in advance of trial implementation to identify and anticipate potential challenges. Researchers and trial staff should develop ideas and plans for how to address trial-related challenges. Community engagement was seen as necessary to help resolve problems that might arise.

Many stakeholders, particularly those from NGOs and those who had been trial participants reported the belief that biomedical HIV prevention trials should assume responsibility for all HIV prevention, care, support and treatment of trial participants throughout the period they are actively enrolled in the project.

FOR COMMUNITY ADVISORY BOARDS (CABs)

Stakeholder input and recommendations for community advisory boards and other community advisory mechanisms

The importance of training those involved in CABs and other CAMs was widely cited by researchers and those from the NGO sector. Such training was seen as a way of improving the ability of individuals to be effective advisors to researchers and trial staff. This would require dedicated funding, sufficient time for training, and a commitment

to ongoing capacity building, because the knowledge needs of CAB members evolve across the course of a trial.

Stakeholders, particularly those who reported CAB experience noted the importance of providing training materials at an appropriate literacy level.

Beyond technical requirements, stakeholders wanted community liaisons hired by the trial to be sensitized to the value of CABs. It was felt that community liaisons should recognize the importance of ensuring and respecting diverse representation within those mechanisms. They noted that there was not a fixed formula for recruiting CAB participants. Each CAB may need to strike a balance between people at risk for HIV and people from the broader community.

Stakeholders who had experience with CAMs believed it worthwhile to consider creating local or national CAMs. These did not necessarily need to be trial specific, but could be ongoing and exist beyond the length of an individual trial. To do so was envisioned as one means of sustaining community levels of knowledge and expertise. A long-term vision of knowledge development was seen as cost effective.

Stakeholders from the NGO sector and those with experience as trial participants in particular felt that the field of biomedical HIV prevention research should recognize that CABs were not the only effective form of community engagement. They emphasized the need to explore other forms for seeking community advice. This could be done on a local basis or by linking up advisory mechanisms and creating a network of such mechanisms.

Stakeholders from the NGO sector suggested it was in the interest of the trial as a whole to make an ongoing effort to evaluate the knowledge of the advisory mechanism. They emphasized ongoing assessment particularly in relation to community engagement and its related trial processes.

FOR COMMUNITY CAPACITY BUILDING

Stakeholder input and recommendations for community capacity building

Several researchers and NGO constituents suggested that it was important to consider what is meant and understood by 'capacity' and what the implications of different types of definitions could be. On one hand there are very technical skills related specifically to the science of biomedical HIV prevention trials, such as understandings of basic science or data analysis skills. On the other hand there are broader forms of capacity such as effective knowledge transfer and public speaking skills.

Community capacity building that involves researchers and trial staff was suggested as a required activity to help potential trial participants and people from the community to understand various aspects of the trial. For example, scientific concepts may not be widely understood. Many of the concepts and terms central to biomedical HIV prevention are in English and lack direct equivalents or easy translation into the local language. Capacity building to foster improved knowledge translation through collaboration among CAMs, trial entities and trial participants was recommended.

NGO sector representatives interviewed noted that effective capacity building for biomedical HIV prevention trials could require specific skills, including the ability to translate complex scientific and ethical concepts and practices to people with little expertise in the area. They identified a great need for efforts to contract or grant resources to independent entities with specific skills to facilitate such capacity building.

STAKEHOLDER INPUT AND RECOMMENDATIONS FOR GOOD PARTICIPATORY PRACTICES

Stakeholders were asked to provide input and recommendations for good participatory practices for biomedical HIV prevention trials in Thailand, and in doing so, to focus on three specific areas: standards of HIV prevention, informed consent and communication.

FOR STANDARDS OF HIV PREVENTION

Stakeholders were asked for input and recommendations about the standards of HIV prevention that should be offered within the context of biomedical HIV prevention trials

In general, the HIV prevention package components described as the most acceptable by trial stakeholders, and which had shown the best rates of uptake, included latex condoms, clean injecting equipment (where available), opiate substitution therapy and HIV testing. Beyond this was focused risk reduction counseling, which was noted as particularly effective because it was cost effective and sustainable in a way that some other prevention components might not be. At the same time, previous trial participants in particular noted that trial-related counseling was or had been generally inadequate or non-existent.

Some researchers and trial staff as well as NGO representatives suggested that local context and attitudes toward these components could influence the standard of prevention and the components of the prevention package that were able to be offered and delivered effectively. They pointed out that in order to deliver effective prevention within the context of a biomedical HIV prevention trial it was necessary to complement prevention components with community-based support.

Researchers suggested it was important to continuously monitor the processes and components that made up the standard of HIV prevention in a trial. They suggested this monitoring could be done both internally and externally to ensure components were delivered to the standard outlined in the protocol. This is important even in the absence of specific regulations or within the context of an existing national standard. The challenge of such monitoring was noted as this could create a research expense which domestic funding mechanisms may not be able to support. However, quality control of prevention efforts within a trial is critical.

Stakeholders indicated that guidance like GPP needed to be adaptable because populations targeted for recruitment to HIV prevention trials are diverse. Adaptability

would ensure that community engagement activities to gain consensus on what services are delivered within a trial context would be flexible enough to serve diverse people's needs.

A point of contention existed in relation to the nature of policies and guidance governing standards of prevention. Some stakeholders felt that standards of prevention could or should be universal and comparable to the highest standard of prevention available internationally. Others felt that standards of prevention should be country specific. That is, some felt that within the context of a biomedical HIV prevention trial, the standard of prevention should be comparable only with the standard of prevention available within the country in which the trial was based.

Others pointed out that if there were differences in international versus local standards of prevention, it was the responsibility of trial sponsors and policy makers to seek to resolve inconsistencies. An example of such a resolution would be to facilitate third party provision of certain prevention services across the course of a trial.

Still others felt that there was little clarity locally on the provision of certain components within a standard of prevention, for example, the provision of clean injecting equipment. In such a context there could be conflicting interpretations of local laws and policies. This could result in a disjuncture between what the community believed should and could be provided under current laws, and what researchers and trial sponsors were willing to offer based on their interpretations of the same local laws and policies. Resolving the issue of differential legal interpretations relative to the standards of prevention offered within a given trial was identified as critical.

FOR INFORMED CONSENT

Stakeholders were asked for input and recommendations about informed consent within the context of biomedical HIV prevention trials

Some researchers noted that in many cases an individual trial participant's ability to give informed consent required that his or her family and community have information about the decision the trial participant was facing. For these stakeholders it was important within the context of a trial to work not only with potential trial participants, and their families, but also with community leaders and CAMs. This would help to disseminate information about trial risks and benefits as well as, disseminate information about adherence and other prevention-related concerns.

Other researchers discussed how important it was for research staff to be well versed in all aspects of a study's protocol and to be able to translate this knowledge into plain language. This was recommended as particularly important for those who had direct contact with trial participants, such as nurses and counselors.

Some stakeholders described utilizing the CAB in the development and refinement of the informed consent process. This reflected the importance of assessing both CAB members and study participants in terms of their comprehension of the informed consent process.

For trial staff, the lengthy time required to convey and discuss all the various components involved in a genuine informed consent process was a constraint. This was emphasized particularly when some of those processes could be quite technical. It was felt that a high quality informed consent process often required more time than might be estimated.

It was suggested also that generally trial participants are not particularly interested in reading long consent documents. Yet these documents are often lengthy because of IRB requirements. They use language that is often very legalistic, and as a result can be challenging to understand. Further, poor translation from English to Thai

may introduce additional challenges. To counter this, it was suggested that researchers and CABs be inventive and attentive when translating this information for potential trial participants. It was felt that consultations or engagement of trial members or community representatives early in the informed consent development process would be helpful.

Others from the NGO sector spoke of the challenges participants could have in understanding that they were fully free to leave the study at any time. Such an understanding can be limited by hierarchical structures and participant dependence on services at point of recruitment. This can be particularly challenging when the trial site is co-located where the participant is already receiving healthcare services. This pointed to the need to better understand how to develop trials within which participants were truly able to cease their participation if that was their choice.

Yet others thought that the quality or complexity of the informed consent might be irrelevant. These stakeholders said money often was the primary motivating factor for many of the people recruited into biomedical HIV prevention trials. They emphasized the reality that if potential participants are approached with a means for them to make money, that they would not mind signing and consenting to a 4-5 page contract. This was seen as especially true for people from marginalized groups. People might sign the long contract despite not necessarily understanding fully what they were consenting to allow to happen. This was seen to be particularly the case when a trial would offer a way to get money on a regular basis, such as in the context of a clinical trial that occurred over a number of years.

Further, community members' decision to participate in exchange for resources could be promoted by community leaders who decide to participate on a CAM. It was felt that community leaders' participation in advising a trial could send a message to community that the study was ethical. As a result, community members might infer that participation in the study was being promoted as advisable by community leaders, even when this was never explicitly stated.

FOR COMMUNICATION

Stakeholders were asked for input and recommendations for communication within the context of biomedical HIV prevention trials

One researcher suggested that communication required good planning. For this researcher it was important for trials to develop processes that focused on consistent and ongoing communication. The ability for participants to ask questions and have their questions answered was seen as essential. Some people might call this kind of process a “communication plan.” Components of such a communication plan could include a budget for regular meeting to allow whatever problems participants may be experiencing to be brought up in that meeting. The communication plan could also include open and mutual communication channels that could function for both face-to-face communication as well as communication using telephones or other technologies. It was noted that the GPP Guidelines were well positioned to inform the communication plans of trials.

Stakeholders from the NGO sector highlighted the importance of clarifying who would be the trial beneficiaries. In other words, would broader stakeholder communities also receive any benefits? Further, once clarified, there was the need to effectively communicate information on trial benefits in order to prevent misinformation. This would include providing clear information as to what trial participants could expect in terms of any trial-related benefits after the project ended. This would ensure that the information was adequately understood.

As one NGO representative explained, communication issues are at the very core of what can prevent the development of good participatory practice. This is because NGOs working on HIV issues often have limited understanding about trial science and processes, which is made worse by international research teams who speak in technical English. The use of medical jargon complicates a participant’s ability to easily comprehend.

Numerous stakeholders suggested that providing information in plain language was of primary importance. Their experience had taught them that participants would not read complex and long documents.

Stakeholders with experience as trial participants in particular highlighted the importance of clear communication channels. These channels needed to be flexible enough to accommodate participant complaints. They suggested that mechanisms for making and addressing complaints should be accessible to ensure that concerns would be addressed, regardless of the source or social status of those lodging or voicing a complaint.

STAKEHOLDER INPUT AND RECOMMENDATIONS FOR KEY STAKEHOLDERS

Stakeholders were asked for input and recommendations for three stakeholder groups: researchers, communities, policy makers/sponsors. Below are their suggestions for each of these three stakeholder groups.

FOR RESEARCHERS

Stakeholders provided input and recommendations for researchers seeking to improve participatory practices in biomedical HIV prevention trials

Many stakeholders discussed the importance of involving community early, even at the study design stage. This advice extended to the design of operational plans and timelines responsible for moving the research forward. It was suggested that if researchers and community members were to collaborate on the design of research, these plans would be more attuned to community needs. Many stakeholders saw CABs as a key mechanism in the success of studies. Some suggested that researchers and others should recognize that CAMs could take many forms. It was suggested that some of these alternate advisory forms might be particularly useful for involving and engaging people who might not feel comfortable within a formal CAB-like structure.

Others discussed how important it was for funding to be made available for community engagement throughout the full duration of a given project. It was felt that researchers are the people in the best position to lobby sponsors, funders and policy makers to fund the time and efforts needed for genuine community engagement and participation.

Some stakeholders from the NGO sector and others who had been trial participants indicated that it would be beneficial for people who worked on biomedical HIV prevention trials to undergo sensitivity training to mitigate prejudicial attitudes about marginalized groups. Such sensitivity was seen as a fundamental component of mutual understanding. It was believed that a trial team with these skills would be better able to achieve the study goals, including high quality community engagement, ethical trial conduct, and protection of the rights and well-being of trial participants.

There was consensus among stakeholders that all parties engaged within biomedical HIV prevention trials needed to carefully and continually consider the obligation to provide care and support to both trial participants and the broader community. They felt that trials should strive where possible to build in mechanisms to ensure comprehensive and widely available care and support.

Those with trial participant experience in particular, commented that their trial involvement would have greatly improved if they had been given an official study identification card upon enrollment. They suggested that such a card would be useful if the police stopped a trial participant. These stakeholders related how in past trials, participants had been stopped by police and accused of possessing illicit or illegal materials such as trial-related pharmaceuticals, condoms or clean injecting equipment. Providing trial participants with an official study identification card was suggested as one way to avoid this happening in the future.

FOR COMMUNITIES

Stakeholders provided input and recommendations for communities seeking to improve participatory practices in biomedical HIV prevention trials

Some researchers suggested it was not only research communities who should provide trial-related education, but also communities and the NGO sector. Further, many stakeholders suggested that community information needs would not end when a trial ends. Rather, the information needs of a community as they related to a trial could extend beyond the life of a trial and beyond the dissemination of trial results. Examples of information needs that could extend beyond the life of an individual trial included the long-term benefits or health outcomes of past trial participation, the influence past trials had on current prevention options, and how past trials had informed subsequent research efforts.

Stakeholders from the NGO sector suggested that funding should be offered to assist communities to take responsibility for self-education about the science and conduct of biomedical HIV prevention trials. They suggested that communities should receive funds to help resource self-education, as well as to help develop mechanisms to ensure accountability. It was felt that communities could self-educate, but that in doing so they would have an ethical obligation for transparency and responsible management.

A number of recommendations for communities focused on training. Some NGO and trial participant stakeholders suggested that training for community members in HIV prevention science and trial operations was very important. This was because at any given time there were only a few people who were very knowledgeable in this area and as a result were frequently called upon for advice.

It was suggested also that there was a need to lobby governments, policy makers and sponsors to make more funding available for community-level training around research processes, basic science, ethics and ethics review and health promotion. It was recognized that the community had an important role to play when lobbying governments, policy makers and sponsors for funding. Communities has an important

role to play also in lobbying for improved communication, better access to prevention tools such as clean injecting equipment within trial contexts, and more universal access to healthcare for those who might seroconvert across the course of a trial.

FOR POLICY MAKERS AND SPONSORS

Stakeholders provided input and recommendations for policy makers and sponsors seeking to improve participatory practices in biomedical HIV prevention trials

Stakeholders from the research community felt that sponsors needed to understand that researchers require sustained support in order to work within the community where a trial takes place. One suggestion for policy makers and trial sponsors was to develop and to make available a set of tools to assist researchers to conduct and to evaluate community engagement. It was suggested that policy makers and sponsors needed to invest in research capacity building for communities and not only for researchers.

A number of stakeholders from the research and NGO sectors reflected on the need to develop mechanisms to support and enrich research teams and CAMs across multiple trials. They recommended a network approach that would enable the exchange of information and best practices over the long term. A network approach of this type was seen as useful for working between different stakeholder groups, trials and research teams. In such a way, researchers could learn about good participatory practices from other researchers. In addition, CAMs could learn about successful research processes from other CAMs. It was suggested that this could bring added value to the conduct of biomedical HIV prevention trials and that policy makers and trial sponsors should seek ways to help support such a network.

Researchers, NGO representatives and community members all suggested that funding agencies would need to take the issues of community engagement more seriously than they had in the past. They suggested that funding agencies could do this by making more resources available for community engagement. To do this, there may be a need to establish separate and sustainable funding mechanisms for community

engagement. It was recognized that it takes a lot of time and investment to form and train a CAM. Therefore, trial funders and sponsors should consider ways to allow for bridge funding between studies so that existing CAMs would not need to be disbanded.

CONCLUSION

In summary, there was consensus among individuals who participated in interviews and FGD that community and stakeholder input was valuable for biomedical HIV prevention trials.

For stakeholders participating in this research, ways forward may take various forms, including CABs and other CAMs. In addition, resources are necessary for the creation and sustenance of CAMs in any trial plan.

CAMs should be provided for as early as possible, preferably in the planning stages of a trial. Suggestions included developing processes to carry CAMs forward after a trial ends. This was seen as a means to promote consistency between trials. This was particularly important in light of the large number of biomedical HIV prevention trials conducted in Thailand.

Communication issues regarding jargon and translation from English into local languages emerged as paramount. There is a need to continue to work to express sophisticated medical and research concepts in ways that can be understood by research participants. The most important messages regarding good communication were that, a) it forms the basis of trust between communities and trials, and is therefore a prerequisite; b) attempts to communicate are not synonymous with communication success; and c) communication needs to be fostered across all stages of a trial, from planning through results dissemination.

Informed consent processes presented a number of obstacles. First, participants' tight time schedules often prevent required in-depth consent processes. Second, consent forms are often incomprehensible, legalistic and long. Additionally, overall respect for the nature and importance of contracts and the dynamics of social

hierarchies can negatively influencing participants' ability to exercise free will to leave a trial.

Community responsibility to learn about trials raised the need for investment in and commitment to training to improve research literacy.

The roles that traditional social order and power dynamics play in the implementation of a trial need to be considered by trial staff. Power dynamics could influence informed consent processes as well as genuine input, for example the ability for participants to make complaints or to provide a research team with feedback. Stakeholders recommended establishing formal channels for receiving and responding to issues raised by community members.

In light of previous trials where research teams had not been able to provide clean injecting equipment, community-based stakeholders recommended that trial sponsors and policy makers work to amend national policy to enable the distribution of the full range of HIV prevention tools without exception or discrimination.

While some of these recommendations may be a challenge to implement, they also present opportunities for inclusive, ongoing, and productive community participation and engagement.

Such opportunities will require investment of time and resources, but many stakeholders suggested that the rewards of such investments would be reaped in future trials, with higher rates of retention, more efficient recruitment, and better relationships between research stakeholders and research teams.

Finally, while this project took place in Thailand, and therefore applies primarily to Thailand, the results can inform the expansion of good participatory practices in other parts of the world where biomedical HIV prevention and other clinical trials in human populations occur.

APPENDIX: ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
CAB	Community Advisory Board
CAM	Community Advisory Mechanism
CBO	Community-based Organization
FGD	Focus Group Discussion
GPP	Good Participatory Practice
HIV	Human Immunodeficiency Virus
IDU	Injecting Drug Users
IRB	Institutional Review Board
MSM	Men who have sex with men
NGO	Non-governmental Organization
PLWHA	People (or person) living with HIV or AIDS
PrEP	Pre-exposure Prophylaxis
TTAG	Thai AIDS Treatment Action Group