

Good Practice for Sex Workers' Participation in Biomedical HIV Prevention Trials



GPP Partner Programmatic Report
for the
AIDS Vaccine Advocacy Coalition (AVAC)

Dan Allman¹ and Melissa Ditmore²

¹HIV Social, Behavioural and Epidemiological Studies Unit
Dalla Lana School of Public Health
University of Toronto

²Independent Consultant
New York

April 30, 2009

Table of Contents

Acknowledgements	3
Section I. Synopsis of Project	4
Organization	4
Location	4
Project Time Period	4
Stakeholder Groups	4
Methodology	4
Key Questions asked in Project	5
Brief Summary of Project	6
Key Recommendations	7
Section II. Project Tools.....	8
Section III. Full Narrative Report	8
A. Preparatory Work	8
B. Project Activities	8
C. Project Outcomes	9
Previous Participation in Biomedical HIV Prevention Trials	9
Place of Residence	10
Familiarity with Ethical Guidance Documents	10
The 10 Good Participatory Practice (GPP) Principles	11
The Principle of Scientific and Ethical Integrity.....	11
The Principle of Respect	14
The Principle of Clear Roles	17
The Principle of Shared Responsibility	20
The Principle of Participatory Management	22
The Principle of Autonomy.....	26
The Principle of Transparency	28
The Principle of a Standard of Prevention	31
The Principle of Access to Care.....	32
The Principle of Building Research Literacy.....	34
Case Study.....	37
Principles at Work.....	37
Lessons to Learn	38
Facilitating Better Outcomes	38
Summary Questions	39
Most Important Principle	39
Most Difficult to Achieve	41
Final Thoughts	42
Next Steps	43
Reflections on Implementation	43
1. Modifications	43
2. Key Challenges	44
3. Proposed Revisions.....	44
Section IV. Appendix.....	45
Questionnaire	45

Acknowledgements

The project, *Good Practice for Sex Workers' Participation in Biomedical HIV Prevention Trials*, would not have been possible without the contributions of many.

Our appreciation to Alex Solange, Sylvia Mollet, Andriana Pagano, Ted Myers, Lori Miller, Emily Bass, Juline Koken, Christian Grov, Cindra Feuer, Deirdre Grant, Jenn Clamen and Stella, and NSWP listserv members.

Our thanks to AVAC's GPP partner colleagues: Asociacion Civil Selva Amazonica, Peru; Centre for the AIDS Programme of Research in South Africa (CAPRISA), South Africa; Community Education Group, Inc. (CEG), United States; Grupo de Incentivo a Vida (GIV) with Unidade de Pesquisa de Vacina Anti-HIV (UPSP), Brazil; Kenya AIDS NGOs Consortium (KANCO) with Kenya AIDS Vaccine Initiative (KAVI) and University of Nairobi Centre for HIV Prevention & Research (UoN-CHIVPR), Kenya; Makerere University-Walter Reed Project (MUWRP), Uganda; National AIDS Education & Services for Minorities, Inc. (NAESM), United States; New HIV Vaccine and Microbicide Advocacy Society (NHVMAG), Nigeria; Perinatal HIV Research Unit (PHRU), South Africa; Planeta Salud, Spain; and the Thai AIDS Treatment Action Group (TTAG), Thailand.

Our acknowledgements to the Working Group which oversaw the creation of the UNAIDS/AVAC document, *Good participatory practice guidelines for biomedical HIV prevention trials*, upon which this project was based: Catherine Hankins, Joint United Nations Programme on HIV/AIDS (UNAIDS), Geneva, Switzerland; Mitchell Warren, AIDS Vaccine Advocacy Coalition (AVAC), New York, United States; Dan Allman, Centre for Research on Families and Relationships School of Social and Political Studies, Edinburgh, Scotland; Emily Bass, AVAC, New York, United States; Manju Chatani, African Microbicides Advocacy Group; Accra, Ghana; Janet Frolich, Centre for the AIDS Programme of Research in South Africa (CAPRISA), University of Kwa Zulu Natal, Durban, South Africa; Ian Grubb, World Health Organization, Geneva, Switzerland; Ramesh Goud, SOS Medical and Educational Foundation, Mumbai, India; Pauline Irungu, The Global Campaign for Microbicides, Nairobi, Kenya; Karyn Kaplan, Thai Treatment Action Group, Bangkok, Thailand; Alexandre Menezes, International AIDS Vaccine Initiative, New York, United States; Richard Mutemwa, Centre for AIDS Research, University of Southampton, Southampton, United Kingdom; Monica Ruiz, The American Foundation for AIDS Research, Washington D.C., United States; Jennifer Sarché, Consultant, San Francisco, United States; Paisan Suwannawong, Thai Treatment Action Group, Bangkok, Thailand; Morenike Ukpong, HIV Vaccine and Microbicide Advocacy Group, Lagos, Nigeria; and Steve Wakefield, HIV Vaccine Trials Network, Seattle, United States.

Finally, to the sex workers across the globe who took time to freely provide their insight.

Thank you for your participation.

We hope we have done you justice.

Section I. Synopsis of Project

Organization

Sex Workers Project at the Urban Justice Center
HIV Social, Behavioural and Epidemiological Studies Unit, Dalla Lana School of Public Health,
University of Toronto

Location

Global

Project Time Period

Project Commenced	July 01, 2008
Questionnaire development and translation	July 01, 2008—October 31, 2008
Data collection	November 1, 2008—January 15, 2009
Data translation and analysis	January 15, 2009—March 15, 2009
Development of Final Report	March 15, 2009—April 30, 2009

Stakeholder Groups

Network of Sex Work Projects (NSWP)
Global Working Group on HIV and Sex Work Policy (GWG)
Paulo Longo Research Initiative (PLRI)
Industria del Sexo
RedLacTrans

Methodology

A 33-question survey focusing on concepts in the UN document around good participatory practices for biomedical HIV prevention research was developed in English and translated into French, Portuguese and Spanish. No incentives were offered. Participants were recruited from mailing lists and contacts with existing sex worker networks. Participants were able to respond to the survey online, on paper, or using electronic messaging. Additionally, structured focus groups and informal discussions were conducted in multiple languages.

Key Questions asked in Project

1. Have you ever been involved as a participant or a community advisor participating in a biomedical HIV prevention trial?
2. If yes, how did you feel about your experience?
3. In which country or countries do you primarily live?
4. As someone who identifies as a sex worker, are you familiar with ethical guidance documents such as the Declaration of Helsinki which guide how research using human participants should be conducted?
5. What other ethical guidelines have you heard about for research which involves human participants?
6. What are ways to protect integrity within a biomedical HIV prevention trial involving sex workers?
7. How can researchers and sex workers within trials prevent ethics and integrity from becoming compromised?
8. How can sex work communities and research teams develop common definitions of respect?
9. What are concrete ways to develop and build this genuine respect between sex workers and researchers?
10. How can researchers best understand sex workers' expectations of a biomedical HIV prevention trial?
11. What can prevent sex workers from communicating their expectations within biomedical HIV prevention trials?
12. What are some of the ways that sex workers can and should be responsible for the research process?
13. What are some of the challenges that sex workers and researchers might experience when trying to truly share responsibility for a biomedical HIV prevention trial?
14. In terms of capacity building, knowledge development or financial resources, what would you or your community group require to realistically become involved in participatory management of HIV research trials?
15. What are the barriers sex workers and researchers might experience within a participatory management context?
16. How can researchers give sex workers and sex work communities independent and autonomous voices in a biomedical HIV prevention research trials?
17. How can researchers working with sex workers in biomedical prevention trials respect and act on suggestions from community members?
18. What are some of the important pieces of information sex work communities need to know about a specific research study when choosing to become involved in biomedical HIV prevention research?
19. What suggestions do you have for dealing with local conditions such as distance, lack of telephone or electricity, to try to make it easier for researchers to communicate with sex worker communities?
20. What prevention services do you think should be included in any HIV prevention trial?
21. What challenges might there be to providing a package of prevention services to sex workers?
22. What are some of the health care and treatment needs and priorities in your community?
23. What are concerns with trial-related health care and treatment access in your community?
24. What kind of activities could researchers do to help your community understand more about how HIV prevention research happens in general?
25. What do you think are the challenges or barriers to building research understanding and literacy in your community?
26. Which of these core guiding principles do you think are most important to sex workers? Why?
27. Which of these guiding principles do you think may be most difficult to achieve in research with sex workers? Why?

28. Can you summarize in 100 words your opinion about the principles of Good Participatory Practice discussed here?
29. Can you think of any principle or principles that might be missing and that would be important for sex workers considering to become involved in a biomedical HIV Prevention trial?

CASE STUDY

30. Which principles of Good Participatory Practice do you think are at work in this case study?
31. What would you suggest are the lessons to be learned from this case study, both in terms of positive and negative outcomes?
32. How might similar positive outcomes be facilitated and how might some of the negative outcomes be prevented?
33. Is there anything else you would like to say about how HIV prevention research should be conducted with respect to working with sex worker communities?

Brief Summary of Project

After premature closures of biomedical HIV prevention trials, many of which involved sex workers, consultations to establish better participatory guidelines for such trials were undertaken by UNAIDS. As a follow up process, this project investigated what sex workers know about research ethics and view as important for good participatory practice.

Researchers consulted with sex workers around the world via electronic communication. Additionally, informal discussions were conducted. Discussion was based on criteria identified by UNAIDS and AVAC. A 33-question survey and discussion guide was available in English, Spanish, French and Portuguese. No incentives were offered.

In total, 74 responses were received of which 51.4% (n=38) were fully complete. Responses came from Asia Pacific (10.3%), Latin America (14.7%), Europe (17.6%) and North America (57.4%). No online responses were received from Africa. 30.6% of respondents reported first hand involvement in biomedical HIV prevention trials. Most (70.0%) were unaware of the Helsinki Declaration, indicating a lack of familiarity with codes of ethics for research.

Respondents expressed strong ideas about research with sex workers. Responses clarified that while some sex workers are against any cooperation with clinical trials and in some cases, all forms of invasive research, most were not. Indeed, many wanted to learn more about research and would consider involvement in research providing they were confident it was ethical and participatory. Many had recommendations for researchers hoping to work with sex workers such as involving stakeholders from the outset, explaining procedures in non-technical terms and translating all materials and information into local languages.

Key Recommendations

This investigation of Good Practice for Sex Workers' Participation in Biomedical HIV Prevention Trials summarizes its findings in 10 key recommendations. These key recommendations are derived from the wealth of information respondents provided:

1. Education about ethics and protocols is imperative. Sex workers described very little familiarity with these procedures. Therefore it is critical that researchers explain these procedures and complex ideas to participants using simple words in local languages. It is the researcher's responsibility to communicate.
2. Consult local sex workers at each proposed location before beginning a trial. Acceptance and use of recommendations of local sex workers, and consideration of accommodations necessary for the lives of local sex workers will facilitate the research.
3. Demonstrate respect for sex workers. Researchers should actively work to incorporate recommendations for sex workers and also to socialize with and get to know them. For sex workers, misunderstandings may be attributed to stigma and discrimination even in situations where other factors may contribute to these.
4. Issues of compensation and time investment can compromise sex workers' income and livelihood. Investment of time and energy in research takes away from sex workers earning time. Participation in research creates expenses which should be covered by research funding.
5. Permit sex workers to express themselves in environments in which they are comfortable and supported. Visit and meet with sex workers in sites where they work in large numbers—in order for them not to be intimidated. Barriers may be related also to literacy, facility with language, and the knowledge and information that potential trial participants might have. Good participatory practice and the extra efforts necessary to communicate will require time, energy and probably money.
6. Training and capacity building will be necessary for sex workers to enjoy good participatory practice in many contexts. Training and capacity building will lead to increased understanding and to greater participation and ability of sex workers to assume greater responsibility. Sex workers should contribute to design and implementation and analysis. Within participatory research, sex workers who share responsibility should share credit for work well-done. Sex workers should be employed (hired, for pay) on the research team in management positions.
7. In some situations, contributions to communication resources, sex worker infrastructure and education, may be necessary. When sex workers have few resources, communication itself may be difficult and costly. For example, providing phones and other innovative solutions can facilitate communication and data collection in text or oral form.
8. Safe sex commodities including male and female condoms and personal lubricant must be easily available and affordable.
9. Provisions must be made for long-term healthcare in the event of seroconversion and side effects.
10. Access to health care in general (beyond the trial) is a great concern. Some sex workers may not have access to health care. It is often more difficult for transgender persons and migrants to access appropriate healthcare. These obstacles need to be addressed in research projects.

Section II. Project Tools

The survey questions are summarized in key questions previously listed. The formatted online survey is attached as an appendix.

A recruitment email was developed and translated. The text of this email is below:

We are seeking your help with an online survey exploring sex workers experiences with research.

The survey asks 33 questions about good participatory practices for sex worker involvement in HIV prevention research.

Examples include studies which use people to test microbicides, circumcision, or vaccines—or trials where people take drugs to try to prevent HIV infection or transmission.

This survey is being conducted by Dan Allman and Melissa Ditmore with support from the Sex Workers Project at the Urban Justice Center, the AIDS Vaccine Advocacy Coalition (AVAC) and the University of Toronto.

All information provided by is anonymous and confidential.

Section III. Full Narrative Report

A. Preparatory Work

Dan Allman and Melissa Ditmore drafted a survey, based on simplifying the UNAIDS GPP Guidance, to be implemented online, and coordinated with AVAC and our team members to have the 33-question survey translated into Spanish and African French. Dan Allman prepared the online survey using surveymonkey™ software. Allman and Ditmore asked Sylvia Mollet to join the team in the role of coordinator for reaching out to francophone sex worker organizations and projects, and arranging for survey responses to be translated from French to English. Melissa Ditmore contacted a liaison for the Spanish language networks, including RedLACTrans, the Spanish-language transgender network of Latin America and the Caribbean. Translators were contracted to translate survey responses into English.

B. Project Activities

Surveys were posted online in English, French, Spanish and Portuguese.

Announcements and invitations were distributed in English, French and Spanish to mailing lists for sex workers and sex work projects. Some announcements received thought-provoking responses on these lists.

Informal consultation using a focus group method were held in Boston and Santo Domingo, primarily in Spanish but with some English in Boston. Paper surveys were entered into the online survey in the language in which they were conducted. Non-English responses were translated to English and entered into the online

survey template, noting the original language in which the survey was completed. Survey responses were collated in a spreadsheet in order to be analyzed for the report.

C. Project Outcomes

Previous Participation in Biomedical HIV Prevention Trials

Respondents were asked whether they had ever been involved as a participant or a community advisor of a biomedical HIV prevention trial (Table 1). Less than one-third (30.6%; n=22) indicated that they had. An additional seven (9.7%) were unsure.

Table 1: Ever Participated in a Biomedical HIV Prevention Trial

	N	%
Yes	22	30.6
No	43	59.7
Don't Know	7	9.7
Missing	2	-
Total	74	100

Asked about their experiences of previous trial participation, half of respondents who had previously participated indicated their experiences were good or very good. While some felt their experience was helpful and interesting,

I thought it was helpful to have a sex worker voice in the vaccine network.

Very interesting but complicated. Talking about prevention with people who are sex workers isn't complicated but going into someone's private life is very complicated.

Based on experiences of participation, others indicated that they expected more, as their needs were not met.

I wanted to help society so I agreed to be a part of HIV pre-vaccine trials and also condom research. I was not given information in a way that I could understand or use it. The trial was set up for the convenience of the researchers so I my life was turned upside down for them. The local research staff were rude and not committed to their job. I never had my questions answered properly especially when trying to find out about side effects and risks....., responsibility of the researchers for my health. Despite having to see the doctor regularly they ignored my symptoms of another problem because they had nothing to do with the trial! Overall I felt used and treated very badly and could not trust or respect the trial staff.

The challenges for HIV biomedical prevention trials meeting the expectations of sex workers and other participants is an area that will be considered with greater depth below.

Place of Residence

Respondents were asked to indicate their country of primary residence (Table 2). More than half (39; 57.4%) indicated North America, 17.6% (n=12) indicated Western Central or Eastern Europe, 14.7% (n= 10) indicated Latin America, and 10.3% (n=7) indicated the Asia Pacific region. Despite efforts, no participants recruited indicated that Africa was their country of origin. This may limit somewhat how the findings here can be generalized, a factor that will be considered at greater length in this report's conclusion.

Table 2: In which country or countries do you primarily live?

	n	%
Asia Pacific	7	10.3
Latin America	10	14.7
Europe	12	17.6
North America	39	57.4
Missing	6	-
Total	74	100

Familiarity with Ethical Guidance Documents

Respondents were asked whether they were familiar with ethical guidance documents such as the Declaration of Helsinki which guide how research using human participants should be conducted. Less than one-third (30%; n=21) indicated that they were. More than half (51.4%; n=36) indicated that they were not familiar with these documents, and almost one-fifth of respondents (18.6%; n=13) did not know.

Table 3: Familiarity with Ethical Guidance Documents

	n	%
Yes	21	30.0
No	36	51.4
Don't Know	13	18.6
Missing	4	-
Total	74	100

Participants were asked about other ethical guidelines they might have known about. Many indicated that they were not aware of any.

None but I know guidelines exist and that researchers are supposed to answer to others about these issues.

Others provided answers which revealed that the very notion of ethics and ethical guidelines is not something that is well understood. Several respondents mentioned that they did not know who Helsinki [was]. Others mentioned such processes as confidentiality, consent, education, respect, ethics committees, and ethics approval, good practice norms, human rights, privacy, institutional review boards, and human subjects certifications. A number of respondents were explicit that they had never heard of any ethic guidelines about research.

Still others were more descriptive in reflecting on contextual factors which prevent sex workers from fully understanding ethical guidance documents and their application within biomedical HIV prevention trials:

No, the information [about ethical guidance documents] towards us, the sex workers, never comes directly. Only in some organizations where if you don't ask you don't receive new information that may be useful for defending yourself, whether in the health field or rights.

The 10 Good Participatory Practice (GPP) Principles

Participants were asked several questions about each of the 10 principles for good participatory practice outlined in the UNAIDS GPP document.

The Principle of Scientific and Ethical Integrity

The first principle was that which concerned itself with scientific and ethical integrity. The question posed to respondents was how such integrity could be protected within a biomedical HIV prevention trial which involved sex workers. The consensus was to provide a trial context in which anonymity and confidentiality could be guaranteed. One mechanism to guarantee this would be for the use of codes and nominal identifiers rather than names across the entire course of the study. Respondents felt also that Integrity was contingent on a professional, private, respectful environment in which there was no obligation or pressure to participate; that trials should have clear and transparent codes of conduct. Respondents felt there should be ready access to clear HIV prevention information and free prevention modalities such as quality condoms and lube.

It was suggested that a trial could protect scientific and ethical integrity by

Balancing the needs of both research and a trail community; a trial must be well-designed, asking valid scientific questions, and meet universal criteria of ethics and social justice.

Another suggestion for attaining the highest degree of ethical and scientific integrity would be to determine the highest standard of such integrity, globally, and enshrine it as the baseline to which all trials should aim.

Offer the same access to services and incentives and benefits around the world, with the highest baseline—perhaps that would be Australia or Western Europe or Canada—as the baseline.

The relationship between local realities and trial best practices was recognized in other ways. Some respondents felt that integrity would require that the design of trials and the decision of where trials were located should be structured by local factors:

[To] not do the research unless there is already a higher than average level of HIV in the sex worker community.

At the same time it was recognized that expectations and understandings of what could constitute ethical and scientific integrity could vary based on the people involved, and that one mechanism to ensure a high standard of integrity would be to consult with sex workers at the trial location.

For some the very notion of putting one's health at risk by participating in a biomedical HIV prevention trial made no sense.

Don't ask them to do anything sexual/health/safety wise they would not normally do. Keep the trial within their own usual practices and experiences.

For others, it was believed that access to health or social care should not be contingent on trial participation:

Access to HIV advice, testing, medical services and other services should not depend on your willingness to participate in a research.

The fact that such trials tended to be funded by large pharmaceuticals was seen by some to be contrary to ethical and scientific integrity; that is, to put the maximization of profit above human well being.

Research should not be driven by any of the for-profit sector—it is immediately biased.

But financial matters could go both ways. While participants felt that profit motives on the part of pharmaceuticals challenged ethical and scientific integrity, they indicated also that payment for participation or the paying of costs incurred through participation was central also to scientific and ethical integrity:

Paying participants and making sure they are very well informed about the research.

Pay sex workers to be your consultants before you study them.

Respondents recognized the role that Community Advisory Boards (CABs) could have in ensuring that research attained and maintained a level of scientific and ethical integrity, as well as the importance for CABs to not be mechanisms for research recruitment only, but also mechanisms for protecting and facilitating the well being of participants and their communities:

CABs need to be more than bodies of people who make recommendations that are then ignored by the researchers. The CABs themselves should have decision making influence or they are useless.

Researchers should be obliged to inform the sex worker organizations in the country of the trial. We don't want to be on the community boards because we think that is just a trick to make it look like its community monitoring but really we only get told what the research teams want us to know and we are used to get sex workers to trust the researchers. We need to be a watchdog not a tame dog! Sex worker organizations also need access to independent scientific advice and analysis.

It was felt that scientifically ethical trials were those that did no harm. As one participant indicated:

No to spermicidal and lubrication products causing micro lesions.

It was recognized also that the good trials were ones where the benefits provided were not only financial; that a scientific and ethically integral trials was one which would leave the community better off than it was before the trial:

Make sure sex workers get something good for being in the trial. Like access to comprehensive health care.

Respondents suggested that ethical trials were those that not only took information from the community, but gave information back to the community as well, through capacity building and knowledge translation mechanisms that would facilitate the adequate provision of a continuum of information across the course of a trial.

It was noted also that a scientific and ethical trials was one where not only the researchers asked questions, but the sex workers too; that perhaps guinea pigs did not have voices or inquiring minds, but that sex workers did, and that they should be encouraged to ask the questions required for them to have confidence in their own knowledge of a trial and its researchers.

Researchers need to be fluent in sex worker issues, on the ground issues, and not out of touch with the community. The community should develop a test of researchers before they are allowed to design a study.

Respondents were asked to comment on how researchers and sex workers within biomedical HIV prevention trials could prevent ethics and integrity from becoming compromised? Respect was suggested as key. Respect of confidentiality and privacy, respect for the individual, and respect for their human rights, including the human right to be educated about a trial and its implications and potential harms and benefits. Mechanisms for helping achieve and maintain this level of respect across the breadth of a trial included:

Being clear on the specified objective and also the participant population should be included in the execution of the research.

Consult with sex workers in the trial location, and compensate sex workers for their time. Translate everything into local languages. Offer genuine informed consent. Do not descend into tokenism or tokenistic treatment. Treat sex workers the same way you would participants in a study about heads of pharmaceutical companies or university presidents! Employ sex workers on the project.

Honesty, mutual respect, being non-judgmental, and not assuming anything.

Not stigmatize sex workers for their job or their risk exposure.

[The] best prevention is that we understand everything about the trials and what we should expect in the way of ethics. We then need a safe clear effective channel of complaints when the practice does not live up to the theory.

Others believed that the best means to prevent trial ethics and integrity from becoming compromised was to simply refuse to participate in such trials:

In refusing to participate; in refusing to mobilize the community to serve as guinea pigs; in writing letters of denunciation to the ethic committee of the project and to multiple partners.

When being contacted by researchers looking for sex workers [to] refuse any suggestions made by

researchers that are not known to be sex worker friendly.

Or to make sure that sex workers were involved not only as trial participants, but as trial researchers also:

Make sure that sex work activist groups are the ones doing the research.

[Resource] the sex work community so that research on sex workers is conducted by sex workers.

Others suggested that the question was simplistic and that reflecting on trials in general was somehow different than the realities experienced by trials in the field:

There is no one answer for this as there are numerous issues that could arise in a biomedical study for this community. Multiple oversight committees need to be developed and utilized to help with the complex and diverse, sometimes aligned sometimes not, needs of the various groups involved.

Some did not agree that trial integrity and ethics were shared between research and researched, but that rather it was perhaps the responsibility of governments, funders, research institutions and researchers.

To educate themselves and be aware of any power imbalances (class, race, level of discrimination in society) and really humbly do their best to prevent compromises.

The Principle of Respect

When discussing how sex work communities and research teams could develop common definitions of respect, there was a degree of diversity among responses. Yet, for the most part responses tended to recognize status differential between sex workers and researchers, and the implications this could have for the provision as well as the interpretation of respectful research activities and processes. Rare was the response that suggested sex workers needed to be more respectful of researchers. The more common response was that it was sex workers who both experienced lower levels, and were owed higher levels of respect.

I don't think it is the job of sex workers to figure out how to respect researchers.

This should be the struggle of research teams after all they need us not us them.

Exactly what is there for sex workers to gain by developing this relationship? Why do we have to solve their problems?

Let the sex workers choose their destiny and take care of your own business. Test your products on yourself.

Why do you talk about communities? I am an individual and, by coincidence, I do the same work as others. Do researchers live in communities of researchers?

The researchers need to go and work in the sex industry for a while before they do the research There needs to be an equal balance of sex workers and non-sex workers on the research team. The researchers could do a short course on moral bias in science

Those respondents who did reflect on respect and how to arrive at it, tended to focus on precursors to or mechanisms for building greater respect. Here, trust built through demonstrable respect was key; the idea

being that when researchers behaved in ways that were respectful to sex workers, trust could be built, and that this was a very strong foundation on which to build respectful research relationships.

One recognized means to arrive at trust, and by extension respect, was through common understandings of what sex work was and was not, beginning with definitions.

Ask for a definition from sex workers...and then collaborate to form a central definition.

Look to the community you are studying for those definitions.

Ask which I prefer to be addressed by, 'he' or 'she'... [show] respect towards transgendered people, with sensitivity.

It requires the research teams (if they are not sex workers) to sit down with sex worker groups over a period of time prior to drawing up the research proposal and develop a memorandum of understanding about terms to be used... etc.

Another means at developing respect was through mutuality, which was the idea that all both researcher and sex workers could come together within the prevention trial context and arrive at

An agreement that is understood and entered into by both parties... where it is well clear the function and responsibility of every one.

Developed jointly by both parties.

With shared rules and clear communication.

It was believed that greater respect could be developed by

Creating an agreement of respect and having the researchers also sign it too.

Respecting the opinions of each other and clarifying any questions that sex workers have.

By putting the cards on the table, from the beginning; by being up front and transparent.

I suppose that making a commitment, both, always and when there is a relationship of mutual respect.

This kind of mutuality related to the development of respect would require that the research team would need to

Try to ignore any stereotypes they may believe about sex workers, and sex workers [would need to] try to not assume that they are being judged or looked down on because of their sex work.

And to

Work together [to] accept sex workers' knowledge [to be] as good as academic education [a form of] professional equality.

It was suggested that respect could be built through participation and inclusion. For example, that

Sex workers need to be involved in the design and implementation of the research at every level and at

every step of the way.

Given adequate skills, it was felt that greater respect could occur as a byproduct of the employment of sex workers as counselors or analysts.

Give sex workers scholarships for school that allows them to do research

Such respect-building exercises could be carried on also through the provision of

Funding to support dissemination of ideas [and] education

Ideas related to involving sex workers as something other than the object of research was a theme that wove through many responses. The idea being that greater mutual respect could be arrived at by not simply remunerate sex workers for trial-related expenses or trial-related lost wages, but to pay sex workers for their time in helping to develop the research, as one might pay any other consultant.

Work together to understand each others' concerns—this means compensating sex workers who unlike researchers are unsalaried. This will contribute to the development of real understanding and common definitions.

Research questions of sex workers should be researched too. The political perspective and goals of sex workers must be incorporated.

Communication was also a theme throughout many responses. Communication was seen as fundamental for the development of shared understandings of respect. This could be communication through the creation of agreements, as well as communication through dialogue.

Listening to each other, both sides.

Be clear about the intention behind the research. Do not objectify or exploit those you research.

Listen to what your local sex worker organizations have to say...listen to what other organizations that work on different issues that might affect sex workers have to say.

It was noted that in the instances of many trials, communication and translation would need to happen concurrently. Translation in this context could mean not only the provision of information in local languages, but also translation which could take research and trial-related concepts and translate these into a laypersons' vernacular. However, suggested here and focused on to a greater degree below, translation which only allowed for one language to another across single mediums could be problematic, as it was not only language which was a challenge, but also literacy, fluency, the complexity of some trial-related concepts, as well as the fact that sex workers' lived experience would not always provide an ideal context from which to engage in a literal, uniform translation; that the best translation between researchers and communities was translation which recognized that

You need time and you have to be patient.

Good communication for mutual respect meant also meeting sex workers where they are at.

Researchers should meet sex workers and listen. Simply listen and absorb what sex workers say.

Research training should help with this if people can abandon preconceptions. Socializing with sex workers will help, too. Offer to throw a party and see how much fun you have dealing with each other as people instead of populations!

Respect wasn't always something that could be developed. That sometimes it needed to be learned, and sometimes it needed to be taught and sometimes different parties needed to work together to help each other develop and understand what respect was to one and another.

The Principle of Clear Roles

To understand better how sex workers felt about the principle of clear roles, two questions were asked: How researchers can understand sex workers' expectations for a biomedical HIV prevention trial, and what might prevent sex workers from communicating their expectations within a trial.

Respondents were direct. The most efficient and effective way to understand expectations was to ask:

Ask 'what are your expectations?' then WAIT, LISTEN and HEAR the answers.

Ask sex workers! 'What are your worries? What do you think will happen? Why? What would make this better for everyone?'

Ask us questions and listen to our worries and problems.

Very importantly—by listening to what the sex workers have to say and not ignoring what we have to say.

Understanding sex workers expectations requires clear explanations about what they are being asked to form expectations about. It was suggested that researchers should explain all about the trial in question and disseminate information in simple language in a way that can be comprehended. Include description of the possible benefits, the potential risks, the safeguards, and the importance.

By explaining the trial, and what they hope to gain/learn from it and the effect the results might have, or what they hope them to be.

Respondents suggested that sex workers' expectations could be understood also by conducting formative research prior to the initiation of a trial.

Conduct...a pre-study to see what sex workers really want, what it is that affects to us, and the dangers and risks to which we are exposed.

Come and look at our problems and concerns in order to understand us better.

Meet us where we are, without playing with us and with respect.

Understand our lives and how we work.

If they would meet us where we are and that they would understand our reality.

Conducting preliminary research to understand sex workers expectations would require some facilitation.

Make...sure that sex workers are able to express their expectations.

Such facilitation was a way of facilitating a process that could be

A more open study which allows and encourages us to express our fears and uncertainties.

Be respectful even though sex workers have different priorities than researchers. Understanding that and sex workers' priorities will help find ways to move forward.

At the same time it was clear that facilitating different forms of communication and methods for understanding sex workers expectations could be challenged by barriers which could prevent sex workers from voicing their expectations. This element related again to both real and perceived social and economic imbalances between researcher and sex workers. Some of these imbalances might rest on particular forms of cultural capital; like education or literacy, other imbalances could rest on gender, sexuality, social, economic, occupational or health status—or some form of power differential.

A frequently cited barrier able to prevent sex workers from communicating their expectations could be the perception or sense that they were being used, taken advantage of, or ignored:

Feeling that...opinions are being dismissed, that they aren't being listened to.

That we do not feel like genuine participants but rather as used objects of study.

The major obstacle is that we are treated like idiots on whom anything can be imposed and that we are not treated like other citizens.

If I don't feel comfortable in the interview or if I don't feel accepted.

If we do not feel confident to participate.

If we don't feel respected and accepted.

If we don't feel that our voice is being heard.

Indeed, some respondents felt that one of the major barriers was the fact that answers which were not the proscribed or expected ones were ultimately ignored or disputed; that in order for the researchers of biomedical HIV prevention trials to genuinely begin to account for barriers to expressions of expectations, they would have to acknowledge that the answers that they wanted or expected to hear and the answers provided by sex workers or their communities might not be the same.

Another barrier to the expression of sex workers expectations was related to literacy, facility with language, and the knowledge and information that potential trial participants might have. It could be that information seeking expressions of expectations might be too clinical, or not in a local vernacular. It could be that the search for such barriers was being done via paper or other written surveys when literacy was a real issue in the community. It could be that the very concepts as they relate to the expression of expectations simply are not socially or culturally meaningful. To this end, respondents suggested barriers to successful expression of expectations could include:

Lack of knowledge around what the trial is about

Researchers only understand a language of scientific jargon that we don't speak.

Language, both translation issues and the need to explain difficult concepts into simple language without research and medical jargon.

Give sex workers time to discuss it amongst themselves and then ask their opinions.

Interviews and interactions are rushed and incomplete because the local hired staff look down on sex workers.

Insensitivity was a further barrier expressed by respondents. This reflected the fact that very often formative efforts to understand the communities researchers hoped to engage with around biomedical HIV prevention trials could inadvertently be stigmatizing.

Sex workers will say more when they are on their territory rather than in a medical office, and when the numbers of sex workers are significant rather than tokenistic.

Activities which presupposed sex workers were at risk, or non thinking, or needy, or immoral could have the effect of turning sex workers off from engagement, and as a result prevent the expression of any genuine expectations. Treating sex workers with respect and acknowledging and validating their contributions could help foster environments deemed safe for the expression of expectations and concerns.

However, with the reality and complexity of the daily lives of sex workers, capacity to engage with researchers over expectations, and the resources to fuel such capacity could be an issue. For some sex workers, low educational backgrounds could inhibit both comprehension and expression while the social hardships and needs of daily living could intervene.

[Lack of] money for transportation.

Feeling like a trial is the only option for getting care and being desperate for acceptance.

Unlike other populations often recruited into biomedical HIV prevention trials (e.g., injection drug users, men who have sex with men, people within countries with high HIV prevalence or where HIV is endemic) the behaviour and relative risk of that behaviour experienced by sex workers is also their livelihood; their work. The reality is that in the context of sex work, the benefit of the individual or the population for research is not only behavioural, but occupational also. This unique relationship between behaviour and occupation within the context of biomedical HIV prevention trials can make for complex interactions, including interactions which required sex workers to share or voice their expectations to researchers.

Compensate us for our time used. You stop serving clients to go help but you still have to eat and put food on the table.

At the core of responses reflecting on that which could challenge the communication of expectations within these types of prevention trials were reflections on the role of trust; the difficulty in establishing it, and the work required to maintain it.

If I have trust that's the most important thing for me.

As long as I trust them.

The Principle of Shared Responsibility

To address the principle of shared responsibility, respondents were asked to reflect on the ways that sex workers can and should be responsible for the research process, as well as challenges that sex workers and researchers might experience when trying to truly share responsibility for a biomedical HIV prevention trial.

For some, shared responsibility meant recognizing how the concept could be defined and applied in a way that was not tokenistic. This was because more generally sex workers were responsible only for being a trial participants and sex work communities were responsible, largely to be resources for participants, and conduits for recruitment. Yet it was suggested that sex workers, as with other at-risk communities, were naturals for assuming roles of shared responsibility given their generally elevated risk of exposure.

I believe that many of us should be involved in this process since we are part of the epidemic due to our exposure to the virus.

Respondents suggested that here as elsewhere, the provision and availability of resources were key to institutionalizing the principle of shared responsibility within an HIV prevention trial context.

I think that if sex worker communities were given the resources they would be able to take responsibility for the research process. They can use their networks to link in other sex workers and make sure all participants are well informed.

If sex workers are getting paid to be involved, then they should have just as much research as the next one.

Paying sex worker groups to do the research and getting them to employ the researchers.

While not evident everywhere, here there was some indication that shared responsibility was a two way street, requiring efforts not only on the part of prevention trial researchers but on the part of sex workers targeted for inclusion.

Sharing concerns of the communities, being clear in the needs of each community, and creating protocols of respect.

Replying to questions honestly, keeping appointments, asking questions when they are unsure of what is being asked.

Responses reflected also that shared responsibility was not a 'checkbox' occurrence, and that it could not necessarily take place just because trial research funders wished it to. Responsibility and the ability and skill to share it could be contingent on a number of other factors also, such as the sharing of power, or the facilitation of empowerment, or the building of knowledge and capacity for sharing.

They can only be responsible, if they are granted the power to participate in the design. If they are treated as mere objects of research, how can one ask for responsibility?

By being given some of the responsibility for it.

It has to be from both sides, give us help for participating.

There was the notion as well, that to discussions of shared responsibility would need to contend with both the benefits as well as the potential challenges of a trial.

Trial participants are responsible for being honest and committed to the process but I don't understand why me or my community should be partly responsible for a research study that we neither own or need? We don't ever get a share of the profits or the credit or even a discount on the final product but they want us to share the responsibility? In Thai the word responsibility literally translates as 'accepting the blame and accepting the praise'... only a fool would agree to simply 'accept the blame.' I've got enough to do putting rice on the table and changing the world!

Here as elsewhere, responses queried the logic of suggesting responsibility could be shared in a context where the potential gains of a trial were not shared as well; that the very notion of positioning a trials as one of shared responsibility in an effort to downplay any conflict which might occur between researchers or trial participants, or in a way to aid trial recruitment, was fundamentally disrespectful and arguably unethical.

Sex workers should be employed by and consulted by researchers. The responsibility lies with the researcher (who controls the situation), and sex workers should enforce that. I want to say that sex workers should be responsible for denouncing bad and unethical research but in reality, in most places, sex workers don't have the support required for that. I'm sorry that researchers know that! Sex work organizations and projects should denounce unethical research, but they don't have enough resources either. Sex workers should not participate in unethical practices. Resist!

Sex workers and sex work groups often feel as though they are being used to get the research data but their opinions are not really valued.

Defining what true shared responsibility might look like and recognizing what might only ever be a purely aspirational element of shared responsibility was not the only challenge. There were other challenges, some of which were rooted in the frequent social and economic differentials between trial researchers and subjects.

Aren't they people of different social classes with different interests per se?

The underlying cultural and emotional division/confrontation prostitutes vs. others is so overwhelming that it can be emotionally very difficult to trust, share and cooperate although you would like to.

The belief was that sharing responsibility was not realistic when one lived on the street, or was ill without adequate medical care, or had children and family members to feed. Adequate remuneration might go some distance to mitigate such a challenge, but respondent's reflected on how realistic that might be also.

I don't know. I haven't participated, but I believe that if they helped us with some kind of money it would be easier since we live in the street.

Paying sex workers for their time—sex workers lose money by participating if they aren't paid for their time. Sex workers have many many concerns beyond the research—it's not their priority the way it is for the salaried researchers. Researchers need to respect this. Research has a bad track record with groups at the margins of society. Own up to that and do better! If you can't do better, if you can't do good, stop, shut down and go home.

Researchers get paid. The financial burden of sex workers is not eased by being involved.

For respondents, the reality was that with responsibility came ownership and ultimately power, and that it

was ultimately the sharing of these and not of responsibility per se, which were the real challenges.

Researchers have ownership and power [but] are and reluctant to share. Researchers have preconceived ideas about sex worker that are inaccurate and misleading.

Beyond power, ownership and the resources which each of these conveyed were challenges which related to cultural sensitivity, stigma and respect. Sex workers were often very different from researchers and research institutions, particularly when those researchers came from some other country or part of the world, and that being able to understand, for example, the meaning or history of sex work within one culture or another, or for that matter the meaning or history of research within one culture or another could act as major challengers to the possibility of establishing mechanisms for shared responsibility.

Can the deep rooted anti-sex work social stigma be overcome by research or will it be entrenched even more?

Dealing with the stigmas associated with sex work and HIV.

That they keep making us invisible without knowing the realities that face us and losing our prejudices.

Making the workers feel safe enough to be honest—especially if they aren't following guidelines that have been set.

Responses reflected the reality that shared responsibility would require certain levels of trust and mutual respect, and that without these any genuine examples of shared responsibility occurring was unlikely.

The first challenge is to mutually maintain the research relationship and to ensure that it lasts, and that we be respected.

If they don't follow the principles of mutual respect.

Mutual mistrust, different ways of seeing the world, different priorities, different loyalties, etc.

The Principle of Participatory Management

Respondents were asked what—in terms of capacity building, knowledge development or financial resources—they or their community group might require to realistically become involved in participatory management of HIV research trials and what barriers sex workers and researchers might experience within a participatory management context.

In a way it is an extraordinary question, when one imagines the range of possible differences there could be between people in different parts of the world working as sex workers, and people who work as researchers. Technical support was required. This is not surprising. Other communities have demonstrated the good that technical support can translate to in terms of research participation. In some instances as mentioned previously, the requirement for technical support would need to build on or traverse an existing need for core literacy skills around abilities to read or/and write. Beyond that, it was believed that sex workers' participatory management would need a better grasp of the science and process of biomedical HIV prevention research trials.

To understand the process better; to understand the study better and in that way we would be able to

commit ourselves a little more.

Training about how to do the research

The idea was that with training, and a broader understanding of biomedical HIV prevention trials sex workers could be more able to genuinely participate in areas of a trial that were not just trial participant related, but to be able also to simply coexist within a greater context of shared understanding and mutual respect:

Participation and respectful coexistence of specialized personnel.

Responsibility on both parts.

As well as

Political acceptance to participate.

Training and participation were not things that could necessarily happen organically or simply through the transfer of resources, or availing sex workers to opportunities. Efforts to help facilitate and to allow sex workers also to help facilitate could lead to greater involvement and more ability for participatory management. Suggestions very broadly entailed.

Involvement in our communities.

Development of self-organizing.

Solidarity work with my community.

Resources, inequitable access to resources, and capacity to access and provision of resources are thematically woven throughout virtually all responses to the questionnaire, and no less here. Many respondents reflected on this area and their importance for the realistic attainment of participatory management. Resources were seen as central both for participation and its facilitation and for the motivation to participate.

Resources to participate in the research, since participation can have its expenses, furthermore that if a study stops it follows through on its remuneration / resource commitments regardless.

Respondents suggested resources were required for direct trial-related activity as it related to trial participant recruitment and retention.

Transportation to go to the clinic, a voucher to buy food or a money incentive.

If the research project is a full-time job, then being compensated for full-time involvement.

As well, resources were required to facilitate the more aspirational goal of participatory management. Resources were seen as being able to facilitate sex workers' greater capacity and greater involvement within a trial context, not only as research participants, but as members of research teams.

We would need to be funded to develop ongoing and long-term relationships within our community these relationships need to be developed through outreach to sex workers, providing them with information about laws and safety in the sex-industry as well as cheap supplies of prophylactics. This funding would need to continue for many years to build up memberships which include a core or University educated sex workers who can submit tenders to conduct the research themselves in partnership with non-sex worker researchers.

Salaries. Training. Mentoring. Time. This is the same that other people working on the project would have, but sex workers may require more capacity building. You may have met a brilliant colleague but when research ends and researchers leave, all the people who may have been employed are suddenly unemployed. This is not permanent work. But recognize the skills involved and the ways sex work can be great training for interviewers! Encourage people to pursue research work and HIRE THEM. Encourage your colleagues to hire them. This is part of mentoring—sex workers are not very different from your students, when given all the same opportunities and advantages.

It was clear though, that it was not simply a case of money in and money out; that the provision of resources within a trial context would not only provide for literal costs like expenditures incurred as a result of participating, but also the resources of time, energy and good faith required to create an environment in which participatory management were possible.

I believe that it requires a lot of confidence on our part and patience from those who undertake the research, as well as the budget necessary to conduct the study and to cover the costs that we incur through our participation. This is not to say that they should pay us, but that they cover the costs of transport and other things related to our participation.

There is no interest to participate in management on voluntary basis. There should be financial resources for hiring people to do the work. And there should be a good reason for sex workers to participate in research. But this reason cannot be a service that is provided only to those who participate in research, because everyone should have access to all services.

Beyond training, participation and the provision of resources, the need for transparency was suggested as required for the creation a trial context where participatory management could be possible. This included transparency about what the research was about as well as transparency about research outcomes.

Complete transparency about what the research is for.

That the research treats me well and is clear on what is expected, and that I be made to understand clearly and to feel that I will benefit from the research results.

Others reflected that it was not simply enough to outline some sort of recipe for participatory management, because such recipes can be difficult to translate into the real world, where there can be large differentials in social and economic well being between the researchers and research subjects of biomedical HIV prevention trials, as well as histories of engagement which have been structured by these differentials.

We don't trust the current models of participatory management as it's all too easy to become a tool for the research teams. The information you're given to translate and share all comes from them. Sex workers don't enroll in trials because they trust the research teams, they enroll because they trust their community leaders. If something goes wrong, the potential damage to relationships in the community is huge. Realistically we would need access to independent scientific advisors able to communicate with sex workers.... then of course we need everything translated into a minimum of 5 languages (some written, some oral). Also of course we need to hold the final say in whether the trial takes place in our community or not and the right to stop it at any point.

As with shared responsibility, participants reflected on a number of barriers which sex workers and researchers might experience when trying to establish a system of participatory management. These included the challenges of power differentials, different worldviews and outlooks, variations in social and economic contexts and the ways in which stigma could act to prevent good participatory management.

It was felt that participation was something that could be interpreted differently by different people, and that participation was often interpreted by researchers of biomedical HIV prevention trials as 'participation without power.'

'Participatory' usually comes to mean participation without power. I think companies and research teams would find it an enormous challenge to hand over any power to a community. Token participation without any real power over the trial's management is dangerous.

One of the outcomes of participatory frameworks that were powerless, or inequitably empowered was the mechanisms for participatory management could become co-opted or used in somewhat coercive ways towards more successful recruitment and more successful retention of trial participants.

If the voluntary nature of participation is compromised; if participation is bought or not voluntary.

The different world views shared by sex workers and researchers could act also as barriers to participatory management. Different world views or different interests might mean that sex workers might want to focus research components on areas deemed unimportant by researchers and vice versa.

Different social background, language, research interests. Sex workers may want to research why some clients refuse to use condoms? Methods on how they can convince them to be happy by using condoms.

Many sex workers...have chosen sex work because they hate bureaucracy, official ways of management, control, etc. So I guess that sex workers would define participation and management in a different way than researchers.

Another barrier based on past experience as well as current life situations, could be the lack of interest on the part of sex workers.

The lack of interest for taking responsibility on the part of sex workers.

This could be because the very notion of participatory management or the kinds of simple tools or resources that one might need to participate or to structure their life so that participation would be possible were simply not available.

I don't have a phone. I live in the street.

[A barrier] is money because we depend on what we earn than if we become involved in something we need things like transport and child care to be taken care of.

If I don't have money to go to the clinic or if I have a client at the same time.

Respondents suggested that stigma and discrimination could prevent effective participatory management also. This is because the kinds of preconceived notions research staff and others can have about sex workers, the legal status of sex workers' activities, or the added challenges of working with sex workers could predispose people to assuming or expecting certain patterns of behaviour.

The illegality of some forms of sex work often makes it hard to develop above board formal positions for sex workers.

Health workers and researchers have been the most likely to discriminate against sex workers. This is probably because sex workers meet health workers and researchers—if we met more plumbers, it

might be similar. Researchers have their own priorities and bring their own preconceptions including stigmatization of sex workers. Researchers need to recognize that and own up and move beyond that in order to be able to work equitably with sex workers. Otherwise, work with a different population.

Sex workers who are educated enough to be involved in a managerial role often do not wish to expose their sex work status to fellow researchers. Researchers working with sex workers often do not credit their other skills as being equal to non-sex work researchers. Sex worker groups often feel that non-sex work researchers want to 'take over' and do not credit the specialist knowledge that sex workers have about their own community.

The fact is that biomedical HIV prevention research can be a very time constrained activity, and the kind of time required to employ the kinds of activities required for true participatory management could be highly challenging to the smooth and timely running of a project.

You have to be patient when dealing with folks that are not from your community... sometimes you have to give more chances if the sex workers in your community face more oppressions than you do.

This is not to say that participatory management is or would always be impossible. Some felt that it was possible, but would require special effort and special attention.

I believe that if everything is commonly agreed upon before the study begin then problems can be avoided.

The Principle of Autonomy

Respondents were asked how sex workers and their communities might be given independent and autonomous voices in biomedical HIV prevention research trials. Some found this question to be unusual as

The idea of doing 'a biomedical HIV prevention research trial' with sex workers is already some way down the path of determining what is relevant for sex workers. In other words, would sex work communities, operating independently and autonomously, decide to do biomedical HIV prevention research?

It is an interesting and valid point, and something which will be reconsidered in the conclusion. For the moment though, consider what other respondents had to say about how best to facilitate the autonomous voice of sex workers within biomedical HIV prevention trials.

Autonomy was seen as a function of not being dependent, and resources were seen as a mechanism to such independence. Providing resources to sex workers was seen simply as compensating them for their efforts—not at participating in trials—as research subjects—but rather as research informants and collaborators.

[Pay] them to share their voice!

Pay sex workers to be involved in formal ways.

Treating sex workers as equals, including equals who are as capable as making mistakes as any other individual was seen also as a means of facilitating autonomy.

By giving us confidence and making sure to see if we are making any mistakes along the way.

Independent voices would also be facilitated through truly collaborative processes that recognized the important contributions of sex workers as well as researchers. Here autonomy was seen as a function of

Making the research truly collaborative.

Working in consensually and in agreed-upon ways.

Working in a collective, collaborative and agreed-upon way.

[Providing] access to independent expert knowledge. [Developing] safe clear effective channels of complaint. Shared power instead of shared responsibility.

Yet one of the most frequently cited ways suggested by respondents to facilitate the autonomy and the independent voice of sex workers as well as trial participants was through the creation of genuine opportunities for input and engagement. Suggestions included:

Collect sex workers' questions. Find sex workers who are... researchers. Create the scientific social atmosphere so that researches do not fear to out themselves as sex workers or former sex workers.

Engage with the sex worker groups prior to submitting funding proposals, before any research questions have been proposed. Give them the money to do the research and contract themselves back in as consultants.

[Create] roundtables where the populations can be an integral part of the study and their voices can be heard.

Researchers need to listen to what sex workers say and incorporate it into their work. Sex workers should be equal partners—that's a lot of work but it's the best way and you should want to do the best you can.

However, would simply providing avenues for input be sufficient for the autonomous independent voice to carry weight within the context of a biomedical HIV prevention trial? To this end, respondents were asked how researchers working with sex workers in biomedical HIV prevention trials could respect and act on suggestions from community members?

The primary way by which researchers could respect and act on the suggestions of sex workers relative to the conduct of HIV biomedical prevention trials would be by listening, by respecting that which they heard, and by applying suggestions.

By respecting our opinions and applying them in meaningful ways to the research context.

I would like it if they would respect our suggestions and do something about them.

Same way as anyone respects and acts on suggestions... Just do it!

Try to respect us and listen to our suggestions.

Certainly in many research contexts, some suggestions can be more appropriate than others. The key would be to inform stakeholders about why or why not something would be applicable to a trial context.

If our opinion enriches the project, to take it in account and if it does not enrich the project, to help us

see why not.

Developing a better understanding of sex work and the issues faced by sex workers could also help researchers develop a more sophisticated interpretation of sex work, and thus respect sex workers and their opinions more.

Put yourselves in our place, understand us and treat us with respect.

Educate yourself on sex worker issues, and practice active listening.

Positioning yourselves where you find us, so you [better understand] the ways in which we have to live.

Here as elsewhere, mutual commitment to listen, acknowledge and follow through was an important element in the facilitation of active and successful involvement.

By following through and investigating if suggestions made by sex workers and communities are necessary.

By following through on the promises they make through the course of their research activities.

Taking into account if there are suggestions, they should be incorporated into the study.

Given the very different contexts in which sex workers and researchers could come from or find themselves in, and given some of the power and other differentials, some were unclear whether the opinions of sex workers could ever truly be incorporated within a trial context. Yet, such difficulty should not necessarily preempt attempts to compromise.

I do not know if it is possible. Suggestions can often be controversial and impossible. At least you should negotiate and try to find compromises.

In the end though, perhaps the best way would be not to continually look for reasons why or why not sex workers and their opinions could or could not be incorporated within a prevention trial context, and rather to

Just do it! Compensate people for their time and employ them to help your project be more sensitive to the community. If you ask people to talk about themselves, they will. Then it's up to researchers to make the connections.

The Principle of Transparency

Respondents were asked to comment on the important pieces of information sex work communities need to know about a specific research study when choosing to become involved in biomedical HIV prevention research. Some felt that this was contingent on the particulars of the study, but that individuals should be made to understand that they should act in their own best interests.

Depends on the study. Everyone needs to understand that they can say no and opt out at any time without penalty. It's imperative to discuss known side effects and options for long-term issues as they arise. Don't push, be clear and let people make their own decisions.

In order to act in their own best interests, it was suggested that sex workers should be informed about all aspects of a study, and that they should be able to ascertain for themselves, what they do and do not need to know.

We must be informed about everything. Absolutely everything. What the study is like. We need to know everything and then it is more difficult for us to become involved simply because we are drawn to elements of the study.

Respondents suggested that areas that would be particularly important to inform sex workers about would include frank appraisals of research hypotheses, funders, political orientations or biases of the researchers, and how trust and confidentiality will be built into the study and secured.

Where are you coming from... what's [the] hypothesis, what will [be done] with the data.

If the research is being conducted by a for-profit org... If the funding for the project is coming from an org which is anti-sex work, church based or hold any values that might compromise the safety and well being of sex workers.

How privacy is being secured? ... Is there any hidden agenda? ... What are the people, the sponsor like? What have they researched before? ... How do they act in order to establish trust?

That the research will research that which it says it will and not something else.

Respondents suggested also that sex workers and their communities would want to know specifically where sex workers fit into the proposed study; how sex workers might be affected by the issues being investigated by the study, and why the research was interested in involving them, as opposed, for example, to involving other people.

[How] the information gathered will actually be used and if it is just to fill in spaces... or to make our situation in our communities [better known].

I don't know very much about this, but I believe that it must be the correct information and to show us how and where we are ourselves affected and we see that we are all part of a community and of the human race.

By helping us to understand how we are affected.

Ultimately though, the most important things sex workers would want to understand would be the risks they might face by being involved in the study, as well as the risks to their families and communities.

Educate us about the research project, good consequences and bad ones.

How will sex workers or society benefit in the long term and short term? Why it's not being done with rich white university students in the West? Why us? Why now? Why here? What it entails (time, pain, embarrassment)? Where to find independent info about the drug/method?

Side effects... If identifying information will be taken... How personal information will be managed... How the research findings may impact on laws and regulations... Who will get the credit for the study?

Respondents suggested that in addition to communication around risks would be communication around the potential benefits of individual or community participation.

We will feel like stakeholders if we can see how the research can benefit us; To be able to understand how it benefits us.

What can I benefit from this? What kind of benefit can this research produce to sex workers and to the

wider community?

That it will benefit the community and that the issues to be studied are actually a concern of the community and really affect the community.

Respondents were asked also to provide suggestions about how researchers could deal with local conditions in order to make it easier for researchers to communicate with sex worker communities.

Suggestions included learning about local conditions.

Researchers who seek to work in these situations need to get out on the ground in them. These are the places where translation may be most critical. Going there will make it easier to understand local factors why people may not want to work with researchers.

Accepting local conditions.

Accept that some conditions mean that clinical research is not safe, possible or ethical. Otherwise be prepared to develop the local conditions to such an extent that research is possible i.e. put in phones, electricity, roads!

To support local conditions.

Be willing to support in some way those conditions. Otherwise, it feels exploitative to be asking participation when there are bigger issues at hand.

And to do what they could within the course of a prevention research trials to improve and resource local conditions.

This problem should be addressed by funding. The preparation of an equal level field is part of the game.

Give sex workers communication tools to keep as incentives.

Help with that, with something or with the bus or something to eat.

Or come earlier to the clubs where we are so it's a little easier to be able to do the interview. Work with us at times when it is convenient for us.

Perhaps foremost in respondents' minds was the suggestion that researchers invest in the availability and development of communication technologies.

The use of [mobile] phones and the internet.

I think the internet, although not all of us know how to use it.

I would suggest internet, mobile phone, and meeting face to face.

The internet and cell phones, etc.

To help with telephone or electricity.

If they could give us a cell phone or a voice mail where we can receive calls.

The idea was that by resourcing communication technology for sex workers, could act as a mechanism to allow researchers to communicate with sex workers around issues relevant to a biomedical HIV prevention trial, but which would also allow sex workers to communicate and network around their own peer networks.

The Principle of a Standard of Prevention

Respondents were asked to comment on the prevention services they thought should be included in an HIV prevention trial. Education for sex workers around HIV was a frequent suggestion for inclusion within a prevention trials education

Educate the people about the HIV virus.

More education, there is a lot of ignorance among us and the majority of people.

However, the most frequent suggestion for prevention services to be provided within the context of a biomedical HIV prevention trial was condoms and other prevention modalities. Respondents were clear in their assertion that such prevention should be accessible and without cost

Free condoms and lube, free syringes and safer injection supplies, free testing, free counseling before and after.

Service packages... for prevention with adequate condoms for the realities of the communities.

Condom and correct condom use promotion.

To teach us the proper use and the importance of condoms, and by providing talks and other information on the subject.

Free unlimited amounts of condoms and lube. Education about how to use them. Sex worker-led workshops on non-penetrative sex. All in local language and vernacular. General health services, beyond gynecological exams.

More about HIV, give us more condoms for oral sex.

STD, prevention of hepatitis, HIV and AIDS, how to reduce the risk.

You should have also latex-free condoms because some sex workers are hypersensitive to latex.

Treatment as a principle within a standard of prevention was much less frequently cited here, but is the focus of greater discussion below.

Sex worker peer projects to promote rights. Full access to HART (if required) PEP, unlimited condoms, lube.

Free medicine, if necessary.

For some, simple prevention means was not sufficient, and should be complimented with forms of structural prevention. Structural prevention in this context could include the promotion or cultivation of respect for sex

work, which was seen as a form of harm reduction which could empower and lead to better working conditions and a better standard of prevention.

Cultivate respect for sex work.

Adequate places for sex workers where they will respect our identity.

I believe that all prevention services are necessary so that we do not feel mistrustful. We need to feel that there are no additional risks to our participation.

Risk taking is related to social security and security of income. Structural prevention is key. This includes working on the sex worker stigma (stigma management) and coming-out groups for sex workers.

Related to structural prevention was what one respondent defined as 'the 100% power pack'; that is a continuum of prevention services which together would define a standard of prevention for sex workers involved in biomedical HIV prevention trials.

We need the entire basic package... knowledge, equipment, skills, access to health care, and power. The first four are important but without the final part of the 100% power pack we aren't safe from HIV. Like everyone else, we need sexual autonomy... so as a part of prevention we need are safe and fair working conditions with full respect for our rights.

Reflecting on the challenges to providing a 'package of prevention services' to sex workers, respondents suggested that in some contexts these challenges were well known and understood and were perhaps not so different in a prevention trial as they would be in other aspects of social life.

The same challenges that have existed for more than 20 years! Denial of our right to safe fair working condition, abuses by authorities, stigma, [and] no commitment to sex workers).

Paternalistic approaches.

If they create a negative discrimination, that's why they have to also work with organizations as well as sex workers, both health care workers and law enforcement (police).

Stigma on the part of health professionals and researchers.

Others felt that there were no challenges that could not be overcome.

I believe there are no challenges so long as the desire to provide the package of prevention services is genuinely there.

It doesn't have to be difficult.

The Principle of Access to Care

Respondents were asked about the health care and treatment needs and priorities in their community and how these might impact the principle of access to care within a prevention trial context. Here access was not only about linear relationships between individuals and access to basic or more complex health care.

They push us to have HIV test but if we have HIV we cannot get free ARV's unless our CD4 count is 200 or less. This means we are usually already sick and so we don't live long. The cheapest ARVs still cost half the minimum monthly wage and it doesn't take long before we have to change to another, even more expensive combination. Mostly I see that sex workers just keep on working to provide for the family until the very last minute, then it's often too late for the drugs to save them. Many of my friends have died from liver failure caused by the TB drugs they have been made to take to protect society!

Rather, responses were varied and attended to barriers also. For example, respondents pointed out that legal structures could impede access to care, particularly in contexts where sex work was criminalized or where those seeking health care were undocumented migrants.

Struggle with prostitution law enforcement. Struggle with special discriminatory taxation of sex workers.

Undocumented migrants and non-resident sex workers [who] do not have access to HIV treatment.

In other contexts shortages of universal health care, the cost of health care or the complexities with the health care system could act as barriers.

Health insurance.

Health expenses reimbursement.

Someone who might help us with the health care system.

Most respondents however focused on the availability and quality of physician services, given that in most respondents' minds, the quality and of health care available within the community was lacking. Respondent's suggested that health care would be more accessible, if it was more open to diversity, less judgmental, and able to provide a wider array of services, given that sex workers could have health needs and concerns that might not necessarily be shared by the wider population.

Doctors with the knowledge and ability to work with transgender.

Not be judged by the doctors, get free drugs.

Stigma. Discrimination. Poor quality services.

Drop-in centres where we have access to our community peer based, non judgmental care.

Syphilis testing—there is an untalked about but high number of cases in the general population.

Recognition of sex work job related illnesses.

General health care, including but not limited to reproductive health services.

That we do not have a place where we can go for health care; where we can have our health needs taken care of; and where we are received and taken care of like the human beings who we are.

Reflecting specifically on concerns or barriers to accessing potential trial-related health care and treatment in their community, respondents suggested that a number of structural barriers could inhibit access.

The cost.

There isn't financial help for the transsexual. They don't give you medical insurance, just in some cases with the hormones.

Lack of treatment at time.

Access to services and treatment for long-term side effects.

Privacy.

Lack of interest in our communities on the part of the State because of moral prejudices.

Stigma from researchers and health professionals.

Judgment... stigma... exploitation.

Access was seen as being prevented also by attitudes or sensitivity on the part of those providing services.

Doctors that are not sensitive to the transgender community.

That doctors and health care workers are not sensitized to who we are and what our issues are, and that they have many phobias about us or distance themselves from us and for that reason we prefer not to go to the doctor.

Or by the narrow scope of services offered in relation to a prevention trial.

I have seen that all care associated with trials or projects has a very narrow scope.... They [trials] are not interested in committing to our health.

Responses also reflected that creating avenues for access to health care within the community could be preempted by large more structural barriers such as anti sex work policy or sanctions.

The anti-migration, anti-trafficking, anti-sex work policies; sanctions for clients and repression of actively seeking for clients (publicity); refusal of access to social rights and lodging, and police violence.

The Principle of Building Research Literacy

Respondents were asked to comment on the kind of activities researchers could do to help their community understand more about HIV prevention research trials. For many respondents, HIV education and education about prevention research and biomedical prevention trials were a starting point. Here it was suggested that the most effective education was that which was culturally appropriate and framed and delivered with respect.

A lot more time educating us with respect. More education until we are clear.

Education and training, but that should be compensated time.

Education in this context should not be directive but rather should be interactive, promoting the active exchange of information and experiences. Information could even be scientific in nature, but would need to be translated in such ways as to be meaningful to those without a scientific background.

Activities which exchange information on HIV and on condom use.

Information [provided] in a way that is understandable and meaningful for us.

Resource peer educators to talk to sex workers about the research.

Scientific information, actual data, and it should be easily understandable to our communities.

Such interactive activities could take the form of community education and community development.

I believe that there must be activities for all the community and that this can also help in the interest to participate.

I believe that they need to hold community meetings because really we don't know too much about these types of things.

Important for respondents was that researchers and biomedical HIV prevention trial sites should not assume what individuals would or would not know about HIV prevention and prevention research; that in some contexts it was social oppressions which influenced behaviour rather than levels of education.

Don't assume we don't know the logistics of prevention... For those who might not have all the facts, create fact sheets... Understand that various societal oppressions may be affecting risk, not lack of education.

A reality for some respondents however, and one expressed here as elsewhere, was that biomedical HIV prevention trials were not an individual or community-level priority, and that there were other much more pressing issues that needed to be attended to on a daily basis. For some, resourcing the basic needs of sex workers and their communities was much more of an immediate concern.

I don't think this is a good use of resources. It is not something I think most sex workers would name a priority.

After responding as to what researchers could do to better inform communities about the realities of biomedical HIV prevention research, respondents were then asked to reflect on challenges or barriers to building research understanding and literacy within the community.

Not surprisingly literacy frequently was identified as an issue.

Education. Many of us women don't know how to write.

Many of us have not gone to school

The lack of literacy. The majority of us don't know how to read and write very little. Using simple language would be better.

A very large issue for many respondents had to do with language. This wasn't necessarily related to people's mother tongues or the languages that were spoken in the community and have the languages might differ than that used by the researchers of biomedical HIV prevention trials. Instead, this had more to do with the kind of language that was used to describe aspects of the study or to describe the risks or benefits of a study. For respondents, one of the large issues was really around the complexity of the language used, even in a

survey that was already much simpler than the GPP document; that frequently the language was too scientific, or too specific, or could be hard for people within the community to relate to.

A lot of the time I don't understand these questions. The language used has to be more simple.

The language needs to be simpler.

Language, both translation and jargon.

The language of research can prevent our participation. The language needs to be simple; less elevated.

More studies and use language that is easier to understand.

The language that they use is complicated sometimes.

The low level of education and the lack of interest on the part of the community.

Beyond language was the notion how scientific concepts might be translated within a community context. The reality was that some scientific concepts were not always easily understood within a community context, and more work was required to translate some concepts in ways which were more understandable.

Sometimes or almost always the doctors or investigators speak a language to us that is not known by us, sometimes we understand better the work when they present/display it to our friends or partners also because they speak our language.

Sometimes we do not understand the medical language. Researchers should communicate with us in our own language.

That a lot of the research is still technical and they don't explain to us or to our communities in language we can understand and also it should be a part of our commitment to our health.

In particular transgender issues were seen as being something that was not always understood across a biomedical HIV prevention research context. The issues and the needs of transgender sex workers could be very different than the issues experienced by other sex workers.

It is important to educate about transexuality.

Educate the community about transgender issues.

More studies for transgender or more people that have HIV.

There aren't a lot of studies for transgendered people.

Some respondents believed that there was a lack of commitment on the part of researchers, and some hesitancy to work collaboratively with sex workers. The result was that some sex workers could find themselves isolated within a biomedical HIV prevention trial context.

I do not think there is a commitment from researchers to work collaboratively with sex workers so that from the outset sex workers are isolated from the research process and are treated as ignorant subjects.

I guess people (sex workers, me included) are not so interested. I had to struggle to answer all the questions because I did not feel so enthusiastic about the questions.

More challenging however, was the reality that these kinds of research projects were not necessarily a priority for sex workers, or for other marginalized populations. A reflection, that the goals and objectives of researchers could be very different than that of sex workers. While there is something admirable about a search for an HIV vaccine or some other form of effective prevention modality, such admiration was not necessarily seen as being shared across all parties involved. A challenge for researchers and by extension funders, was that their objectives within a prevention research trial might not be shared by all members of the community.

It's not a priority.

Different priorities, different ways of seeing the world, different loyalties.

Case Study

Following questions related to the 10 core guidelines, respondents were asked to consider as a case study, the preliminary closure of an HIV prevention trial in Cambodia and comment on the principles they thought was at work.

CASE STUDY: Unresolved Community Concerns during Protocol Development/Pre-Study Activities

In 2004, a trial of pre-exposure prophylaxis or PrEP (which involved testing the possibility of taking a pill a day to see if HIV transmission could be prevented) was scheduled to enroll sex workers in Cambodia. At the time, Cambodia was a country that did not have a national ARV program that made the drugs available. Also, at the time US government restrictions around funding sex workers had recently been put into place, causing US funds for sex workers and their organizations to be withdrawn from Cambodia. During that time, the trial team undertook a range of outreach activities to explain the protocol and its goals to various groups representing sex workers. Some of the concerns raised by these groups included the standard of prevention that would be given to volunteers, and the provisions that would be made to ensure access to care and ARV treatment, should participants become HIV-positive during the trial. Some sex worker groups did not feel that their concerns were addressed well enough by the trial team. International supporters in civil society also joined in voicing concerns and in raising additional suggestions that the trial was setting out to deliberately encourage participants to take risks and get infected. The concern and controversy increased, with direct action against the industry partner in the trial at the 2004 International AIDS Conference. The Cambodian government ultimately announced that the trial would not take place.

Principles at Work

Respondents were able to identify that virtually every core guiding principle was absent from the case study. There was a fault of education, a lack of respect, and serious issues around access to care, autonomy, participatory management, standard of prevention, transparency, scientific and ethical integrity.

All the principles are mentioned here.

They don't apply [the principles] very well in this case.

They were missing everything! Maybe there was clarity that researchers wanted lab animals. But sex workers brought accountability!

None of that was mentioned. No principles. Of all of those they mentioned, they don't seem to have any.

There isn't any principle in this case.

Lessons to Learn

Respondents were then asked what they thought would be lessons to learn from the case study, both in terms of positive and negative outcomes. Rather than editorialize, these answers in particular really do speak up for themselves.

Be suspicious.

Stop the tests.

Don't force the people but educate them without making them feel obligated to continue.

Ask your community its input before you design the study (but compensate them for their time and valuable knowledge).

I believe that it shows how research can have pitfalls and that at the same time we need to take responsibility for our well being in the context of the HIV virus.

In order to survive sex workers need to be suspicious towards everyone, especially those who are claiming that they are helping.

Drug companies and research teams are willing to act unethically if they can. Ethics in trial protocols often do not translate on the ground. Drug companies and research teams do not automatically respond to local community voices especially of marginalized communities in developing countries. Our protests must be backed up by International orgs to be taken seriously, we are not respected. Therefore talking about monitoring ethics and trials at a local level is not useful without any support at international level.

Educate the people better and respond to all their questions.

Sex workers can stand up to bad treatment and should! I hope that better research including participation will happen.

That we have to understand the national mechanisms that guarantee universal access to health care, in it the prevention, treatment, and information related to HIV/AIDS.

Facilitating Better Outcomes

Asked to reflect on how better outcomes within a trial context could be facilitated and how similar negative outcomes could be prevented respondents were equally eloquent about a better path forward.

Advocates can have an impact (good impact). Researchers can't always be trusted. Sex worker orgs and advocates need more resources.

Educate and respect people. Educate the people about HIV.

Educate the person [and] help them understand what they do... and the possibility [they may have to] accept they are positive... they maybe not ready for the study... [but they may] have to accept they are HIV positive.

If there is a common understanding and agreement, there do not have to be negative outcomes from the research process.

Positive outcomes are facilitated if everything is made participative and so that all we feel like we are part of the study. Negative outcomes happen if we are used and told that we are a part, but that in the end our participation is only to allow the researchers to publish what they want to, and what is convenient for them.

Researchers should consult with and listen to sex workers, make partnerships with sex workers! This means paying sex workers for their time and hiring sex workers as part of the research team, and mentoring them—that's capacity and literacy building, as well as in some cases career building.

Stop treating sex workers like rubbish. Treat sex workers as humans.

We have to be clear about the fact that in many nations there are moral prejudices and the assumption that the populations will be actors of their plans, and that their projects will influence the structure of social change so that they themselves can recognize our human rights independently of the way we earn a living (sex work).

We need an international sex worker owned ethics and scientific body that is empowered to advise, investigate and initiate action against dangerous or ethically suspect trials. This could be funded by all the drug companies that want to do research on us.

Summary Questions

Most Important Principle

Throughout what many respondents explicitly stated was a long and somewhat arduous data collection process were some very strong reflections about the 10 core guiding principles at the very center of the UN AIDS good participatory practices document. Having been given the opportunity to comment on each of the 10 core guiding principles and the challenges and barriers associated with each, respondents were then asked which of the 10 core guiding principles they thought were the most important, and why.

By and large most respondents suggested that either the principle of respect or the principle of access to care were the most important. Access to care because

Many of us we do not have it.

Sex workers need access to comprehensive health care.

Access to care, since it is related to the high risk of death.

Also the principle of respect.

With respect we feel confidence and not a lack of respect or the feeling of being used.

The building of research literacy was a principal that was also identified as among the most important.

Because at times we do not understand very much.

Because we do not understand all of what the researchers say to us.

Because researchers will continue to seek out sex workers, and protection from exploitation begins with being fully informed. Also at least we get something concrete and useful out of this principle!

The principle of autonomy was important also as,

This is the thing that I hear most often from sex workers: they want to be autonomous and anonymous.

It is related to the root problem stigma.

Other principles that were identified as important included participatory management, the building of research literacy, shared responsibility, scientific and ethical integrity, the principle of transparency, and working towards a standard of prevention.

Participatory management—this will help you get a real picture rather than what people think you want to hear.

I think research literacy is important, but that's because I see sex workers approached by many researchers.

Standard of prevention, because if we are not practicing prevention in the right way, we are not doing anything.

However, not all respondents felt this was the best question, were eager to answer it, or answered the question within the parameters set. For example one respondent suggested that the most important principle was

To have the same rights like the others. Not to be considered as vectors of the epidemic. Not get used as guinea pigs.

Another respondent suggested that choosing one principle over another was not easy and did not make sense because

They are all important. You can't isolate one over the others because TOGETHER they make good research.

Still another respondent indicated that the very nature of the question was both an insult to their intelligence as well as less than respectful to the research process in general. In theory, the people asking such questions of sex workers' participation in biomedical HIV prevention trials should be familiar enough with the nuances of participation that the answers would be evident.

I think you should think about the why and answer it for yourself.

Most Difficult to Achieve

Having described what they believed was the most important principle, respondents were asked to reflect on the guiding principle they thought would be the most difficult to achieve within biomedical HIV prevention research contexts with sex workers.

Whereas respect was among one of the most important principles identified by respondents it was also the principle that was identified as the most difficult to achieve. Respect was seen as so challenging to a prevention trial context because researchers so often entered the field with certain biases in place. Some of these biases would have to do with status differentials or with stigma or even morality. With researchers and sex workers so frequently occupying different social spheres, asking or expecting researchers or funders or policymakers to adequately and fully respect sex workers could be challenging.

Respect. Sex workers are generally treated badly or like children.

To be respected by the researchers who see us as numbers or cattle.

Respect requires ongoing education and awareness by the researchers of their own privilege, and power, as well as societal oppressions at work.

Respect will be the most difficult because whatever is written on paper, flesh and blood researchers and research assistants and all involved in working on a trial come from society and society looks down on sex workers.

Also identified as particularly important as well as particularly challenging was access to care. Many of the barriers to accessing care have been identified above, but responses noted particularly that it was the issues facing undocumented migrants and other nonresident sex workers that could be particularly challenging.

If undocumented migrants and other non-resident sex workers are included: one of the most difficult is access to care. Because HIV care is accessible only to legal residents.

Access to care—where I come from, this is not automatic.

Education also was seen as challenging. On one hand as a principle it was easy to see how education could be interpreted as important. It was however, because of its importance, that it was seen as being particularly challenging also. This is because education in a trial context should ideally be shared, but in reality rarely is. To this point respondents have suggested that education around the science of prevention trials, and the literacy issues of sex workers could really prevent them from attaining a number of the principles. Interestingly enough, the principle of education is not a component of the 10 core principles. Building research literacy is. And this is one area in which further discussion may be required, whether research literacy can in fact be built if core education skills are not already in place and if in fact it is feasible that core education skills could be developed in order to facilitate the principles of building research literacy, of shared responsibility, and of participatory management to name a few.

More information and education.

Educating everyone.

Education is more important so we know what is going on.

Some respondents found this question hard to answer. Some respondents felt very new to the field, found that core UNAIDS document and the discussions around it were a dense, and that there was a lot to absorb, but that it could be very challenging to create shared understanding;

Very difficult is creating trust and cooperation since the culture of the two communities is very different.

Others however felt that nine out of the core guiding principles should ideally be difficult to achieve. That it was more a question of political will in general, and the political will to address the social injustices that arguably make sex workers such a particularly appealing population for biomedical HIV prevention research.

None of them should be difficult—they just require an understanding on behalf of the researchers that sex workers have the right to be treated as thinking individuals who are more than just their work.

Final Thoughts

Given the opportunity to provide final thoughts, respondents, after having spent a great deal of time answering some very challenging questions, were generous in providing some summary of their experiences, knowledge, and beliefs about good practice for sex workers' participation in biomedical HIV prevention trials.

I feel a bit confused by the principles. They seem to be written from a viewpoint that communities are as keen to work with researchers as they are keen to work with us. This is not true for my community. We don't want to put energy into training them, building bridges or developing their ability to do research on us. We would rather use our energy and resources to train sex workers, build bridges in the sex worker community and develop our own abilities.

I'm worried that it will go into a nice report and never be acted upon.

It is very important to educate transgender people and providers in all the progress, sex education transgender oriented.

The principles must guarantee the inclusion of the communities sharing in these realities and in the access to care, prevention of HIV/AIDS. They must guarantee that the results don't make the population invisible and that we are actors in the results, sharing personal commitments with our health and that of our friends/co-workers.

They are important, we have to maintain them.

They seem designed by researchers to feel better about themselves.

I have not been thinking about this issue before so much.

I think you need to first do a study about the working lives of sex workers and understand how we work and then you would be able to see what is required based on the risk that is present in our daily lives.

That the whole time, since the beginning, the communities, while they feel more involved in this same research, we will face the same challenges with courage and that the needs will also be a part of the response, before HIV/AIDS. 'because we are not the problem.... we are part of the solution.'

Since the 1990's many sex workers here have participated in HIV prevention research. They participate

not for themselves but to help society and many of them have since died. If individual benefits are seen as coercive then at least there should be a community benefit offered. Shared responsibility equal to shared benefit.

We are part of the solution! Work with us!

Sometimes the only ethical way to do research is not to do it.

Be compassionate.

Working united together and committed.

Next Steps

Reports should be translated into African French, Latin American Spanish, and Brazilian Portuguese for distribution among participating networks. As with the translation of the survey, we would need funding for translation or support from AVAC for the translation.

Distribution of the report online and in person in the locations where two focus groups were held. This will incur printing costs in Spanish and English for the focus group participants.

We would be very interested in coordinating efforts to reach out to sex workers for future efforts to carry this forward at a larger institutional level.

Reflections on Implementation

Transgender sex workers participated enthusiastically. A number of transgender participants commented that there is very little research done on transgender people, and that the community could benefit from more. This is insightful, especially considering that many transgender people actively seek medical services that are difficult to obtain in many places, travel to do so, and may use the services of less well-trained practitioners. Transgender people might benefit from research that could lead to new hormone therapies and even perhaps surgical innovations. There was a clear and sometimes multilayered overlap between the needs of transgenders in their daily lives and their thoughts, attitudes and beliefs about biomedical HIV prevention trials. Future research may want to address this group specifically in order to better understand this important and unique population.

1. Modifications

One team member with extensive contacts among transgender networks in Latin America and among Spanish-speaking sex workers suggested two in-person focus groups. One was held in Boston during a Spanish and English language meeting for transgender people. The other was held in Santo Domingo, in the Dominican Republic.

In the context of these focus groups, the surveys were completed in person, sometimes by our team member and sometimes by the interviewee. This was not how the surveys were designed to be implemented. Had we

expected this level of commitment to completing the surveys, we would have prepared the surveys with this in mind.

2. Key Challenges

Time was a constraint—we understand that others were able to deliver their reports sooner. However, we believe that we could have done more in more languages with more time.

Stakeholders did not read the original guidelines, and we knew not to expect them to. AVAC and UNAIDS should not expect stakeholders to read the GPP guidelines, but instead insist that researchers act ethically and sensitively according to the standards of the populations they seek to recruit.

Funding was a constraint—we used new media to communicate with stakeholders because the budget was not enough to permit on-site discussions with people who had been approached by or participated in trials.

Participation was restricted by the budget – we could not compensate participants who completed the survey. The lack of a compensation component within this research project was something indentified by a number of participants. Therefore, any responses, completed or otherwise, were of great value. Future research would want to consider how to compensate respondents while protecting anonymity.

3. Proposed Revisions

We would insist more strongly that the GPP guidelines be made more comprehensible for readers of low literacy levels. Many sex workers, especially those from the developing world, were challenged by the level of the language. This is similar to what researchers need to do: explaining complex issues in simple language.

Future consultation should incorporate regional capacity building with regional focus groups. For those whose reading, writing, computer and research literacy was sufficiently high, the online survey worked well. It also provided a wide geographical base; however, it is clear that levels of reading, writing, computer and research literacy acted to exclude many potential respondents.

Timing should not have been concurrent with major catholic holidays and festivals. Portuguese translation was suggested to us, but it would appear we did not receive responses in this language in part because the timeframe fell between Christmas and Epiphany, and then in the preparations for carnival and lent. Spanish-language participation was made possible only with great efforts made by our team to reach out to Spanish-speaking sex workers.

Section IV. Appendix

Questionnaire

Good Practice for Sex Workers' Participation in Biomedical HIV Prevention Trials

SWGPP

Final Questionnaire

November 1, 2008

INTRODUCTION

This is a survey for sex workers.

These questions ask sex workers about good participatory practices for sex worker involvement in biomedical HIV prevention research trials.

Examples of biomedical HIV prevention research trials are studies which use people to test microbicides, circumcision, or vaccines—or trials where people take drugs to try to prevent HIV infection or transmission.

If you consider yourself a sex worker, these questions are for you.

All information provided by you is anonymous and confidential.

This survey is being conducted by Melissa Ditmore and Dan Allman with support from the Sex Workers Project at the Urban Justice Center, the AIDS Vaccine Advocacy Coalition (AVAC) and the University of Toronto.

This survey does not collect any information about your computer's IP address.

TO BEGIN

1. Have you ever been involved as a participant or a community advisor participating in a biomedical HIV prevention trial?

- Yes
- No
- Don't know

2. If yes, how did you feel about your experience?

3. In which country or countries do you primarily live?

4. As someone who identifies as a sex worker, are you familiar with ethical guidance documents such as the Declaration of Helsinki which guide how research using human participants should be conducted?

- Yes
- No
- Don't know

5. What other ethical guidelines have you heard about for research which involves human participants?

ABOUT GPP

Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials (GPP) is a document that was written by a diverse group of people from around the world, including community advocates, research staff and NGO representatives. The group was brought together by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the AIDS Vaccine Advocacy Coalition (AVAC). The draft version of the guidelines was then revised after more discussions with a wider range of stakeholders.

Good Participatory Practice Guidelines (GPP) is suggested to have ten fundamental principles:

- Scientific and ethical integrity
- Respect
- Clarity in roles and responsibilities
- Towards shared responsibility
- Participatory management
- Autonomy
- More transparency
- Standard of prevention
- Access to care
- Building research literacy

TEN FUNDAMENTAL PRINCIPLES

The authors of the GPP guidelines state that GPP was developed as a way to give researchers and communities—including sex work communities—a common language for discussing activities related to HIV prevention research. The guidelines are intended to help researchers and communities work together on HIV prevention research in a collaborative way.

The document proposes ten principles that are seen as essential to every aspect of collaborations between researchers and communities. Other sections of the document look at specific aspects of trial planning, conduct and closure.

These ten principles are seen to be fundamental, but they are also aspirational.

Aspirational means that they represent goals to strive for, but which may not be fully attained in every setting, every time.

PRINCIPLES

i) The principle of scientific and ethical integrity

This principle emphasizes the importance of conducting trials that are well-designed and which ask scientifically valid questions and meet universal criteria of ethics and social justice. It is about the balance between the needs of research and the needs of a trial community.

6. What are ways to protect integrity within a biomedical HIV prevention trial involving sex workers?

7. How can researchers and sex workers within trials prevent ethics and integrity from becoming compromised?

ii) The principle of respect

This principle speaks to the fundamental need for all stakeholders involved in research to speak and act in ways that value and honour each other’s perspectives and realities. Respect can mean different things in different cultures and contexts.

8. How can sex work communities and research teams develop common definitions of respect?

9. What are concrete ways to develop and build this genuine respect between sex workers and researchers?

iii) The principle of clear roles

This principle reflects the importance for all stakeholders in biomedical HIV prevention trials to discuss their expectations and negotiate the diverse roles and responsibilities that each stakeholder group will take on before, during and after a research study.

10. How can researchers best understand sex workers' expectations of a biomedical HIV prevention trial?

11. What can prevent sex workers from communicating their expectations within biomedical HIV prevention trials?

iv) The principle of shared responsibility

This principle suggests that communities and researchers should be jointly involved in and accountable for the conduct of a research study.

12. What are some of the ways that sex workers can and should be responsible for the research process?

13. What are some of the challenges that sex workers and researchers might experience when trying to truly share responsibility for a biomedical HIV prevention trial?

v) *The principle of participatory management*

This principle suggests that communities be actively involved in trial-related decisions throughout the duration of the study—including helping to make decisions and guide actions and responses to unanticipated situations.

14. In terms of capacity building, knowledge development or financial resources, what would you or your community group require to realistically become involved in participatory management of HIV research trials?

15. What are the barriers sex workers and researchers might experience within a participatory management context?

vi) The principle of autonomy

Definitions of the word autonomy include independence, self-sufficiency, or self-rule. The goal at the heart of this principle is that community bodies and individuals are assured an independent voice in the research process—and that this voice is heard and respected by clinical trial teams.

16. How can researchers give sex workers and sex work communities independent and autonomous voices in a biomedical HIV prevention research trials?

17. How can researchers working with sex workers in biomedical prevention trials respect and act on suggestions from community members?

vii) The principle of transparency

This principle stresses the need for open and timely communication among the trial sponsors, trial site staff, and communities.

18. What are some of the important pieces of information sex work communities need to know about a specific research study when choosing to become involved in biomedical HIV prevention research?

19. What suggestions do you have for dealing with local conditions such as distance, lack of telephone or electricity, to try to make it easier for researchers to communicate with sex worker communities?

viii) The principle of a standard of prevention

This principle explains that research trials must ensure access to a high quality package of HIV prevention services for trial participants. In trials designed to reduce the risk of sexual transmission of HIV, this includes HIV testing and risk reduction counselling, provision of male and female condoms, and screening and treatment for sexually transmitted infections (STIs).

20. What prevention services do you think should be included in any HIV prevention trial?

21. What challenges might there be to providing a package of prevention services to sex workers?

ix) The principle of access to care

This principle underscores the guidance from the Declaration of Helsinki and other ethical guidance documents that participants have the right to access medical care for trial-related injuries. It also stresses that, for HIV prevention trials, the standard of care for HIV treatment, including eventual antiretroviral treatment in participants who seroconvert, has to be discussed and fully endorsed by communities before the trial starts.

22. What are some of the health care and treatment needs and priorities in your community?

23. What are concerns with trial-related health care and treatment access in your community?

x) The principle of building research literacy

This principle describes the need for trial sponsors to invest in and provide overall education and outreach that builds community-wide understanding of how research happens outside the context of a specific trial.

24. What kind of activities could researchers do to help your community understand more about how HIV prevention research happens in general?

25. What do you think are the challenges or barriers to building research understanding and literacy in your community?

SUMMARY QUESTIONS

Thinking about the core guiding principles discussed here:

- Scientific and ethical integrity
- Respect
- Clarity in roles and responsibilities
- Towards shared responsibility
- Participatory management
- Autonomy
- More transparency
- Standard of prevention
- Access to care
- Building research literacy

26. Which of these core guiding principles do you think are most important to sex workers? Why?

27. Which of these guiding principles do you think may be most difficult to achieve in research with sex workers? Why?

28. Can you summarise in 100 words your opinion about the principles of Good Participatory Practice discussed here?

29. Can you think of any principle or principles that might be missing and that would be important for sex workers considering to become involved in a biomedical HIV Prevention trial?

CASE STUDY

Please read the following case study

Unresolved Community Concerns during Protocol Development/Pre-Study Activities

In 2004, a trial of pre-exposure prophylaxis or PrEP (which involved testing the possibility of taking a pill a day to see if HIV transmission could be prevented) was scheduled to enroll sex workers in Cambodia. At the time, Cambodia was a country that did not have a national ARV program that made the drugs available. Also, at the time US government restrictions around funding commercial sex workers (CSWs) had recently been put into place, causing US funds for CSWs and their organizations to be withdrawn from Cambodia. During that time, the trial team undertook a range of outreach activities to explain the protocol and its goals to various groups representing CSWs. Some of the concerns raised by these groups included the standard of prevention that would be given to volunteers, and the provisions that would be made to ensure access to care and ARV treatment, should participants become HIV-positive during the trial. Some CSW groups did not feel that their concerns were addressed well enough by the trial team. International supporters in civil society also joined in voicing concerns and in raising additional suggestions that the trial was setting out to deliberately encourage participants to take risks and get infected. The concern and controversy increased, with direct action against the industry partner in the trial at the 2004 International AIDS Conference. The Cambodian government ultimately announced that

Now, thinking of the core principles

- Scientific and ethical integrity
- Respect
- Clarity in roles and responsibilities
- Towards shared responsibility
- Participatory management
- Autonomy
- More transparency
- Standard of prevention
- Access to care
- Building research literacy

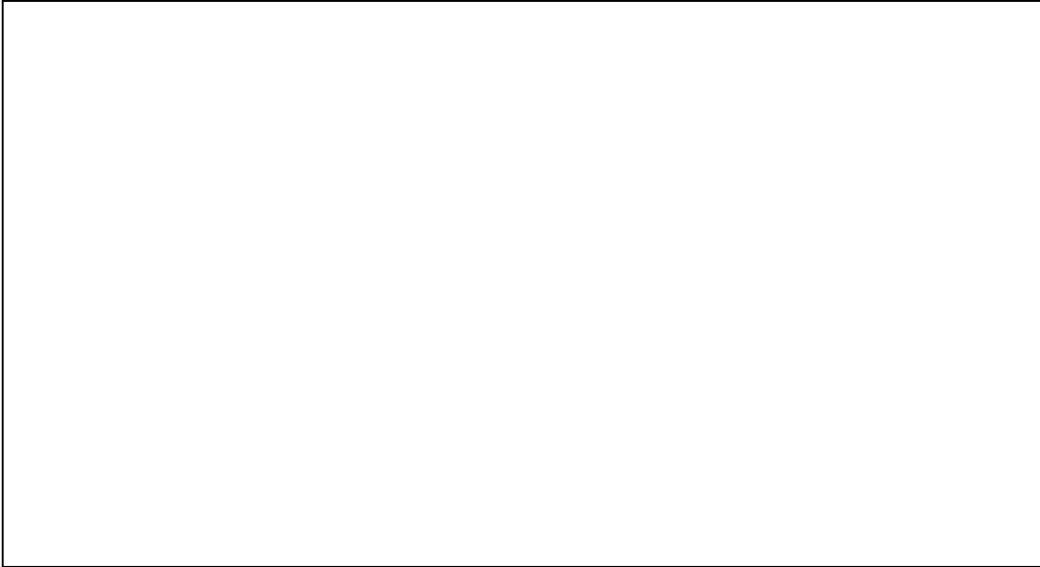
30. Which principles of Good Participatory Practice do you think are at work in this case study?

31. What would you suggest are the lessons to be learned from this case study, both in terms of positive and negative outcomes?

32. How might similar positive outcomes be facilitated and how might some of the negative outcomes be prevented?

ANYTHING TO ADD

33. Is there anything else you would like to say about how HIV prevention research should be conducted with respect to working with sex worker communities?



For more information visit the project wiki

<http://swgpp.pbwiki.com>

also you can email Melissa

mhd-gpp at taumail dot com

and Dan

dan dot allman at utoronto dot ca

THANK YOU