'Who is Helsinki?' Sex workers advise improving communication for good participatory practice in clinical trials

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Received on March 16, 2010; accepted on December 11, 2010

Abstract

After premature closures in 2004 of biomedical human immunodeficiency virus (HIV) prevention trials involving sex workers in Africa and Asia, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and Global Advocacy for HIV Prevention (AVAC) undertook consultations to establish better participatory guidelines for such trials in order to address ethical concerns. This study investigated sex workers' knowledge and beliefs about research ethics and good participatory practices (GPP) and the perspectives of sex workers on research participation. A 33-question survey based on criteria identified by UNAIDS and AVAC was translated into three other languages. Participants were recruited through mailing lists and contacts with existing sex work networks. In total, 74 responses from Europe, the Americas and Asia were received. Thirty percent of respondents reported first-hand involvement in biomedical HIV prevention trials. Seventy percent indicated a lack of familiarity with codes of ethics for research. This paper focuses exclusively on communication issues described in survey responses. Communication was an important theme: the absence of clear communication between trial participants and investigators contributed to premature trial closures in at least two sites. Sex workers had recommendations for how researchers might implement GPP through improved communication, including consultation at the outset of planning, explaining procedures in non-technical terms and establishing clear channels for feedback from participants.

Background

The closures of biomedical human immunodeficiency virus (HIV) prevention trials involving sex workers in Cameroon [1] and Cambodia [2] in 2004 were unprecedented: no previous trials had been halted due to community and participant protest. The closures indicated that current procedures to protect research participants such as human subjects review boards and 20th century codes for research ethics such as the Declaration of Helsinki [3] may not be adequate [4]. However, subsequent analysis of the trial closures emphasized a dominant perception among researchers that sex workers were against research [5, 6] rather than addressing the legitimate ethical concerns expressed by sex workers [7]. This changing context framed the authors' consultation with sex workers from different parts of the world about what they believe is necessary for genuine participatory practice.

In the years following the closure of the abovementioned trials, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and Global

doi:10.1093/her/cyq087

Advocacy for HIV Prevention (AVAC) initiated the development of a set of guidelines for good participatory practice (GPP) in biomedical HIV prevention trials [8, 9]. While these guidelines have and continue to evolve from a series of principles to a set of standards in line with standards for good clinical practice, in their early incarnation these guidelines articulated 10 primary principles for successful participatory practice within trials: scientific and ethical integrity, respect, clear roles, shared responsibility, participatory management, autonomy, transparency, a standard of prevention, access to care and building research literacy. These principles do not all directly address communication but communication is critical to the implementation of most. Indeed, researchers who utilized similar methods and who paid due diligence to effective communication enjoyed successful recruitment and retention of participants [10–12]. Researchers who have collaborated with community-based organizations have documented that such collaborations contributed to greater research participation by minorities [13], in part due to direct communication with community members. Following the release of the first draft of the GPP document, AVAC commissioned consultations with trial sites and potential trial participants in order to ascertain reactions to GPP principles within applied settings. This paper is the product of one such consultation. The purposes of this paper are to explore the role of communication within clinical trial contexts that involve sex workers, and to help researchers understand how to build better mechanisms for communication within the design and conduct of clinical trials.

Purpose

This paper focuses exclusively on communication issues, including consultation, translation, research literacy, respect and addressing feedback from participants. Breakdown in communications between trial participants and clinical trial sites is not uncommon, particularly when involving marginalized populations [14–16]. The absence of clear communication between trial participants and trial investigators contributed to premature trial closures in at least two sites [1, 2]. In such trial contexts where project communications falter, trial staff including recruiters, interviewers, screeners, site managers and medical technicians can be put in the position of mediating between participants and researchers. The community advisory boards (CABs) of these trials comprise community members and researchers with the intention of presenting the concerns of community members to trials in a structured way. In some cases, due to a lack of research literacy, some CABs can struggle to translate research to community members and community concerns to researchers [1, 2, 16]. The challenges of community engagement and participation in clinical trials and HIV prevention research are well documented [17–20]. Such challenges to good communication can lead to lapses in GPP and even in some case to lapses in ethical trial conduct.

Methods

A 33-question survey focusing on concepts in the UNAIDS/AVAC document around GPP for biomedical HIV prevention research was developed in English and translated into French, Portuguese and Spanish [8]. The survey included open-ended and closed questions addressing experiences with research participation, knowledge of research ethics and what would be necessary conditions for GPP with sex workers in biomedical HIV prevention research. No incentives were offered to respondents. Participants were recruited from mailing lists and existing sex worker networks. Contacts within African and Latin American and Caribbean networks were contracted to reach out to and coordinate responses from sex workers, including Spanish and francophone sex worker organizations and projects. Participants were able to respond to the survey online or with pen and paper. Demographic information collected was limited to region of response in order to demonstrate and maintain commitment to anonymity. This project was undertaken as a consultation about biomedical HIV prevention research, and as a consultation, IRB review was not undertaken.

The collection of demographic information was limited due to the absence of an IRB review.

To analyze, online and paper survey responses were collated into a Microsoft® Excel spreadsheet. This enabled data to be transferred to other programs for qualitative analysis, and also permitted manual examination of the data as a whole [21, 22].

The responses were analyzed to identify recurring themes. A 'grounded theoretical analysis' approach [23] was used in which macro level principles and concepts related to GPP were linked to micro-level examples provided by respondents [23]. This was accomplished by identifying within the data micro-level recurring themes. The main themes are reflected in the findings below. Some macro-level themes in the survey were based upon the UNAIDS/AVAC Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials [8] such as research integrity. Where required, typographical errors within responses have been corrected for ease of reading.

Results

Seventy-four responses were received, of which 51.4% were fully complete. All applicable responses were included in our analysis, despite missing data. Responses were received from the online survey (n = 66, 89.2%) and on paper (n = 8, 10.8%).

Respondents were asked to indicate their place of primary residence. More than half (39; 57.4%) were from North America, 17.6% (n = 12) Europe, 14.7% (n = 10) Latin America and 10.3% (n = 7) the Asia Pacific region. Despite efforts, no participants indicated Africa as their primary residence.

Nearly one-third of respondents (30.6%, n = 22) indicated that they had ever been involved as a participant or a community advisor with a biomedical HIV prevention trial. An additional seven (9.7%) were unsure. Respondents were asked whether they were familiar with ethical guidance documents such as the Declaration of Helsinki [3] that 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. Participants were asked about other ethical guidelines they might have known about. Seventy percent (n = 52) indicated a general lack of familiarity with codes for research ethics. This was of particular note because throughout the development of the original GPP document, an assumption was that trial participants and CAB members would be familiar with ethical standards. Answers revealed that the very notion of ethics and ethical guidelines was not well understood. For example of the Helsinki declaration, one respondent asked: 'Who is Helsinki?' This highlights the potential variability in the need for capacity building for community representatives within CABs and the pool of potential research participants, and by extension, a need to further invest in capacity building around these issues throughout the duration of trial. Yet, despite the lack of knowledge about formal ethical standards, many responses reflected an intuitive understanding of these standards.

Responses described contextual factors that prevent sex workers from fully understanding ethical guidance documents and their application within biomedical HIV prevention trials. Some responses referred to scientific literacy and the need for information to be translated not only into local languages but also in simplified ways that would avoid 'clinical language'. Responses included 'Researchers only understand a language of scientific jargon that we don't speak', and 'Translation into local languages, including laypersons' vernacular … is critical', as well as 'The majority of us don't know how to read and write very little. Using simple language would be better'.

In places where multiple languages are spoken, communication may require multiple translations. One response suggested that because of local diversities 'We need everything translated into a minimum of five languages (some written, some oral)'. Another said:

> 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.

Responses reinforced the understanding that language is fundamental to communication, beyond translation. Potential participants preferred locally spoken languages to less familiar languages, and expressed the preference that researchers ensure that the terms, concepts and words used are appropriate to their audience, many of whom may have low levels of education. Communication requires mutually understandable vocabulary and therefore entails researchers working to find the words that are meaningful to potential participants, while still allowing them to communicate with precision.

Consulting sex workers from the inception of a project

Respondents recommended including sex workers at all steps from the conception and design of the study onward, saying, 'Sex workers need to be involved in the design and implementation of the research at every level and at every step of the way' and 'Consult with sex workers in the trial location'. Another respondent said:

> 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, how 'best practice' will be defined, etc.

Some sex workers expressed a desire to be able to vet researchers coming to their communities, based on criteria such as researchers' understanding of the issues sex workers face and their ability to communicate in plain language:

> Researchers should be legally obliged to contact sex worker organizations in the trial country and learn how to communicate with sex workers properly.

The responses demonstrated that sex workers are not indifferent or hostile to all research. However, the responses indicated that sex workers expected to be treated respectfully, and to have their rights to self-protection recognized. Suggested means to show respect included involving sex workers in planning, explaining the trial to them in language that they can understand and to properly compensate them for their time.

Ethical integrity

Confronting ethical problems in research was a persistent theme: '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'.

Some responses expressed skepticism about the ways current measures for inclusion were implemented and described the costs to sex workers and their communities for participating in studies without any concrete benefit and sometimes with risk to community organizations and community members:

> 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.

This response that sex workers enroll in trials 'because they trust their community leaders' emphasizes the importance of local sex worker organizations. If the leaders of a community endorse a trial, participation may be high. However, if the trial then generates concerns and worries in participants, this can adversely affect the community. Sex workers involved in a trial whether as potential participants or promoters have a strong incentive to seek information about the research, in order to evaluate the potential risks of participation for themselves and their community.

A few responses referred to the need for independent sources of information, in order to properly evaluate the ethical considerations and the

merits of individual protocols: 'Realistically we would need access to independent scientific advisors able to communicate with sex workers' and 'We also need access to independent scientific advice/analysis'.

The following response recommends capacity building in the form of education about trials, which would enable sex workers to judge whether participating could be risky or beneficial for them:

> They could provide cash for communities to find and hire our own independent consultants to train our community in what we should look for in a trial; what questions we should ask; what should ring alarm bells; what are our local and international rights.

Within clinical trial contexts, ethical reviews tend currently to be conducted by universities or other professional institutions with limited input from the communities from which potential research participants may be drawn. A particularly inspired response advocated for the creation of ethical review boards that prioritize the interests of marginalized communities such as sex workers:

> 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.

Some of the responses quoted above refer to resources and capacity building. Other responses were more direct when asked 'What would you or your community group require to realistically become involved in participatory management of HIV research trials?' One said 'I believe that we need to understand the process better; to understand the study better and in that way we would be able to commit ourselves a little more'. Others said:

> Researchers should consult with and listen to sex workers, make partnerships with sex workers! This means paying sex workers for their time and … mentoring them - that's capacity and literacy building.
>
> I think that if sex worker communities were given the resources they would be able to take responsibility … .They can use their networks to link in other sex workers and make sure all participants are well informed.

The desire for independent information—a second opinion—reflects the recognition that researchers often have research interests, which may not align with sex workers' interests. Openness about the differences in the goals and interests of sex workers and researchers, clearly communicated between researchers and possible research participants, would clarify why specific things are important to researchers and sex workers.

Communication

Consultation between clinical trial investigators and their research populations relies upon communication and the responses collected within this project reflected this. Many responses emphasized the importance of communication between trial participants and researchers. Stigma and discrimination associated with sex work were described as obstacles to the clear communication needed for participatory research methods:

> 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 have their own priorities and bring their own preconceptions including stigmatization of sex workers.

Sex workers perceive stigma from researchers in cases where they do not feel credited for their contributions to a study:

> 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.

Some responses referred to the fear of stigma and discrimination as preventing sex workers on research teams from disclosing their own experience in the sex industry to their research colleagues. For example, one respondent suggested that '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', while another respondent felt it was important to 'Create the scientific social atmosphere so that researchers do not fear to out themselves as sex workers or former sex workers'.

Communication channels and procedures to address grievances and complaints were emphasized. Respondents said 'We then need a safe clear effective channel of complaints when the practice does not live up to the theory' and

> The best prevention is if we know everything about the trial and what we should expect ethically. Then we need a safe, clear, effective line channel of complaint when the theory doesn't match the reality.

Repeated references to formal communication procedures for complaints and responses to them suggest that sex workers worry that their input will be disregarded, particularly regarding grievances.

Core guiding principles

When asked which aspects of the core guiding principles described in the UNAIDS/AVAC guidelines should be prioritized [8], sex workers emphasized the importance of building research literacy and respect. At the same time, most respondents suggested prioritizing a number of these principles because, in the words of one participant, 'They are all important. You can't isolate one over the others because *together* they make good research'.

Respect as an additional core principle was interpreted by many as the opposite of the stigma and discrimination experienced by sex workers, as emphasized above. Respect was also predicted to be one of the most difficult of the 10 principles to implement. One participant said 'Respect requires ongoing education and awareness by the researchers of their own privilege, and power, as well as societal oppressions at work'.

Respondents also acknowledged the investment required to increase capacity and research literacy among sex workers, saying, 'Capacity building is time consuming, and it is the same with research literacy'. However, the responses received demonstrated the value of increasing research literacy among sex workers and desire and willingness to do so.

Limitations

A major strength of this study was the articulate and well-informed responses based on respondents' experiences. However, an online survey can only be completed by those with internet access, and a paper survey can only be completed by those who are literate. These factors can lead to sampling bias. It is not possible to know whether or to whom the recruitment announcements were forwarded, or which recipients declined to answer the survey fully, and why. Given the nature of the consultation and the information being collected, little demographic data were collected, and even less has been reported. This is a necessary limitation. While it would be useful to further investigate the type and content of responses by region, country and gender of respondent, for example, our consent process with potential respondents included the proviso that such depth of analysis would not be undertaken.

Conclusions

As described above, the recommendations from sex workers for GPP focused primarily on communication issues. However, improved communication is only one of a number of prerequisites for GPP, which requires a multi-layered effort addressing

a range of different issues. Among the other issues raised by participants in this consultation were the need to improve research literacy, the need to further involve sex workers from the inception of a trial, the need for a sex-worker-owned ethics and scientific body and the need for contributions to infrastructure to support communication. We believe that addressing these issues is necessary to promote more ethical and better-quality research. However, addressing these issues alone would not be sufficient, and would benefit from attention to improving social and structural conditions for sex workers also. Wolfe [24] points to the need for structural and social changes in the approach to other marginalized groups in order for specific treatments not only to be effective but also to be offered at all. This is not unlike the changes in research culture and the social contexts in which research is conducted, required in order to promote equitable participation in research by sex workers.

Often the institutional contexts within which biomedical HIV prevention research operate, do so under their own series of inhibitors, such as deterministic contexts which act as a backbone for the research enterprise and which by extension may structure sex workers' abilities and experiences of the research. These include biomedical and ethical norms and regulations regarding research, the institutional cultures promoting both timely completion of studies and publication of results, the requisites required by funders and donors that enforce the degree of activity within a given trial that can be dedicated to capacity building and forms of communication and the strong social, humanist and capital forces which seek to develop efficacious commodities able to slow, if not arrest or reverse, global rates of HIV infection and transmission [25]. Improving communication between research communities and sex workers may allow some of the barriers to better participatory practices identified by this study's sample to be addressed; yet, the success of such enabling mechanisms will require the attention of donors, funders and community leaders to the kinds of communication and capacity-building activities allowed within clinical trials, as well as the normative value and benefit ascribed to such activities throughout the conduct of these trials.

Participants in this consultation were clear that despite previous problems they had experienced or had heard about in clinical trials, most saw ways forward and expressed interest in research. Their responses offered insight and guidance for clinical research involving sex workers based on experience and hopes for future participatory practice in research. Additionally, respondents offered pragmatic ideas for ethical review within communities.

While one-third of respondents had participated in clinical research, more than half of all respondents were unfamiliar with ethical standards for research such as the Helsinki Declaration [3]. Some respondents were very descriptive in reflecting on contextual factors that prevent sex workers from fully understanding ethical guidance documents and their application within biomedical HIV prevention trials, such as jargon and lack of translation.

Responses to this survey demonstrated the wish on the part of respondents to better understand research ethics and procedures. Increasing the research literacy of people who may be recruited as clinical trial participants is important. This research suggests this can be achieved through a greater emphasis on communicating research ethics and other trial particulars in the vernacular with which potential participants are familiar. This would resonate with the findings of others who have explored the roles of participation and research ethics in the context of sex worker's involvement in research [26, 27]

The general lack of familiarity with research ethics guidelines demonstrates the importance of increasing the research literacy of sex workers who might be recruited for clinical trials. Explaining ethical guidelines and trial procedures in plain, intelligible language is an indispensable first step in expanding research literacy among sex workers at possible trial sites. Elsewhere, informed consent forms have been found to require a reading and comprehension level above that of most individuals in the United States [28]. The lack of comprehension of consent forms may be compounded in contexts in which education rates may be lower [29].

As with other communication challenges described here, the promotion of truly informed consent within a clinical trial context requires special attention to clear communication [30].

Trial design that incorporates additional emphasis on communications between trial staff and trial participants may require a multistep process. Although consultation with targeted populations at the trial design stage may require additional ethical review processes, information learned about local context at potential trial sites could prove invaluable for trial design. Superior knowledge of local contexts may illuminate particular risk factors or inspire innovations in recruitment methods. Formative research that has led to culturally appropriate changes in trial implementation and communication have had positive effects in a wide variety of geographical and cultural contexts [10, 31–34]. It is suggested that such efforts may also contribute to retention rates during trials [13, 29, 34].

In many contexts, the use of plain language and translation into local languages are initial steps. However, communication in consultation also requires listening to concerns and answering questions. Questions may arise as part of capacity building, consultation or at any stage of the research. Some questions may reveal important concerns. Researchers may need to clarify, for example, how people who experience long-term side effects or who experience harm within a clinical trial context will be treated within the study and/or following the study's completion.

Genuine conversation and consultation require potential participants to be confident and comfortable enough to speak freely. Good communication practices between sex workers and researchers can be fostered in a milieu in which the challenges of stigma are recognized and addressed. Combating stigma is particularly important because adverse interactions, conflict or discomfort may be wrongly perceived as or attributed to stigma and discrimination even when such interactions are not rooted in stigma.

Within this study, the need for two-way communication and formal procedures for acknowledging and working with the concerns of and complaints from sex workers were emphasized. It was suggested that such procedures should ensure that problems and concerns of sex workers regarding participation in clinical trials could be addressed to the satisfaction of all concerned, through the application of methods, techniques and efforts that demonstrate researchers' respect for these concerns.

In situations where communication requires resources that trial participants or people consulted may not have, it may be necessary to contribute to communication costs or infrastructure. This may mean, for example, transportation costs, telephone costs, costs incurred with the use of SMS text messages or access to electronic messages.

Implementing GPP is resource-intensive and requires not only funding but also human resources in the form of staff, including staff dedicated to communication with community members [32]. Because staff are typically the first point of contact and main conduit of information between trial sites and participants, facilitating successful communication between staff and trial participants should be primary.

In sum, the implementation of sex workers' recommendations will require some investment of resources, for:

- Consultations with sex workers including investigations into local situations that will contribute to the design of a trial,
- Translation and capacity building for sex workers and
- Specific personnel who will carry out these responsibilities.

Opportunities for future research include investigating whether GPP, including formal channels of communication for problem solving, can contribute to more successful trials through increased retention, how community-based organizations can make their involvement more effective in the dissemination of study results and information [35], and what variation may exist in sex workers' own perceptions of participation with clinical trials by country, gender, and knowledge and experience of trial structures and outcomes.

Funding

AVAC: Global Advocacy for HIV Prevention to D.A.; Public Health Solutions, the National Development and Research Institutes, Inc. and the National Institute on Drug Abuse (T32 DA07233) to M.H.D.; AIDS Bureau, Ontario Ministry of Health and Long-Term Care, and the Faculty of Medicine, University of Toronto to HIV Social, Behavioural and Epidemiological Studies Unit. Funding for open access charge: The CIHR Social Research Centre in HIV Prevention.

Conflict of interest statement

None declared.

References

1 Forbes A, Mudaliar S. *Preventing Prevention Trial Failures: A Case Study and Lessons for Future from the 2004 Tenofovir Trial in Cambodia*. Washington, DC: Global Campaign for Microbicides at PATH, 2009. Available at: www.global-campaign.org/clientfiles/Cambodia.pdf. Accessed: 8 January 2011.

2 McGrory E, Irvin A, Hiese L. *Research Rashomon: Lessons from the Cameroon Pre Exposure Prophylaxis Trial Site*. Washington, DC: Global Campaign for Microbicides at PATH, 2009. Available at: www.global-campaign.org/clientfiles/Cameroon.pdf. Accessed: 8 January 2011.

3 World Medical Association. *Code of Ethics of the (Declaration of Helsinki) for Experiments Involving Humans*. 1964. Available at: http://ohsr.od.nih.gov/guidelines/Helsinki.html. Accessed: 8 January 2011.

4 Mills EJ, Singh S, Singh JA *et al*. Designing research in vulnerable populations: lessons from HIV prevention trials that stopped early. *Br Med J* 2005; **331**: 1403–6. Available at: http://www.bmj.com/cgi/content/extract/331/7529/1403. Accessed: 8 January 2011.

5 Mills E, Rachlis B, Wu Ping *et al*. Media reporting of tenofovir trials in Cambodia and Cameroon.*BMC Int Health Hum Rights* 2005; **5**: 6. Available at: http://www.biomedcentral.com/1472-698X/5/6. Accessed: 8 January 2011.

6 Singh JA, Mills EJ. The abandoned trials of pre-exposure prophylaxis for HIV: what went wrong? *PLoS Med* 2005; **2**: e234. Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0020234. Accessed: 8 January 2011.

7 Loff B, Jenkins C, Ditmore M *et al*. Unethical clinical trials in Thailand: a community response. *The Lancet* 2005; **6**: 1618–9.

8 UNAIDS/AVAC. *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials, 1st edn*. 2007. Available at: http://data.unaids.org/pub/manual/2007/jc1364_good_participatory_guidelines_en.pdf. Accessed: 8 January 2011.

9 UNAIDS/AVAC. *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials, 2nd edn*. draft version for public comment. Available at: http://www.avac.org/ht/a/GetDocumentAction/i/28488. Accessed: 8 January 2011.

10 Jenkins C. *Violence and Exposure to HIV among Sex Workers in Phnom Penh. Cambodia*. Washington, DC: USAID, 2006.

11 Jenkins C, na Ayuthaya P, Hunter A. *Kathoey in Thailand: HIV/AIDS and Life Opportunities*. Washington, DC: USAID, 2005. Available at: http://www.soros.org/initiatives/health/focus/sharp/articles_publications/publications/compendium_20070319/health_methodologies/katoey_20070402.pdf. Accessed: 8 January 2011.

12 Gutierrez Luna A, Angeles Llerenes A, Wirtz VJ *et al*. Strategies and ethical considerations for the recruitment of young men who have sex with men: challenges of a vaccination trial in Mexico. *Clin Trials* 2009; **6**: 365–72.

13 Kogan JN, Dennehy EB, Miklowitz DJ *et al*. Increasing minority research participation through collaboration with community outpatient clinics: the STEP-BD Community Partners Experience. *Clin Trials* 2009; **6**: 344–54.

14. Robinson ET, Baron D, Heise LL *et al*. *Communications Handbook for Clinical Trials. Family Health International* Available at: http://www.fhi.org/en/RH/Pubs/booksReports/comm_handbook.htm. Accessed: 8 January 2011.

15. El-Sadr W, Capps L. The challenge of minority recruitment in clinical trials for AIDS. *J Am Med Assoc* 1992; **267**: 954–7.

16 AVAC Community Consultations on Good Participatory Practice Guidelines. *Partner Report-Back Meeting 30 April–2 May, 2009, Johannesburg. South Africa*. New York: AVAC, 2009.

17 Tindana PO, Singh JA, Tracy CS *et al*. Grand Challenges in Global Health: community Engagement in Research in Developing Countries.*PLoS Med* 2007; **4**: Available at: http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0040273. Accessed: 8 January 2011.

18 Bhan A, Singh JA, Upshur REG *et al*. Grand challenges in global health: engaging civil society organizations in biomedical research in developing countries.*PLoS Med* 2007; **4**: e272. Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040272. Accessed: 8 January 2011.

19 Allman D, Myers T, Cockerill R. *Concepts, Definitions and Models for Community-Based HIV Prevention Research in Canada*. Toronto, Ontario: HIV Social; Behavioural and Epidemiological Studies Unit, University of Toronto, 1997. Available at: http://www.cbrc.net/library/90-cbrclibraryresearchtools/195-concepts-definitions-and-models-for-community-based-hiv-prevention-research.html. Accessed: 8 January 2011.

20 Ellen JM, Wallace M, Sawe FK *et al*. Community engagement and investment in biomedical HIV prevention research for youth: rationale, challenges, and approaches. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2010; **54**: S7–11.

21 Swallow V, Newton J, Van Lottum C. How to manage and display qualitative data using 'Framework' and Microsoft Excel. *Journal of Clinical Nursing* 2003; **12**: 610–2.
22 Meyer DZ, Avery LA. Excel as a qualitative data analysis tool. *Field Method* 2009; **21**: 92–113.
23 Wasserman JA, Clair JM, Wilson KL. Problematics of grounded theory: innovations for developing an increasingly rigorous qualitative method. *Qual Res* 2009; **9**: 355–82.
24 Wolfe D. Paradoxes in antiretrovial treatment for injecting drug users: access, adherence and structural barriers in Asia and the former Soviet Union. *Int J Drug Policy* 2007; **18**: 246–54.
25 Folayan MO, Allman D. Clinical trials as an industry and an employer of labour. *J Cult Econ.* in press DOI: 10.1080/17530350.2011.535376.
26 Pyett P. Doing it together: sex workers and researchers. *Res Sex Work* 1998; **1**: 11–13.
27 Shaver F. Sex work research: methodological and ethical challenges. *J Interpers Violence* 2005; **20**: 296–319.
28 Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med* 2003; **348**: 721–6.
29 Bertoli AM, Strusberg I, Fierro GA *et al*. Lack of correlation between satisfaction and knowledge in clinical trials participants: a pilot study. *Contemp Clin Trials* 2007; **28**: 730–6.
30 Rucker-Whitaker C, Flynn KJ, Kravitz G *et al*. Understanding African-American participation in a behavioral intervention: results from focus groups. *Contemp Clin Trials* 2006; **27**: 274–86.
31 Corneli AL, Piwoz EG, Bentley ME *et al*. Involving communities in the design of clinical trial protocols: the BAN study in Lilongwe, Malawi. *Contemp Clin Trials* 2007; **28**: 59–67.
32 Paskett ED, Reeves KW, McLaughlin JM *et al*. Recruitment of minority and underserved populations in the United States: the centers for population health and health disparities experience. *Contemp Clin Trials* 2008; **29**: 847–61.
33 Thapinta D, Jenkins RA. Starting from scratch: program development and lessons learned from HIV vaccine trial counseling in Thailand. *Contemp Clin Trials* 2007; **28**: 409–22.
34 ven der Horst C, Chasela C, Ahmed Y *et al*. Modifications of a large HIV prevention clinical trial to fit changing realities: a case study of the breastfeeding, antiretroviral, and nutrition (BAN) protocol in Lilongwe, Malawi. *Contemp Clin Trials* 2009; **30**: 24–33.
35 Bartholomew LK, Cushman WC, Cutler JA *et al*. Getting clinical trial results into practice: design, implementation, and process evaluation of the ALLHAT Dissemination Project. *Clin Trials* 2009; **6**: 329–43.