

# **Implication for real life HIV Prevention Trials: community perspectives**

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# Outline

1. Background
2. Discuss some concepts
3. The possible challenges

# Background

The guidance point 13 of the WHO/UNAIDS ethics guidance document.

*Researchers should engage appropriate (key/main) stakeholders in tailoring [negotiating] the design, implementation and oversight of risk reduction interventions*

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Consultation should also include not only the package but also the design of its provision and the monitoring of the interventions. Enhancement of the risk reduction package is also possible and the mechanism needs to be addressed upfront in the protocol

# Background - 2

When new partially effective technologies evolve, its inclusion as components of a prevention package for new or ongoing prevention trials depends on **negotiation** with **appropriate stakeholders** within each trial **community**

# Community

Definition in Box 1 on page 17 of the GPP

*separate and overlapping group of people infected and affected by HIV in various ways. Could be delineated by geographical boundaries of the research site.*

Multiple layers of communities equally importance to an HIV prevention trial

Negotiation with communities is not all about preventing potential problems but also, because of the need to engage a level of expertise that helps improve the quality of the trial design

# Stakeholders

1. Communities including those representative of the trial participants
2. Regulatory agencies
3. Programme implementers
4. Health workers
5. Advocates
6. Media persons

While key stakeholders need to be involved in a negotiation process, interested parties should have an open invitation to participate in these consultative processes leading up to a negotiation.

# Negotiation

How feasible is this when the two parties do not have equal power to negotiate?

How knowledgeable are the communities on the science and ethics of these researches to be able to effectively negotiate for a prevention package content, the design of its provision and the monitoring of the intervention?

How legally binding would such negotiation be where a negotiator does not have all the needed information to make an independent informed decision?

# Three questions to address

1. What challenges could multi-site trials present when deciding the standard of prevention for the trial?
2. Implication of varying prevention packages across settings, or different sites in the same country
3. Implication of making new prevention tools available in a trial when not available elsewhere in the country?

# Challenges -1

Negotiation is key BUT how do you ensure negotiation is based on adequate information and understanding of the issues. How legally binding would a negotiation based on limited information and understanding be?

This can possibly be addressed by facilitating HIV Prevention research literacy within these 'designated' research communities (Eastern and Southern African countries, Thailand) and amongst potential research participants (sex workers, MSM, at high risk individuals)

# Challenges - 2

Negotiation of a prevention package should not be masked by the need to answer scientific questions. Science could always design new tools to answer its questions without compromise on ethical standards. Current statistical tools may be limited in answering the science question in the presence of multiple layers of prevention; the challenge should be to develop new statistical tools and not lower ethical standards

# Challenge - 3

Would the prevention package in a trial become too burdensome for trial participants? Not likely:

1. When the range of prevention options increases significantly, statistical analysis could help in identifying combinations that could provide optimal prevention for various prevention designs which may possibly be provided by trial sites leaving others as options for participants.
2. Trial participants do not need to use all the options made available though they need to be counseled on availability of all the tools
3. The pressures of the 'conflict of obligation' may put trials under pressure to facilitate use of multiple tools. Trial counseling should focus on mixed methods best suited for the individual

# Challenge - 4

The provision of a new prevention tool within a trial when not available within the community needs to be based on information. This likely would not pose a challenge for the community if:

1. Based on negotiation prior to implementation
2. Past examples exist: disparity in access to health care in trials; disparity in access to management of potential resistance developed during ARV based prevention studies

Communities may use this to negotiate for its inclusion in national health packages (good); may want to negotiate access to persons beyond the trial eg partners of trial participants (challenge)

# Challenge - 5

Challenges of specific tools:

1. If PreP is demonstrated as effective, use would likely be independent of national policies, independent of VCT and possibly provided within health care systems not prepared for this demand (same experience with male circumcision). In the face of these realities, what determines its inclusion as a prevention package
2. With the current studies of possible early treatment of HIV infection in the acute phase as a prevention tool, and PreP, how do you manage these in trials for serodiscordant couples?

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