How Much is Enough?
Standards of Prevention in HIV Prevention Trials
Consultation report and recommendations

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Background

As effective new HIV-prevention tools are developed, researchers face ethical and logistical questions about how and when to include them in the prevention package provided to trial participants in ongoing and future HIV-prevention trials. Current UNAIDS/WHO guidance recommends that decisions about adding new tools to the prevention package be made in consultation with "all relevant stakeholders" but leaves open questions of process and implementation.

In March 2009, GCM, UNAIDS, and CDC convened an international consultation to develop practical approaches to key questions related to the standard of prevention in individual trials and the overall context of HIV-prevention research:

1. When and under what circumstances are researchers ethically obligated to **make a new prevention tool available to study participants in a future trial**?

2. Under what circumstances would it be necessary to **stop or modify an ongoing trial because a method has been shown to be effective in another trial?**

3. What impact will **adding new prevention modalities have on the ability of future trials to evaluate the efficacy of the HIV-prevention tools they are testing?**

4. How can the field **balance obligations to trial participants with the urgent need for new HIV-prevention methods?**

Existing Guidance

UNAIDS/WHO (2007) Guidance Point 13

Researchers, research staff, and trial sponsors **should ensure: ….that appropriate counseling and access to all state-of-the-art HIV-risk-reduction methods are provided to participants**

New HIV risk reduction methods should be added, based on consultation among all research stakeholders including the community, as they are scientifically validated or as they are approved by relevant authorities

Outstanding Issues :

Definitions

- state of the art
- proven
- established
- validated
- approved by relevant authorities

Implementation challenges

- stakeholder consultation
- negotiation
- conflict resolution

Recommendations

Participants at the consultation – nearly 60 people working in HIV prevention research, advocacy and policymaking – developed points of agreement and developed a set of specific criteria to inform decision making around adding new prevention methods to the prevention package in trials. Some of the key recommendations and points of agreements are listed below.

Points of Agreement

Adding New Prevention Methods or Strategies to Trials	If an international normative body and/or national policymaking process **recommends a new method or strategy** for the population group enrolled in a trial, then **all trial participants should be ensured access to it**. Any departure must be **clearly and persuasively justified on scientific and ethical** grounds and clearly communicated to all stakeholders.
Service Provision and Referral	**Referral for prevention services is acceptable if quality services are available in the trial community**. Such referrals should be actively monitored to ensure access and quality.
Cost	Direct services or referrals should be provided **at no additional cost to the participant.**
Ongoing PrEP Trials	In the absence of clear safety or futility concerns, the current generation of **PrEP** (oral pre-exposure prophylaxis) **trials** (which are testing different routes of exposure in different populations) **should be allowed to continue to completion**, even if one or more demonstrate effectiveness.

Recommendations for Deciding When to Add New Methods

Weight of Evidence and Trial Population	Consider the **weight of evidence for estimates of efficacy and effectiveness** of the new HIV-prevention tool or strategy and the **relevance to the trial population and route of transmission.**
Feasibility and Effect on Trial Endpoint	**Is it feasible to provide** the new HIV-prevention tool or strategy given local availability, manufacturing capability, and other factors? Will adding the new modality undermine the **trial's ability to isolate the effect of the test product**?
Innovation vs Sustainability	Should investigators **provide access to methods that are not yet available in national programs**? Decisions should balance opportunity for **innovation and scaling up local care** with **concerns about sustainability, national sovereignty, and local equity.**
Consultation and Negotiation	Additional work is needed to **develop, implement, and evaluate approaches to ensuring stakeholder participation** in decision-making, negotiation, and resolving conflicts.
Ethics of Public Health	Ethical frameworks emphasize the rights of individuals enrolled in trials. A **framework for "public health ethics" is needed to balance the needs and rights of trial volunteers with the urgent need for new HIV-prevention approaches.**

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