Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials Second Edition 2011
Why were the GPP Guidelines created?

- Developed in response to the PrEP (pre-exposure prophylaxis) trial controversies in 2004 and 2005
  - Misunderstandings and poor communication among research stakeholders in Cambodia and Cameroon
- What happens in one trial, with one product, in one community, happens to all of us:
  - Participants, investigators, trial sites, funders, communities, developers
Consultations in 2005
Durban (South Africa), Abuja (Nigeria), Pattaya (Thailand), and Geneva (Switzerland)

Creating Effective Partnerships for HIV Prevention Trials

The HIV epidemic has changed the way that HIV-focused clinical research is conducted. Trial participants and communities have demanded that they be included in defining research priorities, determining how trials will be conducted, and monitoring trial implementation. Many researchers have worked to respond to these demands through efforts such as including people living with HIV and community representatives on review committees and establishing community advisory boards to work on specific protocols and trials.
Researchers should engage appropriate stakeholders in design, implementation and oversight of risk reduction interventions, tailored to the specific needs and risks of the community.

National and international groups should evaluate the feasibility of independent organization of community-based interventions in priority hubs. Where feasible, such efforts should be rigorously evaluated.

Sponsors, researchers and relevant stakeholders should continue efforts to resolve concerns about the conduct of appropriate risk reduction interventions for injecting drug users including the use of injecting equipment such as needles.

Recommendations

- Funding agencies should provide resources to develop and document innovative approaches to partnership and community engagement, in addition to established mechanisms such as Community Advisory Boards.

- UNAIDS/WHO should sponsor the development of guidelines for “Good Community Practice” to inform best practice approaches to partnership in the context of HIV prevention trials, as well as provide standards for monitoring and evaluation.

- National governments and UNAIDS/WHO should explore establishing national or other boards to review, approve and monitor research partnership approaches similar to those for regulatory or ethical review.

- Partnership agreements should include clear delineation of roles for all stakeholders and should specify responsibilities—and rights—of sponsors, governments, community, advocacy organizations and media, and researchers.

- Sponsors and researchers should specify in protocols what commitments have been made to provide services, care and treatment to become HIV-infected and other health benefits (and on whom and how such services will be provided, by whom and at what cost).

- National research oversight bodies should develop realistic treatment of study sponsors for failing to meet their legal obligations and requirement to provide funds necessary to support the health needs of participants and to ensure study and treatment-related expectations and basic health needs are met.

- UNAIDS should convene a technical group to identify specific approaches to providing care and treatment for intercurrent infections including insurance plans, payments to trial participants, contracts with government or private providers, escrow accounts or other approaches.

- Researchers should formalize referral networks, ensure that local services to which trial participants are to be referred have the capacity to provide needed services, and provide resources and capacity development to strengthen these services.

- All stakeholders should continue debate at international and local levels to determine their respective obligations to trial volunteers who discover they are HIV-infected at screening and should agree on how services can be provided.

- Researchers and sponsors should link with initiatives to pilot and expand access to treatment services to attract resources for communities participating in research so that services for trial volunteers and other community members can be expanded.
Why were the GPP Guidelines created?

- Effective partnerships could be built among all research stakeholders.
- Future misunderstandings could be avoided.
- The relationship between research entities and stakeholders could be guided by a set of guidelines, just as for other aspects of clinical trial conduct.
GPP Development

- International, multidisciplinary working group, with global input from stakeholders.

- The GPP guidelines describe **HOW** Guidance Point 2 “Community Participation” in the companion UNAIDS/WHO guidance “Ethical Considerations in Biomedical HIV Prevention Trials” can be applied.

**Guidance Point 2: Community Participation**

To ensure the ethical and scientific quality and outcome of proposed research, its relevance to the affected community, and its acceptance by the affected community, researchers and trial sponsors should consult communities through a transparent and meaningful participatory process which involves them in an early and sustained manner in the design, development, implementation, monitoring, and distribution of results of biomedical HIV prevention trials.
What do we mean by stakeholder engagement?

- Stakeholder engagement does not mean recruitment.
- A process of utilizing the expertise that stakeholders have to improve the research process and shape it together.

Diagram:

Stakeholder Input and Engagement

- Research questions
- Protocol
- Recruitment
- Enrolment
- Follow-up
- Results
- Dissemination of results

Research Life-cycle
Why stakeholder engagement?

It ‘makes the research better’

- stakeholders can give research teams advice about research questions, procedures and conduct
- stakeholders, especially community stakeholders, have critical knowledge about local cultures and dynamics of the HIV epidemic and can help ensure that the research and procedures are culturally sensitive and appropriate
- advice can lead to better recruitment, better retention, better adherence, better data, and better likelihood of uptake of HIV prevention interventions should they be safe and effective
Why stakeholder engagement?

Stakeholder engagement not only makes the research better, it is ethical

If community stakeholders such as non-governmental organisations (NGOs), community-based organisations (CBOs), or individuals affected by HIV or by the research want to engage in the process and help shape it, then it is their right to do so.
• AVAC held global consultations on the first edition of the GPP guidelines in 2008-2009

• draft second edition was open for public comment from July 2010-January 2011; feedback was included in the draft revision

• second edition was released June 2011 and launched in Rome at IAS conference

• translations underway in French, Spanish, Russian, Arabic, Chinese, Thai, Khmer, Vietnamese, Portuguese
Objective of the GPP Guidelines

- set global **standard practices** for stakeholder engagement
- provide trial funders, sponsors, and implementers with **systematic guidance** on how to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials
• primarily written for trial funders, trial sponsors, and trial implementers

• stakeholders not directly involved in funding, sponsoring, or implementing trials can use the GPP guidelines to **understand the methods** of stakeholder engagement and to **monitor and evaluate** such efforts
Research Stakeholders: Per GPP

• individuals, groups, organisations, government bodies, or any other individuals or collections of individuals who can influence or are affected by the conduct or outcome of a biomedical HIV prevention trial

• the term “stakeholders” in GPP is all-encompassing, describing any individual or collection of individuals who has a stake in a biomedical HIV prevention trial
Community Stakeholders: Per GPP

- both individuals and groups that are ultimately representing the interests of people who would be recruited to or participate in a trial, and others locally affected by a trial

- trial funders, sponsors, and implementers, as well as government bodies or representatives of high-level authority structures, are explicitly excluded from the term “community stakeholders” but are clearly considered trial stakeholders
Examples of Research Stakeholders

Global Stakeholders

National Stakeholders

Broader Stakeholders

Community Stakeholders

Trial Participant

Examples

- NGOs
- local policymakers
- local media
- medical professionals
- community advisory boards
- local health service providers
- peers
- trial site staff
- government institutions
- regulatory bodies
- ethical review committees
- international organisations
- funders
- sponsors
- media
- local religious institutions
- community leaders
- local NGOs
- international NGOs
- parliamentarians
- ministries of health
- WHO/UNAIDS
- trial sponsors and networks
- sponsors
- national NGOs
- participant's family
- friends
- schools
- colleagues
Good Clinical Practice (GCP): about responsibilities to trial participants

Good Participatory Practice (GPP): about working with research stakeholders
Contents of GPP, 2nd Edition

**Section 1:**
The Importance of Good Participatory Practice

The Importance of Good Participatory Practice defines the key terms used in the document and describes the realities and the underlying determinants of the HIV epidemic, the context of conducting biomedical HIV prevention trials, and why a participatory approach is necessary to effectively conduct trials.

**Section 2:**
Guiding Principles of GPP in Biomedical HIV Prevention Trials

Guiding Principles of GPP in Biomedical HIV Prevention Trials outlines the set of principles that serve as the foundation of the relationships among trial funders, sponsors, and implementers and other stakeholders.

**Section 3:**
Good Participatory Practices in Biomedical HIV Prevention Trials

Good Participatory Practices in Biomedical HIV Prevention Trials describes optimal practices for trial funders, sponsors, and implementers to follow when designing, conducting, and concluding biomedical HIV prevention trials. Under 16 topic areas, this section outlines expected stakeholder engagement activities that take place at each stage of the research life-cycle.
Topic Areas are divided into five subsections:

A. Definition
B. Relevance to good participatory practice
C. Special considerations
D. Good participatory practices
E. Additional guidance
3.5 Communications plan

3.5.A. Definition

The communications plan describes policies and strategies that will increase broad awareness of the trial, facilitate dissemination and understanding of correct information about trial design, conduct, and results, and coordinate communication between the research team and relevant stakeholders.

3.5.B. Relevance to good participatory practice

Ongoing, transparent, and accurate communication with relevant stakeholders about proposed and ongoing research is essential for respectful, transparent relationships and builds trust among stakeholders. Additionally, consultation with relevant stakeholders will help research teams design communications strategies that are effective and help create a supportive and conducive environment for trial initiation and implementation.

3.5.C. Special considerations

The communications plan exclusively addresses external communication. However, effective internal communication, especially across multidisciplinary teams, is a prerequisite to attaining effective external communications.

3.5.D. Good participatory practices for communications planning

1. Research teams and relevant stakeholders comprehensively identify potential audiences within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams and relevant stakeholders discuss and negotiate a communications plan to support open channels

3.5.E. Additional guidance

See Communications Handbook for Clinical Trials: Strategies, tips, and tools to manage controversy, convey your message, and disseminate results.28
Community Advisory Boards (CABs) are one of many ways that research teams can engage with stakeholders.
Examples of How to Engage

Community Advisory Boards (CABs): often necessary but seldom sufficient for adequate stakeholder engagement plans

There may be many more effective ways for research teams to engage with other stakeholders
What does GPP say about Protocol Development?

3.8.D Good participatory practices for protocol development

1. Trial sponsors and network leadership provide opportunities and time for local research teams to contribute to trial protocol development.

2. Trial sponsors, network leadership, and local research teams provide opportunities and time for local stakeholders, in particular community stakeholders, to contribute to trial design issues and procedures such as products to be tested, trial objectives, recruitment strategies, informed consent materials and procedures, reimbursement policies, counseling approaches, follow-up procedures, and post-trial access to trial products.

3. Research teams maintain clear and transparent communication about the protocol development process with relevant stakeholders, in particular, formal stakeholder advisory mechanisms.

4. Research teams provide relevant stakeholders with draft versions of the protocol and make technical information as accessible as possible by providing protocol summaries and translated materials, or by facilitating workshops, as necessary.
Monitoring and evaluation of GPP

- **Were the practices followed (monitoring)?**
  - ✓ research teams can assess themselves
  - ✓ community stakeholders such as community groups or CABs can assess research teams
  - ✓ monitors can do assessments

- **What was the impact of the stakeholder engagement (evaluation)?**
  - ✓ How did engagement improve the research?
    - Was stakeholder feedback on research design and conduct useful?
  - ✓ What do various stakeholders think about the quality of the engagement process and the relationships?
    - Did community stakeholders feel their inputs and feedback were listened to and addressed?
GPP is a process

- It will be different in every setting. There is no one answer.
- It will depend on country, institution, sponsor, community setting, etc.
- Sharing lessons learned is key to building capacity and improving research conduct.
Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

METHODS

PROTOCOL DEVELOPMENT

We developed the concept and protocol for this study using methods that came to be approved as “good participatory practices” by UNAIDS. The development of the protocol was sponsored by the National Institute of Health’s Division of Acquired Immunodeficiency Syndrome (DAIDS).
Who can require GPP be followed?

- funders, sponsors, and implementers
- national governments
- ethics committees or institutional review boards
- research teams can decide to adopt and implement them on their own
- community stakeholders can have contracts with research teams to follow GPP
- NGOs and others can advocate for GPP adoption
Thank you!

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