Good Participatory Practices for vaccine clinical trials

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Good Participatory Practice Guidelines: Implications for research sponsors

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The Good Participatory Practice (GPP) guidelines for biomedical HIV prevention trials:

Set global **standard practices** for stakeholder engagement. They 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.
GPP: Where the story began

PrEP research controversy:
2004 – Cambodia trial not initiated
2005 – Cameroon and Nigeria trials discontinued
GPP History

2004
PrEP Controversies

2007
GPP launched

Good participatory practice
guidelines for biomedical HIV prevention trials
Guidelines development

- Recognized need for effective partnerships between **research teams** and **stakeholders**
- Other aspects of clinical trial conduct are informed by guidelines; stakeholder engagement should be, too
- **1st edition** (2007) – developed by international, multidisciplinary working group, with global input from stakeholders
- **2nd edition** (2011) – developed after feedback from global consultations and piloting
Consideration of Stakeholders

Global Stakeholders

National Stakeholders

Broader Stakeholders

Community Stakeholders

Examples:
- national NGOs
- parliamentarians
- ministries of health
- media
- regulatory bodies
- ethical review committees
- international foundations
- sponsors

NGOs
- local policymakers
- local media
- medical professionals

Local religious institutions
- friends
- schools
- colleagues
- pears
- trial site staff
- local health service providers

Trial Participant

CBOs
- participant's family
- local policymakers
- community advisory boards
- local health service providers

International NGOs
- trial sponsors and networks
- WHO/UNAIDS
- international organizations

International NGOs
GPP is woven into the lifecycle of a trial
What is GPP Not?

• Not recruitment
• Not retention
• Not a CAB
• Not participant-trial site interactions
• Not about a single trial
• Not “nice to have”
• Not GCP, but...

• It IS core to the research and development process
Did You Say GCP?

GCP ≠ GPP

Research Investigator

GCP

Trial participants

GPP

Research teams (and trial sponsors and funders)

Stakeholders

Stakeholders

Stakeholders

Stakeholders

Stakeholders
Not Just a CAB
Implementation Globally

- National GPP plan and N-CAB in Thailand
- National CAB Forums, incorporation into ethics review processes in South Africa
- Incorporation into ethics guidelines in Uganda

- Adaptation to other fields, e.g., TB, Ebola
- “Global” GPP/CE Forum, Q3 2015
- Endorsement by Presidential Bioethics Commission
- Global consultations, e.g., proposed ECHO trial, MTN-017
- Stakeholder Engagement CoP

- GPP training, tools for sites
- FACTS 001
- iPrEx
- ASPIRE – results prep
- IAVI partner research centers
Evaluating community engagement in global health research: the need for metrics

Kathleen M. MacQueen, Anant Bhau, Janet Frohlich, Jessica Holker, Jeremy Sugarman and the Ethics Working Group of the HIV Prevention Trials Network

Lessons Drawn From Recent HIV Vaccine Efficacy Trials

Jonathan D. Fuchs, MD, MPH,† Magda E. Sobieszczuk, MD, MPH,§ Scott M. Hammer, MD,§ and Susan P. Buchbinder, MD†‡

Implementing good participatory practice guidelines in the FEM-PrEP Preexposure Prophylaxis Trial for HIV Prevention among African Women: a focus on local stakeholder involvement

Engaging community to support HIV prevention research

Seema Sahay and Sanjay Mehendale
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 of 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.
Section 1: The Importance of Good Participatory Practice
- Who are Stakeholders?
- What is Stakeholder Engagement?
- The Wider Context of HIV
- The Dynamics of Biomedical HIV Prevention Trials
- Rationale for GPP Guidelines
- Applying GPP

Section 2: Guiding Principles of GPP in Biomedical HIV Prevention Trials
- Respect
- Mutual Understanding
- Scientific and Ethical Integrity
- Transparency
- Accountability
- Community Autonomy

Section 3: Good Participatory Practices in Biomedical HIV Prevention Trials
- Formative Research Activities
- Stakeholder Advisory Mechanisms
- Stakeholder Engagement Plan
- Community Education Plan
- Communications Plan
- Issues Management Plan
- Site Selection
- Protocol Development
- Informed Consent Process
- Standard of HIV Prevention
- Access to HIV Care and Treatment
- Non-HIV-Related Care
- Policies on Research-Related Harms
- Trial Accrual, Follow-Up and Exit
- Trial Closure and Results Dissemination
- Post-trial Access to Trial Products or Procedures
Implementation tools

- GPP Blueprint
- Trial site binder/file
- Planning templates
- Assessment toolkit
Online training curriculum

- Designed for multiple audiences, adaptable
- Primary focus on trial implementers
- Aids in strategy, work plan development
- Interactive asynchronous content
- Moderated by GPP experts
Monitoring and Evaluation Toolkit

- Set of tools for monitoring engagement activities
- Online database for data entry and standardized reporting
- Developed with TB Alliance, input of working group
- Piloted with multiple trial sites
- Introduced Sept 2014
- Official launch Q3 2015
Implementation: National

- Uganda – incorporating GPP into national ethics guidelines
- Training for IRB members
- Zambia – national stakeholder consultations
- Thailand – national awareness through site trainings
Implementation: Global

• Adapted version for TB drug trials, 2012; Ebola trials, 2015
• GPP Online Training Course
• Abstract driven session at HIV R4P conference, 2014
• Combined Community Engagement Forum, Sept 2015
Summary

- Good Participatory Practices, 2\textsuperscript{nd} Edition have provided a key framework for ethical HIV prevention research
- GPP: inclusive, early, and durable stakeholder engagement
  - \textit{GPP is woven into the entire lifecycle of a research effort}
- Future:
  - Need to generalize for other infectious diseases, especially those seen in outbreaks.
  - Applicability for non-communicable disease research?
  - Sufficient engagement of behavioral and social change research?
Resources

• GPP for HIV Prevention: http://www.avac.org/good-participatory-practice
• Training & Implementation Tools: http://www.avac.org/gpp-tools
• Online Training Course: http://www.avac.org/gpp-online-training-course