Good Participatory Practice (GPP) Then and Now

European RAVE
HIV Prevention Science & Advocacy Training
Paris
12-13 June 2014

Cindra Feuer
AVAC: Global Advocacy for HIV Prevention
What is GPP

- GPP guidelines were developed to facilitate building of effective partnerships among all research stakeholders – just as other aspects of trial conduct are informed by guidelines
Why were the GPP guidelines developed?

- In response to PrEP trial government shut-downs in Cambodia and Cameroon in 2004 and 2005. (PrEP trials in four of five countries prematurely closed)

- To facilitate the building of effective partnerships among all research stakeholders including “community” to ensure successful trials
Cambodia: 2004 Stopped before enrolment:

Advocacy by Womyn’s Network for Unity (WNU), Union of Cambodian Sex Workers

Complaints
- No provision for treatment for side effects incurred in study—wanted insurance
- $3 monthly stipend not enough
- No response to WNU’s questions
- Foreign trial staff
- Bypassed WNU as community representatives
- NGOs afraid of PEPFAR sex worker pledge
Cameroon

**Cameroon**: 2005 Stopped after enrolment

Advocacy by Réseau Ethique Droit et Sida (REDS)

Complaints

- Researchers wouldn’t share protocol at first
- All documents in English
- No female condom in prevention package
- No negotiations for post-trial access to study product (Tenofivir as PrEP)
- No provision of treatment for seroconverters
PrEP trials halted or cancelled

**Cambodia** Stopped before enrolment
Controversy stemming from local and international activist groups’ concerns about ethics and standards of health care for volunteers during and after the trial

**Cameroon** Stopped after enrolment:
Controversy related to international debate around trial ethics and standard of care that originated with Cambodian trial

**Nigeria** Stopped by trial sponsors after enrollment due to concerns about local sites’ capacity

**Malawi** Stopped before enrolling:
Concerns on the part of Malawi Ministry of Health that studies of tenofovir as PrEP could complicate use of the drug as a treatment for HIV-infected individuals
Common themes

- Communities organized themselves, external allies and channels of communications
- Requested protocol changes
- Researchers handling of community’s suggestions
- Lack of trust in ethical review process
- Informed consent comprehension
- Access to treatment
- Lack of safety data
- Inability of local researcher to speak for trial
- Media engagement
- Community willingness for dialogue
- **RESEARCHERS LACKED PLANS FOR COMMUNITY INVOLVEMENT**
- **LACK OF TRANSPARANCY AND MECHANISM FOR ONGOING PROBLEM-SOLVING**
GPP timeline

- 2005 conceived
- 2007 initial publication
- 2011 updated with global input including sex workers
- 2013 GPP standard trial practice
Why GPP

- In response to trial controversies
- Help prevent misunderstanding and miscommunication among research stakeholders
- Premise: what happens with one product, in one trial, in one region affects all biomedical HIV prevention stakeholders – trial participants, research teams, funders, sponsors, community stakeholders, and product developers
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
- Integrity
- Transparency
- Accountability
- Community Stakeholder Autonomy

Section 3: Good Participatory Practices in Biomedical HIV Prevention Trials

- Formative Research Activities
- Stakeholder Advisory Mechanisms
- Stakeholder Engagement Plan
- Stakeholder 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 Trial-Related Harms
- Trial Accrual, Follow-Up and Exit
- Trial Closure and Results Dissemination
- Post-trial Access to Trial Products or Procedures
Build transparent, meaningful, collaborative, & mutually beneficial relationships among stakeholders with ultimate goal of shaping research collectively.

Answer the research question!
“The issues presented by singling out sex workers for inclusion in PrEP trials are not unique to sex workers and could be experienced by many at-risk groups. Yet, there will be issues unique to sex workers in general and individual communities in specific. Efforts to identify, understand and remedy unique issues are justified. Meaningful involvement as defined by sex workers should be sought if benefit to trial and community is the aim.”

—Dan Allman and Melissa Ditmore, Sex Workers Project at the Urban Justice Center, GPP contributors
It’s a Journey

- Process through which trial funders, sponsors, and implementers build meaningful relationships with stakeholders
- Goal is to shape the research process by using the expertise of stakeholders
- It is *not* recruitment!
And It is Not Just by CAB
GPP in action: MDP 301

• Study site worked closely with women’s work places to hold informational meeting and weekly reproductive health clinics at work place
• City-wide elections to sit on community advisory committee (CAC). Among CAC members were trial participants
• Workshops and community meetings to explore concerns
• Community theater to educate wider public about trial and need for new tools
• Regular community stakeholder meeting including government officials, representatives from local care facilities and community reps
• Development of Standard of Care Guidelines in consultation with community
GPP in action: FEM PrEP

- Initiated community program activities 2 years in advance
- Informal and formal stakeholder advisory mechanisms
- Informational meetings with men
- Broad outreach to NGOs, FBOs, hospitals, bars, taverns, women’s groups, informed about PrEP, PrEP research and FEM PrEP
- Outreach activities went beyond trial focused activities—condom distribution, STI referrals, etc.
- Trial newsletter, talking points, adapted materials to build support among key opinion leaders
- Results dissemination discussed in context of ongoing biomedical px field
“Invisible Outcomes of GPP”

- Cellulose Sulfate microbicide halted early (2006)
- MDP 301: 0.5% PRO 2000 microbicide doesn’t reduce risk (2009)
- FEM PREP: Once daily oral Truvada halted early (2009)
- VOICE: Tenofovir gel and oral tenofovir halted (2011)
- VOICE: Oral Truvada doesn’t reduce risk (2013)
MICROBICIDES DON’T WORK FOR WOMEN!

RESEARCH IS WASTING VALUABLE RESOURCES!

SCIENTISTS TESTING USELESS PRODUCTS ON VULNERABLE WOMEN!
Normalizing GPP

- **iPrEx** – first trial to design protocol using GPP as a guide for concept and protocol (and mentioned in the NEJM publication)
- **MTN**, including **VOICE, CHOICE, MTN 017, ASPIRE** – pioneered partnerships with civil society and policy makers in pre-protocol concepts and actual protocol development
- **FACTS 001** – first trial to integrate GPP throughout the entire protocol development process, including site-level GPP plans and training
- **IAVI/AVAC partnership** – assessments and training at site level, unrelated to any trial
What is Good?

- Research that truly reflects the surrounding community
- Research that is supported by stakeholders
- CABs that identify their role as watchdog
- Feedback – negative, positive or neutral – that is addressed by research teams
- Not the best recruitment numbers
- Most often, the absence of an outcome – “an invisible outcome”
What GPP is NOT

- Not recruitment
- Not retention
- Not a CAB
- Not a tick-box, a magic formula, or a guarantee
- Not participant-trial site interactions – Good Participant Practice?
- Not about a single trial
- Not a “nice to have” or “cherry on top”

It IS core to the research and development process
GPP timeline

- 2005 conceived
- 2007 initial publication
- 2011 updated with global input including sex workers
- 2013 GPP standard trial practice
- 2014, beyond Phase III?
  - Mechanism for continued discourse and relationship building
  - Applying GPP to demonstration studies, influencing policy and real-world implementation
Stay tuned for the new online GPP course from AVAC and Bridge HIV/SFDPH – see Stacey Hannah and Jonathan Fuchs for more information!

For more info as well as a range of GPP tools, training materials and resources, visit www.avac.org/gpp