GPP@10

Marking 10 Years of GPP Implementation

AVAC
Global Advocacy for HIV Prevention

www.avac.org
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A decade ago, **UNAIDS** and **AVAC** published the **Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials (GPP).** Created to provide a consistent global standard for stakeholder engagement across the research life-cycle, GPP has emerged as a point of reference for how to engage stakeholders. It has also given rise to a robust community of practice.

After ten years of implementation, AVAC offers a look back at GPP and a vision for its future – and we explain why GPP's true potential lies in the hands not just of research groups, but of civil society, trial participants, and an array of stakeholders in the research endeavor.

Q A 10 Years in, a Critical Q&A

Who *really* has to do GPP?

GPP Guidelines are written for trial sites, funders, and sponsors – that is, research entities. External stakeholders, such as advocates, policy makers, and communities are encouraged to use the guidelines to hold research entities accountable. Stakeholders can also seek to implement or monitor implementation of GPP components themselves. AVAC and partners are finding this 'external' approach to GPP is a powerful way to hold research entities responsible for community-centric trials.

When and where does GPP happen?

The most logical place for GPP to be implemented is at a trial site, within the clinical trial life-cycle, and this is indeed where it is most frequently utilised. It also has far broader applications:

- Wits Reproductive Health and HIV Institute in South Africa has incorporated GPP as a central component of its work - well beyond clinical trials. They have developed a GPP Standard Operating Procedure, a GPP Leadership Course and are working toward becoming a GPP Centre of Excellence.
- Janssen Pharmaceuticals has created a GPP Task Force, developed company-wide GPP Considerations Guidance, and is leading efforts to implement GPP in HIV prevention clinical programs.
- The Treatment Action Literacy Campaign in Zambia, a grass-roots activist group, initiated GPP-focused activities around the PopART study being conducted throughout the country.

What value does GPP add to clinical trials?

As GPP is implemented over time, research teams and other stakeholders build long-term trust and a deeper understanding of how trials will affect communities. This improves trial design and conduct and increases the chances that trial results will be well-understood, accepted, and acted upon, whatever the outcome. Here are some ways that stakeholder engagement has shifted trial designs and approaches – for the better:

- The CAPRISA research center in South Africa has built a long-standing relationship with the community, independent of trials, including providing benefits such as support to local schools. This has resulted in increased trust by the community, who provides honest insight into how members perceive and participate in trials.
- The drug company Gilead amended the protocol of an efficacy trial for a next-generation PrEP product and created new advisory mechanisms after receiving intense feedback from concerned advocates about the trial's design and the lack of any community engagement.
- The Microbicide Trials Network conducted wide stakeholder engagement for MTN 017, the first ever global rectal microbicide study. The network has stated that participation, adherence, and thus trial results benefited from trust built within communities and amongst national stakeholders through their consultation processes.

Does GPP guarantee smooth trials? And good data?

It's important to remember: GPP is not a guarantee of trial results. GPP can give researchers a better sense of how communities will perceive trials and products – but it cannot alone make participants stay in a trial, adhere to a trial regimen, or make products work. And GPP does not eliminate the chance of controversy, but it does provide a framework for navigating controversy, when, and if, it does occur.

Past

2004/5

Halting of PrEP clinical trials: Cambodia, Cameroon & Nigeria

Prompting AVAC to observe "The primary lesson of these controversies is that communities must be meaningfully, productively engaged in research."

2006

Work on GPP Guidelines begins

Preceded by almost a year of consultation, the UNAIDS/AVAC working group begins drafting GPP Guidelines.

2007

GPP Guidelines launched

After months of review and revision with stakeholders, the 1st edition of GPP Guidelines is launched.

2010

First GPP training

AVAC, with partner IAVI, conducts first in-person GPP training.

GPP in NEJM

New England Journal of Medicine publishes iPrex efficacy trial results; Methods section begins "We developed the concept and protocol for this study using methods that came to be approved as 'good participatory practices'."

2011

2nd edition of GPP Guidelines launched

Presidential Commission

US President Barack Obama's Commission for the Study of Bioethical Issues references GPP as a "key resource for ensuring ethical research."

2012

GPP Training Curriculum launched

A practical tool to support expanded GPP training.

GPP adapted for TB drug development

Critical Path to TB Drug Regimens adapted GPP for HIV px to develop GPP Guidelines for TB Drug Trials.

GPP adapted for Thailand

The Thai Action Group published Stakeholder Input and Recommendations for GPP in Biomedical HIV Prevention Trials in Thailand (2012).

Establishment of National CAB in Thailand

A forum for GPP implementation at a national level.

2014

GPP Blueprint released.

A companion to the Guidelines, this step-by-step guide presents questions, worksheets and explanations that can help guide site staff to develop stakeholder engagement plans.

GPP Online Training Course launched at HIVR4P conference, Cape Town, SA

This online tool dramatically expanded access, and reduced cost, of GPP training for global constituents.

GPP becomes a national standard

GPP is incorporated in to the Ugandan National Research Ethic Guidelines.

M&E Toolkit is released

This resource supports clinical trial sites in evaluating GPP programming.

Ongoing Consultative process

2016

World Health Organization

WHO adapts GPP for emerging pathogens

WHO published Good Participatory Practice Guidelines for Trials of Emerging Pathogens.

SA GPP Engagement Forum

Establishment of South Africa National Stakeholder Engagement Forum.

Present

2017

Expanded and adapted GPP Online Training

Including Advanced Implementers' Course, GPP Leadership Course, GPP for Research Ethics Committees, and translated courses in Thai and Portuguese.

GPP adapted for TB vaccine research

Aeras published Good Participatory Practice Guidelines for TB Vaccine Research.

GPP Advisory Committee formed

GPP Global Think Tank

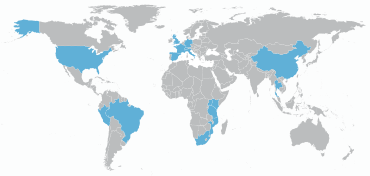
Bringing together implementers and supporters to take stock and chart a way forward.

10 year anniversary of GPP!

2018

Expanded number of clinical trial sites using GPP

Reflecting a shift towards GPP as standard practice.



An ever-growing group of alumni advocates, including more than 300 individuals from 21 countries trained using the online course.

Future

Recommendations for Future Implementation

GPP Centers of Excellence

AVAC and partners propose the establishment of Regional Centers of Excellence that will include GPP activity models and best practices, resource repositories, and a GPP Leadership Program. These Centers will serve as a resource and training hubs for institutions throughout Africa, decentralizing GPP practices and strengthening local understanding and implementation.

GPP Community of Practice

Building from the online training course, GPP trainings and other workshops, a global Community of Practice will serve as a common forum to connect GPP implementers to share best practices, support implementation and compile lessons learned.

GPP integrated across disease areas

GPP Partners are committed to making stakeholder engagement a standard part of clinical trial process. Significant work will need to go into introducing and adding GPP to the processes of regulatory bodies, ethics review bodies and scientific journal editors. The first step in this process will be identifying a core set of GPP elements for clinical trials broadly, beyond just HIV prevention.

Compliance Mechanism

The field must develop mechanisms that link GPP activities to defined indicators, both for affected communities and for clinical trial conduct and related outcomes. Efforts are underway to strengthen and more fully implement monitoring and evaluation tools for GPP programs, as well as to develop a GPP Theory of Change.

The Basic "Ps" for GPP

Purpose

Expectation that stakeholders will be consulted in the design and conduct of the research in which they are invested – and that ethical and scientific endpoints and public health outcomes will be better served by doing so.

Principles

Built on principles of research ethics:

- Respect
- Mutual Understanding
- Integrity
- Transparency
- Accountability
- Autonomy

Process

Meant to be sustained throughout the research life- cycle, beginning with the design of clinical trials and continuing through to the release of data and roll-out of a final product.

"GPP helps the community become active partners in HIV clinical research. Before GPP, we were limited to advising on study brochures and pamphlets. Now, we have a methodology for involvement in the full research life-cycle, from planning a study to the release of data, and beyond."

- Udom Likhitwonnawut, Thai NGO Coalition on AIDS/ Civil Society

"Good Participatory Practices have transformed the way that biomedical research is conducted around the world. While HIV researchers and communities have historically wanted to work together in meaningful partnerships, the process of actually doing this in a transparent, consistent, teachable, and metrics-driven way was impossible until GPP was developed. In the era of emerging infectious diseases such as Ebola, Zika, and pandemic influenza, GPP for HIV research has illuminated the way forward for impactful relationships between researches and communities in a growing number of fields."

- Dr. Nelson L. Michael, Director, US Military HIV Research Program

"As a community advocate, the principles and participatory tools of GPP have enabled me to be responsive and accountable to the well-being of local and global populations."

- Neetha Morar, South African Medical Research Council

The Future: GPP in '3-D'

Deliver

Deliver GPP through a global Community of Practice (CoP) and regional Centers of Excellence (CoE).

CoP forums allow implementers to connect virtually across geographies and disciplines and regional CoE's serve as local hubs for strengthening local understanding and implementation.

Document

Strengthening the body of literature on GPP to support implementers.

Peer-reviewed publications are an important mechanism for disseminating GPP lessons-learned beyond implementers and champions. They also help build familiarity with GPP among people who can then advocate for its application elsewhere.

Diversify

Promote stakeholder engagement as standard practice within the clinical trial process – beyond the field of HIV prevention.

Implementing GPP training amongst regulatory and other oversight bodies will ensure that principles and practices become a standard to which clinical trials are consistently held.

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Founded in 1995, AVAC is an international, non-profit organization that uses education, policy analysis, advocacy and community mobilization to accelerate the ethical development and global delivery of biomedical HIV prevention options as part of a comprehensive response to the pandemic.

AVAC is based in the US, and focuses on issues and priorities in countries where prevention research and implementation are ongoing. Specifically, we seek to deliver proven HIV prevention tools for immediate impact; demonstrate and roll out new HIV prevention options; and develop long-term solutions needed to end the epidemic.