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.

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

2004/5
- Halting of PrEP clinical trials: Cambodia, Cameroon & Nigeria

2006
- UNAIDS/AVAC working group begins drafting GPP guidelines

2007
- GPP Guidelines launched
  - After months of review and discussion with stakeholders, the 1st edition of GPP Guidelines is launched

2008
- Work on GPP Guidelines begins
  - Preceded by almost a year of consultation, the UNAIDS/AVAC working group begins drafting GPP guidelines

2010
- First GPP training
  - AVAC, with partner VLA, conducts first in-person GPP training

2012
- GPP Guidelines	launched
- Presidential Commission
  - US President Barack Obama’s Commission for the Study of Biomedical Innovation references GPP as a “key resource for ensuring ethical research”

2014
- GPP adapted for TB drug development
  - Critical Path to TB Drug Regimens adapted GPP for HIV to develop GPP Guidelines for TB Drug Trials

2016
- GPP Blueprint released
  - A companion to the guidelines, this step by step guide provides questions, work tools and explanations that can help guide site staff to develop stakeholder engagement plans

- GPP Online Training Course launched at HIV2016 conference, Cape Town, SA
  - This online tool dramatically expanded access, and reduced cost of GPP training for global constituencies

- WHO adopts GPP for emerging pathogens
  - WHO publishes Global Good Participatory Practice Guidelines for Trials of Emerging Pathogens

2017
- Expanded and adapted GPP Online Training
  - Including Advanced Implementer Course, GPP Leadership Course, GPP for Research Ethics Committees, and translated courses in Thai and Portuguese

- 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

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 advisory Program
  - 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 their portfolio. Significant work will need to go into introducing and embedding GPP to all processes, from regulatory bodies to ethics review bodies and scientific journal editors. The first step in this process will be identifying a set of GPP elements for clinical trials broadly, beyond just HIV prevention

Compliance Mechanisms
- 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
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 researchers and communities in a growing number of fields."

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

The Basic “Ps” for GPP

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<th>Purpose</th>
<th>Principles</th>
<th>Process</th>
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<td>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.</td>
<td>Built on principles of research ethics: Respect Mutual Understanding Integrity Transparency Accountability Autonomy</td>
<td>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.</td>
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- Udom Likhitwonnawut, Thai NGO Coalition on AIDS/ Civil Society

"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.

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.