INCREASING NATIONAL IMPACT AND UPTAKE OF GOOD PARTICIPATORY PRACTICE GUIDELINES FOR BIOMEDICAL HIV PREVENTION (GPP): THREE COUNTRY CASE STUDIES

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BACKGROUND

The *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* (GPP) provide a systematic framework for stakeholder engagement. GPP has been applied at site, network and sponsor levels to enhance trial-specific and general site operations. GPP contains recommendations, not requirements and no entity is established to ensure implementers' compliance. There is increasing interest in incorporating GPP into national trial oversight processes as a way to strengthen positive impact on research conduct and for concerned stakeholders

ENGAGING STAKEHOLDERS IN EFFECTIVE PARTNERSHIPS FOR DESIGN AND IMPLEMENTATION OF HIV PREVENTION RESEARCH IS VITAL TO ETHICALLY ROBUST, LOCALLY APPROPRIATE CLINICAL TRIALS.

We review case studies from South Africa, Thailand and Uganda. Each country is key to biomedical HIV prevention research and has implemented strong engagement and GPP programs.

NATIONAL MODELS

UGANDA

UNCST[2] oversees ethical and regulatory approval of research nationally. In 2012, UNCST initiated a revision of national guidelines for research involving humans to reflect contemporary best practices in participant protection.

GPP programs have been implemented at trial site level since 2010. GPP was cited in publications about Fem-PrEP[6] and Partners PrEP[7], two key trials conducted in the country.

Research organizations engaged UNCST in GPP efforts. Consequently, UNCST incorporated GPP principles in their national guidelines revision, setting GPP as standard practice for research.

SOUTH AFRICA

A national GPP framework was formulated out of consultations with experienced trial sites in throughout the country. Sessions included trial implementers, CABs[8], civil society representatives, local/regional REC[9] members, and NSP[10] committee representatives.

A GPP role for REC members has been explored within biomedical HIV prevention trial review. Training efforts for REC members were reviewed, identifying outstanding needs, especially training on community and stakeholder engagement. As a first step, an REC member-specific training component is being developed as part of the AVAC Online GPP Training Course.

Recently published regulations for health research with human participants recommend consultation with representatives from the participating community or other relevant stakeholders—strengthening the legal framework for stakeholder consultation in South African health research.

THAILAND

By 2012, HIV prevention research centers throughout the country recognized GPP as standard practice for community engagement and systematically implemented engagement efforts according to GPP workplans.

Building out of this work, in 2013, TNCA[3] led the establishment of a NCAB[11]. The NCAB consists of CAB members from four research institutions and one MSM[12] research-focused CAB. The NCAB serves as a coordinating mechanism for CABs, increasing their research competency and ability to provide independent input to host research organizations.

In 2014, NCAB members have begun to influence national level research oversight committees regarding stakeholder priorities for the research agenda and GPP implementation. The National Sub-Committee on Biomedical HIV Prevention, for instance, has asked NCAB members to develop a national GPP plan.

RESULTS AND NEXT STEPS

NATIONAL GPP IMPLEMENTATION EFFORTS HAVE ACHIEVED INTERIM RESULTS IN EACH COUNTRY. NEXT STEPS ARE PLANNED TO MOVE TOWARD GREATER IMPACT.

- National Cross-CAB Forum using GPP for workplanning
- GPP incorporated into national ethics guidelines, to be rolled out with RECs
- GPP to be included in REC training, with possible incorporation into review
- Robust site level implementation achieved
- Recommendation framework for national GPP implementation developed
- Buy-in achieved from national research council, regulatory council, Department of Health
- District, provincial, and/or national researcher-stakeholder engagement forums to be held
- Consideration to be made on criteria for high-impact engagement plans in protocols
- Recommendations to be rolled out in 5 provinces
- NCAB capacity built on research concepts and national research agenda
- NCAB plans to issue PrEP position statement and other advocacy actions
- NCAB members to institutionalize GPP in national research committees and HIV prevention policy and programming
- NCAB formulated positions on PrEP research and rollout

GPP ACTIVITIES AND MILESTONES

2011

Ongoing
GPP rolled out with International AIDS Vaccine Initiative partner research centers in South Africa and Uganda

July
UNAIDS/AVAC publish GPP 2nd edition

February
GPP implementation as core component of FACTS 001 trial in South Africa begins

November/December
GPP cited as standard for community engagement in clinical trials by US President Obama's Commission for Bioethics

2012

April/May
Thai Treatment Action Group publishes Stakeholder Recommendations in HIV Biomedical Prevention Trials

July
GPP presented at Uganda Annual National Research Ethics Conference as guidance for engagement in research and national adoption

October
Critical Path to TB Drug Regimens releases GPP Guidelines for TB Drug Trials

2013

May
TNCA establishes NCAB in Thailand

December
NCAB members agree on PrEP research and rollout position in Thailand

2014

May
NCAB conducts GPP seminar, involving Thai research institutions

July
Revised Uganda National Guidelines for Research Involving Humans launched, including GPP

September
GPP Online Training Course launched; adaptation for South Africa REC members begins

November
GPP themed Cross-CAB Forum held in Uganda

ACRONYMS AND REFERENCES

[6] Mack N, et al, 25 Oct 2013
[7] Ndase P, et al, 1 Jun 2014
[8] Community Advisory Board
[9] Research Ethics Committee
[10] National Strategic [HIV] Plan
[11] National Community Advisory Board
[12] Men who have Sex with Men

CONCLUSIONS

Initial steps to incorporate GPP into national mechanisms and ethico-legal frameworks supports the following conclusions:

1. National adoption can enhance sustainability of engagement beyond individual trials.
2. Guidelines and policies at national level will only be realized when put into practice.
3. Current experiences provide models for other countries.

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