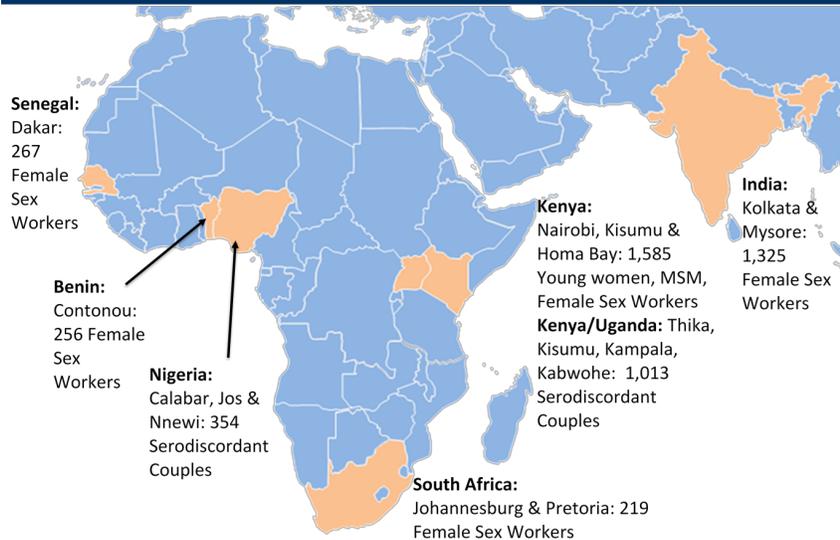


# Lessons from seven early oral PrEP demonstration projects

## Background

### BMGF PrEP Demonstration Projects



Beginning in 2013, the Bill & Melinda Gates Foundation (BMGF) funded seven oral PrEP demonstration projects in seven countries.<sup>1</sup> The projects enrolled a range of population groups: serodiscordant couples (SDC), men who have sex with men (MSM), female sex workers (FSW), and young women (YW). The settings included concentrated, mixed and more generalized HIV epidemics.

These were among the first projects to deliver PrEP to people at risk in resource-constrained settings following proof of efficacy. They offer insights that can inform

the design and conduct of future demonstration projects for HIV prevention technologies.

Demonstration projects can influence the scope and pace of normative guidance and national introduction and scale-up of a product. Early demonstration projects can help build capacity in delivering new products and understanding of these products among study staff, participants, policy makers and communities who may serve as champions for these new products.

## Analysis Overview

This piece summarizes key lessons for future demonstration projects, and a [companion document](#) outlines lessons for PrEP introduction.

All seven projects included extensive research components. The Prevention Market Manager project<sup>2</sup> aggregated and analyzed project-level data and complemented this quantitative analysis with interviews of project teams, implementers, normative agencies, Ministries of Health, and BMGF as well as a review of available publications and project documents. The full *Analysis of BMGF-Funded PrEP Demonstration Projects* is [here](#). These findings and recommendations reflect the viewpoint of PMM.

## What we learned

The following considerations are critical for *future demonstration project design*:

<sup>1</sup>Early demonstration project leaders were Benin: CHU Québec & University D'Abomey-Calavi; India: University of Manitoba, DMSC & Ashodaya Samithi; Kenya: LVCT; Kenya & Uganda: Partners/University of Washington; Nigeria: National Agency for the Control of AIDS; Senegal: African AIDS Research Council; South Africa: Wits RHI

<sup>2</sup> Through the [HIV Prevention Market Manager \(PMM\) Project](#), AVAC and CHAI seek to facilitate an efficient and effective rollout of HIV prevention products.

**Go big or go home.** The projects ranged in size from 219 to 1,585 PrEP initiators, but most had fewer than 500 participants. Only one included young women and MSM. Such small projects make it extremely difficult to translate the lessons to national scale-up without additional demonstration projects. Enrollment overall and by population needs to be large enough to provide meaningful results. If a suite of projects is funded, the projects should be designed so that results can easily be aggregated and compared. For example, data collection and analysis related to key indicators such as contacts, initiation, retention, and so forth should be consistent across projects.

**Start early and deliver results quickly.** Planning for these projects began while clinical trial results were still being analyzed and prior to normative guidance. Projects were able to catalyze momentum following efficacy findings and some were able to deliver results in time to inform immediate national scale-up. Demonstration projects and delivery of analysis and results should be practical and planned so they can inform even ambitious decision-making timelines.

**Coordinate.** Staff from these seven projects met periodically, compared experiences and developed a common report structure. Over the life of these projects, more than 140 additional demonstration projects were funded and started, but the lack of coordination among funding and implementing agencies meant that insufficient attention was paid to mitigating unnecessary duplication in project design, to sharing lessons or aggregating data for policy makers and normative agencies. Governments and funders should ensure that approval of future demonstration projects is contingent on clear articulation of the way each proposed project complements and adds to existing or ongoing evidence.

**Non-Negotiable**  
**Participant access to the product following a demonstration project must be ensured.**

**Emphasize early and open dissemination.** Findings from most of these projects were slow to be disseminated due in part to delays in approvals and implementation, and to prioritizing publication of the results. Donors and implementers of demonstration projects should reorient incentives and deliverables to emphasize timely access to information that can be used for decision-making by policy makers and providers throughout the life of the project. Interim analyses can inform policies in real-time.

**Orient projects toward implementation over research.** These seven projects were designed as research projects and were, to some extent, constrained by their protocols. Ideally, demonstration projects would be designed to be nimble and responsive to changing external circumstances (such as rapidly developing interest in product implementation) and mirror real-world conditions (including clinical and support services that are replicable in rollout). To inform delivery at scale, we recommend engaging a range of actors in demonstration project design from the outset: community members and advocates, as well as experts in implementation research, service delivery, new product introduction, and behavior.

**Answer questions that are most important to countries and normative agencies.** The projects demonstrated the feasibility of initiating clients on PrEP across a range of settings and populations. However, study questions and findings did not always align with the topics and issues prioritized by implementers, policy makers and WHO. By the time PrEP introduction was imminent, policymakers were interested in how to deliver PrEP in communities and identify those who would benefit most from PrEP, patterns of use, and adherence support, among other factors. Ensuring that demonstration projects are answering the most critical questions of WHO and countries considering product scale-up would speed product introduction.