



### PrEP: A piecemeal search for a niche

In last year's *AVAC Report*, we called for a core set of PrEP demonstration projects. While there has been some progress toward that end, there is no overarching strategy. The majority of planned and ongoing projects are taking place in the United States, and many of the international projects are open-label or follow-on demonstration projects being conducted by the research sites and teams that conducted the PrEP efficacy trials that found benefit (for a lexicon of post-trial evaluations, see page 39).

Research teams have a critical role to play in moving a strategy like PrEP forward. But government AIDS control programs are also key in moving towards roll out. Now is the time to forge these linkages. Without them, open-label extension studies may be seen more as an extension of the research than part of a national effort to evaluate a new strategy. (As one case in point, consider Uganda, where the Partners Demonstration Project is ongoing, but the AIDS Control Program head has already declared that PrEP isn't going to be added to the country's prevention programming.)

The current array of demonstration projects will provide useful information, as will other open-label studies and an array of projects in the United States. But, overall, this is still a piecemeal search for a niche for this potentially powerful product. There is no overarching strategy for ensuring that demonstration projects answer key questions pertaining to PrEP in sex workers, men who have sex with men (MSM), or serodiscordant couples. This doesn't mean that PrEP won't end up being used by or offered to these groups. But the current demonstration projects will leave gaps in the knowledge that could be used to build effective programs.

This suite of demonstration projects may be all that happens. Accepting this reality, there are still next steps that can be taken to maintain momentum. Specifically:

- **Normative agencies and funders and other partners working on demonstration projects should provide a cohesive analysis of the kinds of information that the current suite of projects will and will not provide—** explaining what will be known, and when.

- **Normative agencies, research funders and early-adopter countries should articulate what guidance will be expected or needed in three to five years:** what comes after the current guidance on demonstration projects, and the mention of PrEP in the WHO’s comprehensive ARV guidelines?
- **A multi-stakeholder group that includes funders, researchers, policy makers and advocates from countries where PrEP might be introduced should collaborate on forward-looking strategy to fill specific gaps**—such as whether and how to introduce PrEP to African MSM, the gender dynamics of PrEP and treatment as prevention in serodiscordant couples; the acceptability of PrEP to sex workers—who are the focus of several demonstration projects.

### Planned PrEP Demonstration Projects in Resource-Poor Settings as of December 2013

There are a range of planned or ongoing demonstration projects or open-label extension studies happening in the United States and Europe. This table includes those few projects in resource-poor settings that are not linked to one of the efficacy trials. A complete list is available at [www.avac.org/prep](http://www.avac.org/prep).

Trial/project	Sponsor/funder	Location	Population	Status
Partners Demonstration Project	Led by a team of scientists from Kenya, Uganda and the US; funded by NIMH/NIH, USAID and BMGF	Kenya, Uganda	Serodiscordant couples	All four sites open and enrolling as of August 2013; results expected in 2016.
LVCT and SWOP	Implemented by national partners in collaboration with WHO, UNAIDS, O’Neill Institute of Georgetown University, London School of Hygiene and Tropical Medicine, Imperial College London; funded by Bill & Melinda Gates Foundation	Kenya	Young women, female sex workers and MSM	Formative research in planning phase.
Nigerian National Agency for the Control of AIDS		Nigeria	Serodiscordant couples	Formative discussions underway.
Wits Reproductive Health and HIV Institute		South Africa	Female sex workers	Expected start date of February 2014, with expected completion September 2016.
Durbar (DMSC) and Ashodaya Samithi		India	Female and transgender sex workers	Feasibility study underway.
Implementation of PrEP	Oswaldo Cruz Foundation	Brazil	MSM and transgender women	Starting January 2014.

### Voluntary medical male circumcision: Non-surgical devices poised on the brink—with questions on price, positioning and more

In April, the World Health Organization prequalified PrePex, a nonsurgical device which allows adult male circumcision without the use of sutures.<sup>4</sup> Other devices are in development. A guidance note for integrating these devices into VMMC programs is forthcoming. Studies have launched to evaluate the safety, feasibility, and ideal service delivery models for device-based circumcision.

Information from the evaluation studies will clarify the anecdotes and assumptions that currently characterize talk about the device—with positive comments like “it will be quicker, easier, cheaper” countered by stories of odor, discomfort or early displacement of the device, which must be worn for seven days. PEPFAR, which has funded the bulk of surgical male circumcision procedures worldwide, is also conducting many of these device evaluation studies. There is close coordination among the studies in different countries. Since PEPFAR is also an implementing partner for existing surgical VMMC programs, there is a clear

<sup>4</sup> WHO. "Information on the PrePex device for adult male circumcision for HIV prevention." [http://www.who.int/hiv/topics/malecircumcision/prepex\\_device\\_update/en/2013](http://www.who.int/hiv/topics/malecircumcision/prepex_device_update/en/2013) (accessed December 1, 2013).