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).

<table>
<thead>
<tr>
<th>Trial/project</th>
<th>Sponsor/funder</th>
<th>Location</th>
<th>Population</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners Demonstration Project</td>
<td>Led by a team of scientists from Kenya, Uganda and the US, funded by NIMH/NIH, USAID and BMGF</td>
<td>Kenya, Uganda</td>
<td>Serodiscordant couples</td>
<td>All four sites open and enrolling as of August 2013; results expected in 2016.</td>
</tr>
<tr>
<td>LVCT and SWOP</td>
<td></td>
<td>Kenya, Uganda</td>
<td>Serodiscordant couples</td>
<td>Formative research in planning phase.</td>
</tr>
<tr>
<td>Nigerian National Agency for the Control of AIDS</td>
<td>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 &amp; Melinda Gates Foundation</td>
<td>Nigeria</td>
<td>Serodiscordant couples</td>
<td>Formative discussions underway.</td>
</tr>
<tr>
<td>Wits Reproductive Health and HIV Institute</td>
<td></td>
<td>South Africa</td>
<td>Female sex workers</td>
<td>Expected start date of February 2014, with expected completion September 2016.</td>
</tr>
<tr>
<td>Durbar (DMSC) and Ashodaya Samithi</td>
<td></td>
<td>India</td>
<td>Female and transgender sex workers</td>
<td>Feasibility study underway.</td>
</tr>
<tr>
<td>Implementation of PrEP</td>
<td>Oswaldo Cruz Foundation</td>
<td>Brazil</td>
<td>MSM and transgender women</td>
<td>Starting January 2014.</td>
</tr>
</tbody>
</table>

**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. 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

---

route for moving from the results of these studies to broader introduction in public health programs.

This year AVAC will be looking for these evaluation studies to provide clear, concise information about men’s and women’s experiences with and perceptions of devices, provider attitudes, resource needs and the cost-effectiveness of these devices compared with standard surgical procedures. This information should guide decisions about where to introduce non-surgical devices—and where they should not be scaled up.

For non-surgical devices to be introduced, they must be affordable. As AVAC Report went to press, such a price still hadn’t been determined for PrePex, the one device that has been prequalified by WHO to date. The manufacturer, Circ MedTech is in negotiations with the Global Fund to Fight AIDS, Tuberculosis and Malaria and PEPFAR on possible bulk procurement, which could lead to a drop in the currently quoted price of US$20 per device plus an estimated US$6 for the accompanying supply kit. At this price, non-surgical circumcision using PrePex isn’t cost-effective compared to surgical procedures. The device should be affordable—equivalent to and/or cheaper than surgical procedures—to move forward. Additional research

---

There is a range of evaluation studies underway to learn more about how non-surgical devices can be used for adult male circumcision. These evaluations, also called implementation pilots, address questions about safety, efficacy, etc. The World Health Organization has already determined that one device, known as PrePex, meets required standards of quality, safety and efficacy for international use. Evaluations of PrePex and other devices will provide information on how to use these strategies in the real world. Most evaluations are enrolling, ongoing or recently completed. Results can be expected within a year.

For up-to-date information on voluntary medical male circumcision visit malecircumcision.org and avac.org/malecircumcision.

- **Manage expectations**: these devices aren’t automatically simpler, cheaper or preferable to surgery.
- **Use evaluation studies to flesh out cost-effectiveness models** comparing surgical versus non-surgical procedures.
- **Set a fair, affordable price for the device.**
- PEPFAR and other device evaluation teams should help ensure that ministries of health and other decision makers receive balanced information on the devices from a range of sources—including advocates, modelers and implementers, as well as the companies marketing the products.