- **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.*

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.

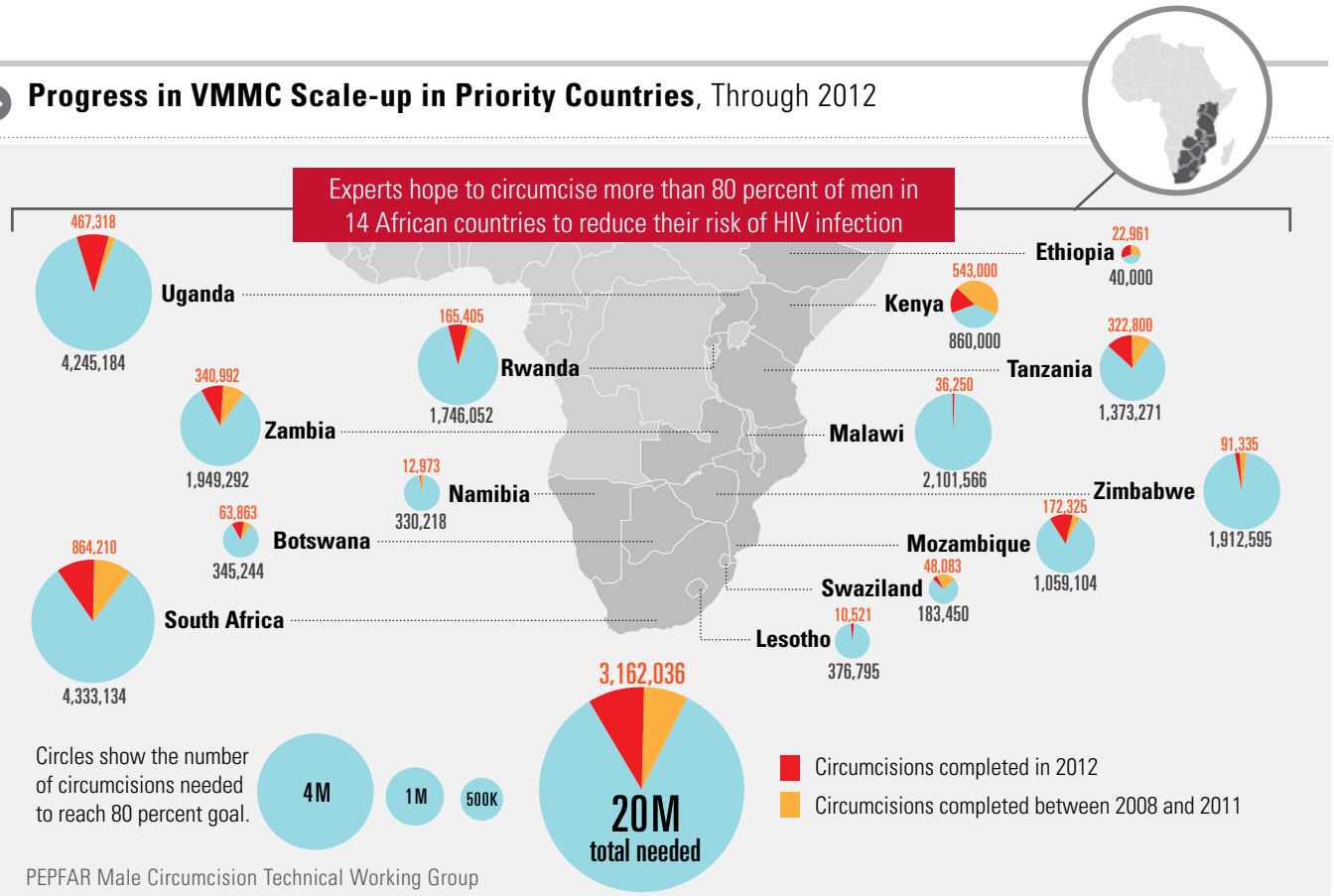
Voluntary medical male circumcision: Non-surgical devices poised on the brink—with questions on price, positioning and more

In April, the World Health Organization prequalified PrePex, a nonsurgical device which allows adult male circumcision without the use of sutures.[4] 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

[4] 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* (accessed December 1, 2013).

Progress in VMMC Scale-up in Priority Countries, Through 2012



PEPFAR Male Circumcision Technical Working Group

Counting Cuts: Getting better at monitoring VMMC

Circumcision should be one of the easiest things to monitor—yet the numbers are out of date. As *AVAC Report 2013* was going to press, total figures for 2012 had just been released. The good news is that the updated figures showed even greater progress than has already been documented. Scale up is moving in the right direction. The problem is that without regularly updated figures, country- and global-level planning efforts are hampered. It is hard to identify gaps in funding by donors or country governments—and to identify countries that are doing exemplary work that can provide insights for their neighbors. To stay on track to begin to end the epidemic, it is critical to track progress in real time. Monitoring and reporting needs to improve—VMMC is one area to watch.

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.[5] 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

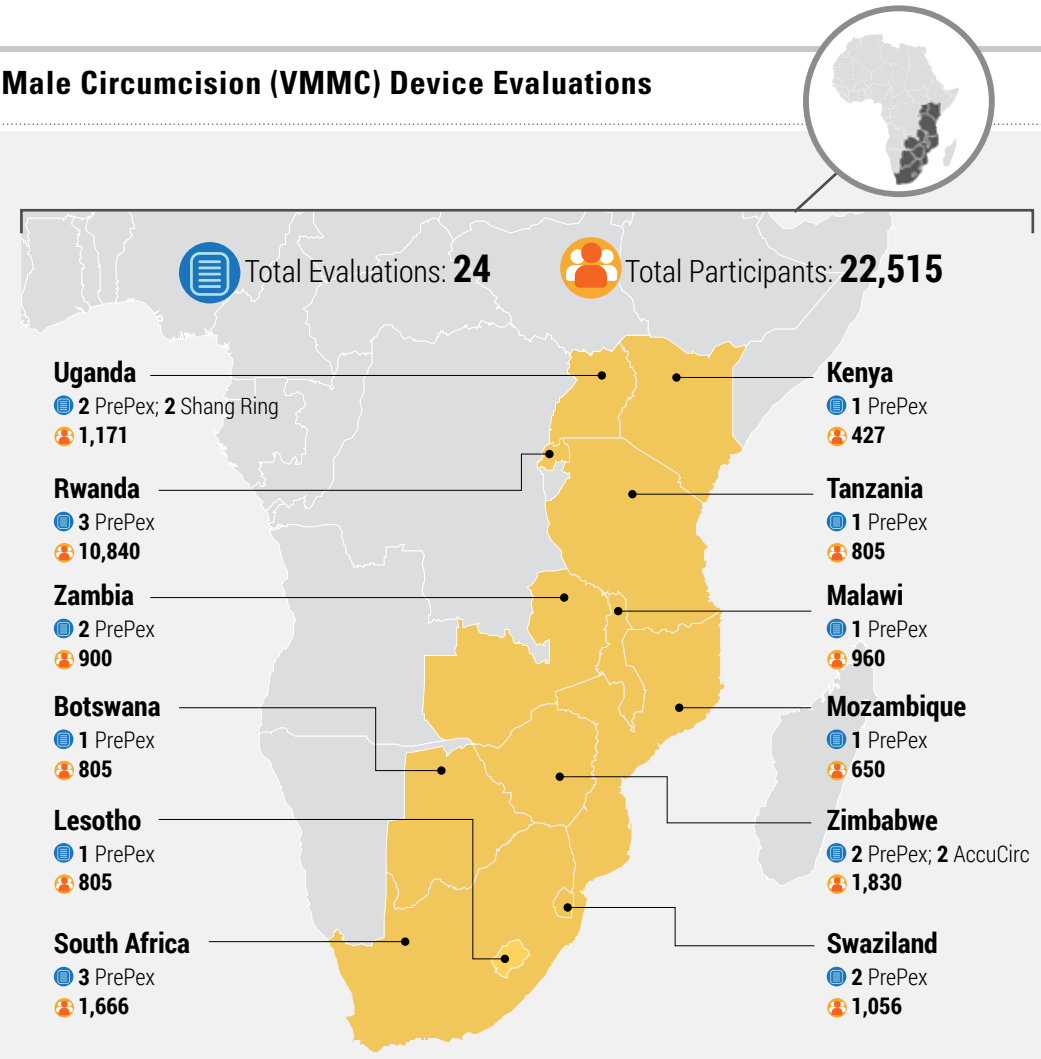
[5] Njeuhmeli, E. "Voluntary medical male circumcision: Summary of Devices Costing and Modeling Studies." PEPFAR (2013) *http://www.malecircumcision.org/resources/documents/6-ENjeuhmeli-Summary%20Device%20Costing%20Studies.pdf* (Accessed December 1, 2013).

is needed to understand whether introduction of devices would affect overall demand for male circumcision; what the incremental costs of adding devices to existing surgical programs would be; and where cost-savings for surgical and non-surgical programs could be found. To keep non-surgical device introduction on track, it is key to:

- **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.

Voluntary Medical Male Circumcision (VMMC) Device Evaluations

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.*