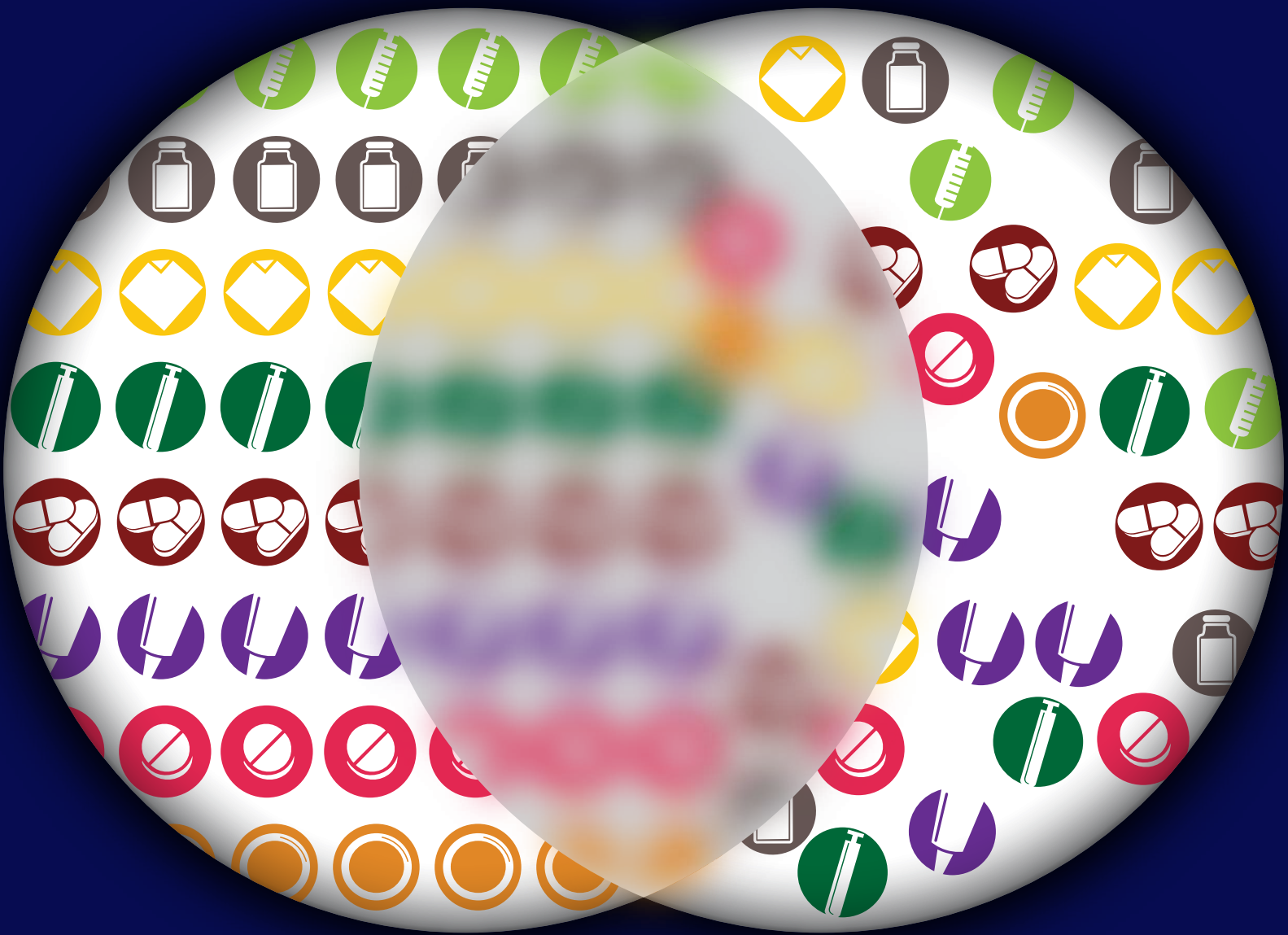


# AVAC REPORT 2013: Research & Reality

## EXECUTIVE SUMMARY



[www.avac.org](http://www.avac.org)

# Research & Reality

This year's *AVAC Report* is about the new realities of biomedical HIV prevention research.

In the last few years we've seen major advances, but also have had sobering realizations about the difficulties of developing new HIV prevention options that can succeed both in trials and programs in the real world. Landmark vaccine, microbicide and PrEP trial results energized the biomedical HIV prevention field. Yet, follow-up work from all these trials has been slower than necessary. In the search for new prevention tools for women two recent trials have found very low rates of adherence. These trials have given rise to important questions, not only about women's willingness to use the test product, but about the research process itself.

None of the challenges is a complete surprise. But even the issues that were anticipated—e.g., adherence to daily prevention strategies and scaling up beyond pilot projects—are far more complex in reality. Today the field has a depth of experience that should be reflected in future actions. Now is the time for better problem solving, more critical thinking and coordinated action.

We argue that the field needs to take a fast, focused look at fundamental assumptions and missed opportunities across the HIV prevention research field—and retool its approaches so that the next generation of research delivers advances that women and men want and will use.

## Research Reality Checks

*AVAC Report 2013* looks ahead to the coming year with four key recommendations on issues that lie at the intersection of research goals and real-world conditions.

- Launch complex trials to answer complex questions.** Clinical trials can seem like a detour from our attempt to control AIDS with the tools available today. This is especially true when the proposed trials are complex and costly—and are part of research agendas that could take years to have a concrete impact. But in many areas, including AIDS vaccines, as well as hormonal contraception and HIV risk, this research is critical and must proceed.
- Map rollout beyond pilot projects.** Pilot projects help move clinical research findings into the real world. They are a chance to learn how to deliver a new product. But pilot projects and normative guidance don't guarantee introduction. In 2014, donors, implementers and national governments need to review progress in pilot

projects of daily oral PrEP and non-surgical devices for medical male circumcision—and launch strategic implementation plans where appropriate.

- Invest in innovative approaches to virologic suppression.** Simply starting antiretroviral therapy (ART) doesn't preserve a person's health or prevent HIV transmission. What matters is sustained treatment and suppression of HIV. Advocates need to make the case for investment in treatment adherence programs, better viral load monitoring in resource-poor settings, and sustained research into new antiretroviral treatments, therapeutic vaccines and functional cures.
- Align programs, models and funding to stay on track to end AIDS.** Models are being used to set targets and define core interventions for high-impact prevention in many settings. In 2014, models and programs need to be connected in a feedback loop so that models are informed by research, programs are informed by models and models are improved by real-world experience. This requires sustained funding and visionary leadership at national and international levels.

## Refocusing the Women's HIV Prevention Research Agenda

This report's central focus is the search for female-initiated prevention options. Today, there are only three ongoing efficacy trials of biomedical prevention strategies—and all of them involve vaginal microbicides. These trials are being tracked with interest and concern, in large part because of

adherence challenges in some recent studies. Whether positive or not, the results will shape the field. But we cannot wait until the data are in to take action. Now is the time to articulate a broad and ambitious approach to finding new prevention tools for women.

### Our Top-Line Recommendations for Women's Prevention Research



#### **Don't abandon vaginal gels and other user-dependent methods for women.**

There are competing interpretations of what low adherence in past trials says about the products women will and will not use—and why. Funders and research teams need to use smart research and trial design to move past competing views and generate plans for innovative trials.

#### **Keep searching for methods to improve adherence and measure their effectiveness to determine what works.**

Many new adherence measures are being used in trials today. Funders and trial networks need to sustain investment in innovation and evaluation of approaches to identify ones that work—and those that don't.



#### **Invest in research to better understand why participants—especially women—enroll in trials.**

It's clear that there are many reasons why people enroll in a trial and use (or do not use) a product. If these reasons are not well defined by researchers and communities, products may be discarded unnecessarily.

#### **Plan for success, so that valuable time—and the opportunity to reduce new infections—isn't wasted after positive trial results.**

Delays experienced with the rollout of PrEP and voluntary medical male circumcision (VMMC) should not be repeated in other areas. Researchers need to begin defining a core package of demonstration projects for products that are currently in efficacy trials.



#### **To help ensure clear efficacy findings trials should seek to select participants who are most likely to adhere to a product regimen.**

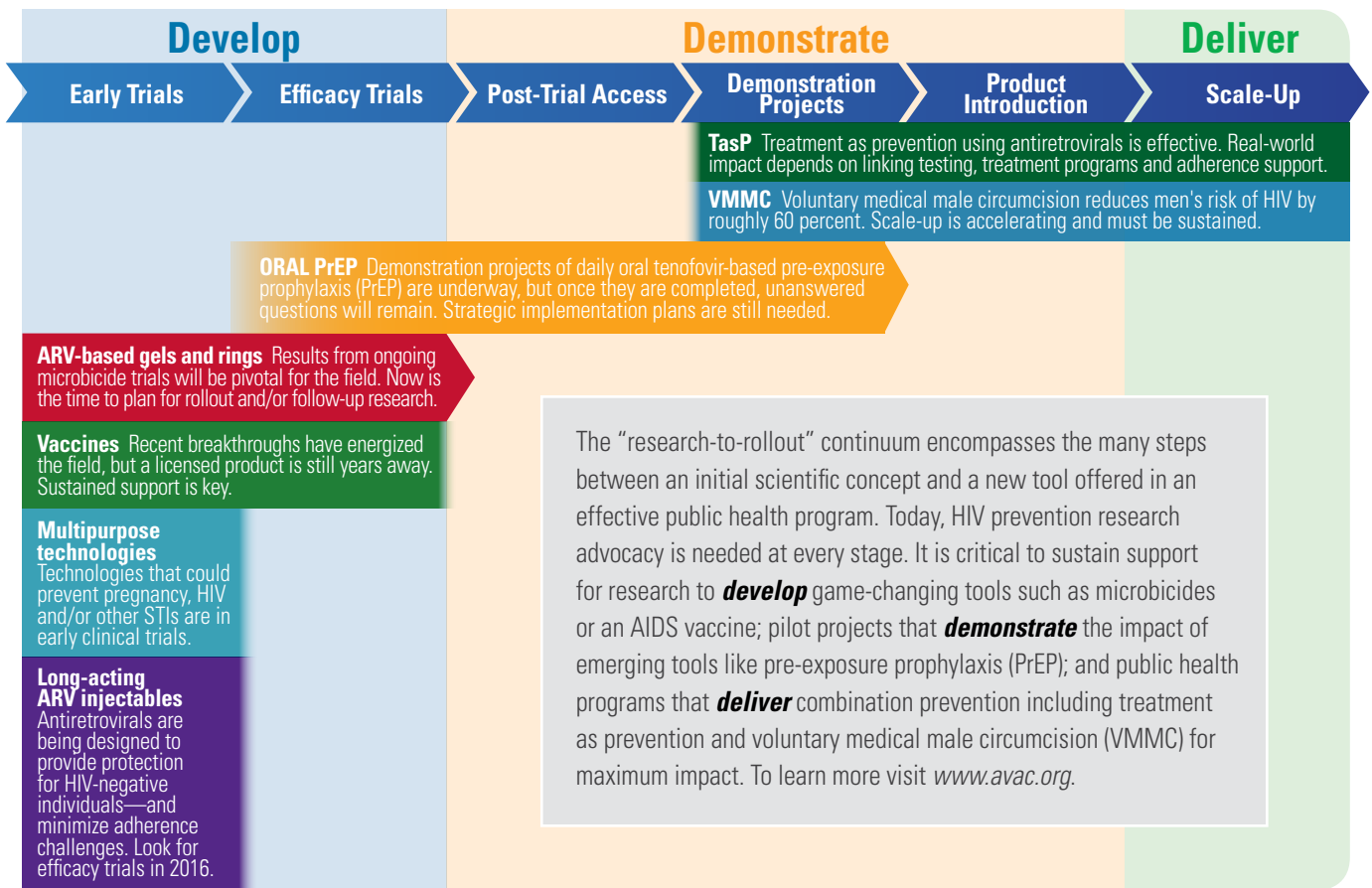
The women who most need new HIV prevention strategies may have difficulty adhering to a product regimen in a clinical trial. Trial designs and follow-up plans should reflect this reality.

#### **Prioritize informed civil society involvement to build a community of champions in support of an eventual product.**

For new prevention options to make a difference, community support is essential—even with the most well designed trials and products.



➔ **The HIV Prevention Research-to-Rollout Continuum, December 2013**



**About AVAC**

Founded in 1995, AVAC is an international non-profit organization that uses education, policy analysis, advocacy and community mobilization to accelerate the ethical development and global delivery of biomedical HIV prevention options as

part of a comprehensive response to the pandemic. AVAC works in partnership with organizations and individuals in countries and communities impacted by HIV around the world. To learn more about our programs, and to join our network visit [www.avac.org](http://www.avac.org).



For the latest updates in HIV prevention, visit the AVAC website at [www.avac.org](http://www.avac.org). It includes our publications, as well as comprehensive coverage of the full range of biomedical HIV prevention interventions in an easy-to-use format. You can sign up for email updates, order publications, explore our databases of HIV prevention clinical trials and research literacy tools, and learn about our partners and programs.



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