

# Change Assumptions, Raise Awareness

## Key Facts and Messages to Use on HIV Vaccine Awareness Day 2011

May 2011

Did you know that AIDS vaccine research is as energized as it has ever been?

If you did, that's great—and if not, you're not alone. As HIV prevention research advocates work to understand the implications of the FEM-PrEP, iPrEx, CAPRISA 004—all trials that tested ARV-based prevention in HIV-negative people—vaccines have received less attention. This HIV Vaccine Awareness Day (HVAD), we hope you'll use the conversations you have been having with your various partners and allies to change some assumptions and raise awareness about AIDS vaccines, with a specific focus on developments related to the Thai prime-boost vaccine trial (RV144), the first AIDS vaccine trial to show evidence of protection

**Here are some key facts to incorporate into your advocacy work.** (There is more background on each of these points below.)

- The result from the Thai prime-boost vaccine trial (RV144) remains key evidence that an AIDS vaccine is possible.
- Results from the search an explanation about why the vaccine strategy evaluated in the Thai “prime boost” trial protected some people will be available later this year
- Over the next 12–24 months, there will be a range of developments to confirm and expand on the result in a way that could lead to licensure.

**Here are some key messages:**

- An AIDS vaccine is possible and as necessary as ever—even with the findings from PrEP and ARV-based microbicide trials. In fact, the best scenario for ending the epidemic is if we have all these new tools and more.
- The AIDS vaccine field is “following the science” of the RV144 result, and, while it could have moved faster, many key steps are taking place.
- Next steps will involve more communities, including gay men and other MSM, within Thailand and will also expand to other regions of the world including sub-Saharan Africa. Advocates throughout sub-Saharan Africa and other hard-hit regions, as well as communities of gay men and other MSM are needed to follow, influence and monitor the field.
- It is time to change assumptions that an AIDS vaccine is impossible, or impossible for Africa, or impossible in our lifetimes. Let's raise awareness of what is possible given the right resources and leadership.

**Background for the key facts:**

*The result from the Thai prime-boost vaccine trial (RV144) remains key evidence that an AIDS vaccine is possible.*

RV144 was a 16,400-person trial of a vaccine strategy comprised of an ALVAC prime and an AIDSVAX boost. ALVAC uses a canary-pox vector to present small synthetic fragments of HIV to the immune system. AIDSVAX is a synthetic version of an HIV surface protein. In September 2009, the world learned that there was evidence of modest protection among the Thai volunteers in RV144. After three years of post-vaccination follow-up, there were 51 infections among people who received the vaccine and 74

among those who received the placebo. The observed level of benefit of 31.2 percent was statistically significant with a p-value of 0.04 and a 95 percent confidence interval having a lower bound greater than zero. [For more in RV144 visit [www.avac.org/rv144](http://www.avac.org/rv144).]

*Results from the search an explanation about why the vaccine strategy evaluated in the Thai prime-boost trial protected some people will be available later this year*

Once the Thai trial data were released, the broader AIDS vaccine community became engaged with the search for an explanation for the apparent protection. The result is a collaborative effort among many different laboratories. More than 20 different assays (evaluations of different types of immune function) will be conducted on the available samples from the Thai volunteers. These assays will compare immune responses in vaccine recipients who remained HIV-negative and those who acquired HIV during the course of the trial. (The main risk factor for participants was unprotected sex; the vaccine itself cannot cause HIV.) Data from this endeavor are anticipated by the third quarter of this year. If there is a clear answer about which immune responses were associated with protection, this will help guide future product selection and design.

In the coming months, AVAC will publish a longer analysis of the state of the field, including an assessment of what the RV144 trial suggests about leadership, coordination and funding needs for the future.

While it is important to maintain a watchful, critical eye on the clock—and we urge speed and efficiency going forward—it is also critical for advocates to raise awareness that follow-up research has been planned and will launch in the coming years.

*Looking out over the next 12–24 months, there will be a range of developments to confirm and expand on the result are critical steps toward licensure trials.*

Things to watch for in the next 12–24 months include:

- Results from the RV144 correlates of protection analysis some time in the third quarter of this year.
- Finalized protocols for follow-on trials using regimens closely related to the RV144 strategy.
  - One of these trials will likely take place in Thailand and enroll gay men and other men who have sex with men. RV144 enrolled a low risk, general population cohort. A trial of a similar strategy in gay men will provide information about whether the regimen works in a population at higher risk.
  - Another trial is likely to take place in southern Africa and will test a regimen related to the RV144 strategy in one of the regions of the world where a vaccine is needed most.

***The bottom line: An AIDS vaccine is possible. Advocates need to watch, inform and engage in ongoing efforts that could potentially include several ambitious, complex clinical trials. Visit [www.avac.org](http://www.avac.org) for more information and updates.***