



AIDS VACCINES AT THE CROSSROADS

EXECUTIVE SUMMARY

When the AIDS Vaccine Advocacy Coalition (AVAC) was formed on World AIDS Day in 1995, we were optimistic that with more resources, more cooperation and more scientific knowledge, an AIDS vaccine could be found in time to stem the growing epidemic. A decade later the field has more resources, more cooperation and more depth of scientific knowledge—but still no AIDS vaccine.

While we've learned much in the past decade and made great strides in scientific, policy and ethical arenas, the road ahead is still a long one. We travel this road with thousands of others—researchers, policy makers, advocates, trial volunteers and their communities. Thousands more will need to join us before we reach our goal.

In the *AVAC Report 2005: AIDS Vaccines at the Crossroads*, we lay out what we see as some of the major challenge areas we all will face and offer recommendations for navigating them.

We are also increasingly aware that the global terrain on which trials will be conducted and a vaccine will eventually be provided is rapidly changing. The overall global response to the AIDS epidemic is also at a crossroads.

- + The raging global pandemic increases both the need for, and the complexities of, bringing vaccine prevention to the world.
- + Provision of existing prevention options and trials of new prevention technologies present the world with difficult research design and ethical issues.
- + Though treatment programs are receiving needed priority and attention, access to treatment is still far short of need.

We realize that future AIDS vaccine trials and eventual rollout will be done in the context of other prevention trials, changing required baseline standards of prevention and care, and evolving knowledge expectations and involvement of the communities where trials will be conducted.

AVAC is committed to continuing to be a voice in the ongoing discussions about these issues. For example, the 2005 AVAC Report includes an article to follow up on our report on the trials of tenofovir as pre-exposure prophylaxis (PREP), published earlier this year.

As we work to accelerate the development of a safe and effective AIDS vaccine, many of the thousands of new volunteers will come forward in the face of fear, uncertainty or stigma, and at a time when there is increasing public concern about medical research. There is a growing need to ensure adequate scientific and research literacy among trial volunteers and communities so that individuals can make informed decisions about participation. And there is also a need for researchers to increase their community literacy—to understand the needs, motivations and expectations of the communities from which volunteers will be drawn.

All of us in the global community of researchers, policy makers and advocates must work together to ensure that trial participants can have the understanding and confidence they need to be a part of the global enterprise of AIDS vaccine development.

In this report, we offer recommendations for the field in general, the Global HIV/AIDS Vaccine Enterprise, policy makers, researchers and communities. Some of these recommendations will be familiar because we've made them before, and we reiterate them because we believe they are still needed and useful. We also provide an update on tenofovir PREP research.

And some analysis and recommendations are new. For example, we take an in-depth look at intellectual property issues and offer some “small step” recommendations that we believe will help move the field forward.

So, we stand here at a crossroads. We know that our roadmap is ever-evolving and by definition cannot be straightforward.

We at AVAC are committed to always finding and nurturing a diverse cadre of new AIDS vaccine advocates all over the world. We are committed to strengthening the worldwide

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coalition of humans who understand and support the road to a vaccine. And we are enthusiastic about our role and the work ahead of us in the next years.

We hope you will find the report useful and re-energizing, and we look forward to your feedback and guidance on how the AIDS Vaccine Advocacy Coalition might best help to pave the road forward.



WHAT AVAC RECOMMENDS IN AIDS VACCINES AT THE CROSSROADS

In *AIDS Vaccines at the Crossroads*, AVAC documents what we see as the needed tasks in the search for an AIDS vaccine during a time of redirection. In brief, our list of resulting recommendations includes:

For AIDS Vaccine Scientists:

- + Carry out a smart, evidence-based science agenda, even when that means giving up once favored products, combinations or trials that lack incrementally superior data.
- + Tell everyone the basis for those decisions and explain them in ways all stakeholders can understand.
- + Do prompt work on important areas of new constructs such as mucosal or innate immunity.

For the Global HIV/AIDS Vaccine Enterprise and Other Collaborations:

- + Set technical and legal procedures to facilitate knowledge sharing.

- + Be forthright and public about overcoming intellectual property obstacles that might inhibit private sector involvement.
- + Overcome those obstacles with model and public sharing arrangements, harmonization and reasonable reward distribution.

For Funders:

- + Supplement existing mentoring and investigator grant programs that expand the number of young scientists, especially international scientists, who make this work their career.
- + Rich country governments that have not yet invested adequately in AIDS care, prevention and research need to step up their efforts.

For Clinical Trial Leaders

- + Listen carefully to civil society and communicate openly and often with the communities on whom, for whom, and with whom research is performed.
- + More fully integrate prevention, testing and treatment with clinical trials.
- + Researchers testing tenofovir as pre-exposure prophylaxis need to better coordinate their studies and determine whether additional trials are needed. Collaborative efforts among trial sponsors and communities are urgently needed to address ethical and other concerns.

For the Blueprint and Roadmap Makers:

- + On the many different organizational blueprints and agendas, you've said what you mean. Now is the time to mean what you say. The science agendas are great ones. Now implement them with due speed and enthusiasm!
- + Examine past experiences of setting milestones and learn about common pitfalls made in establishing processes and making projections, then use that information as a reality check for the future.

For Government Policy Makers and Influencers:

- + Support some of the current Bioshield II legislation in the US for infectious disease but amend it to correct problems with both its liability and its intellectual property incentives features.

- + Organize advance purchase incentives as soon as possible and create additional incentives for vaccine developers.
- + Provide open public access to research results including peer-reviewed articles of work funded by taxpayer dollars.
- + Support the research collaborations, and keep them continually accountable. But don't underestimate the power of independent research.

For All AIDS Vaccine Stakeholders and Advocates:

- + Press forward with both existing prevention methods and expanded access to treatment that are responsive to local needs and demands today.

AIDS Vaccines at the Crossroads includes the following sections:

THE PAST YEAR: UPDATE, ANALYSIS & RECOMMENDATIONS

reviews the past year and provide an update and analysis on several key issues for the field including:

- + The **Global HIV/AIDS Vaccine Enterprise** and what we can expect as it begins to implement its scientific plan.
- + **New directions in collaboration**, including CHAVI, OCTAVE, PAVE and the forthcoming Gates Foundation grants.
- + What the **Adeno5 proof of concept trial** and others to come mean for the field.
- + The importance of **making go/no-go decisions more quickly and accurately**.
- + How **promising antibody and mucosal immunity research** may accelerate the development of new candidates into the pipeline.
- + The increasing importance of **developing world research collaborations**.

GET ENTERPRISING is an open letter to the soon-to-be-named executive director of the Global HIV/AIDS Vaccine Enterprise, detailing the eight key issues we believe the new director should tackle from the first day on the job. These include:

- + **Communicate frequently and transparently.** Reach out to all of those who are working with and interested in the field.
- + **Set policies for sharing and coordination of data and technology.** Put publicly available policies and procedures into place to ensure full and fair sharing of data and technology.
- + **Ensure the ability to take risks.** Seek out and foster innovation in basic research, vaccine development, community advocacy, and regulatory and intellectual property issues and other areas.
- + **Bring new investigators into the search.** Ensure that there are adequate incentives for young researchers (from developed and developing countries) to enter the field.
- + **Make the Enterprise truly global.** Seize the opportunity to be a truly global leader and reach out to all who have contributions to make.
- + **Involve civil society in a meaningful way.** Work to incorporate civil society's valuable insights into the framework of the Enterprise.



- + **Take on the politics and ethics of clinical trials.** The Enterprise cannot focus only on scientific bottlenecks and leave the political and ethical bottlenecks to resolve themselves.



- + Establish realistic milestones and a process for monitoring progress. Within the first six months on the job, you should articulate a set of milestones for the Enterprise to achieve over the next two years.

FOLLOW THE MONEY: MONEY, DEVELOPMENT & RESEARCH

looks at the state of funding for AIDS vaccine research and development in the context of increased attention to global development issues and the changing landscape of access to treatment and existing prevention. We also provide an update on legislation in the US that will affect AIDS vaccine development.

INTELLECTUAL PROPERTY AT THE CROSSROADS: UNIQUE CHALLENGES FOR AIDS VACCINES

examines the ways in which intellectual property issues affect the ability of researchers to test the best vaccine concepts. We offer recommendations for overcoming some of the major barriers to cooperative AIDS vaccine research, including:

- + Expansion of existing consortia and patent pools.
- + Use of preclinical “covenants not to sue.”
- + Harmonization of intellectual property rules and regulatory issues across jurisdictions.

- + Commitments to access or benefits for populations where vaccines are tested.

- + New systems for sharing protected data.

DON'T SHOOT THE MESSENGER: AN UPDATE ON TENOFOVIR RESEARCH

examines how controversies surrounding clinical trials of tenofovir have brought a number of festering issues in international clinical research to public attention. We reiterate the recommendations we made earlier in the year, including better coordination among disparate trials and multiple sponsors and more planning and preparation for making tenofovir globally accessible if it is widely licensed for use as PREP.

ADVOCATES' WORK IS NEVER DONE

looks back at the road we have traveled for the last decade and ahead to where the field, and we as advocates, may be headed. We lay out our vision of where the science is and ask other advocates to work with us to marshal the politics, human-to-human communication, good journalism and commitment needed to facilitate the increased advocacy and policy incentives that will help keep the field moving forward.

The full version of *AIDS Vaccines at the Crossroads* is available online at www.avac.org, or to request a print copy, email avac@avac.org.

THE AIDS VACCINE ADVOCACY COALITION (AVAC)

Founded in 1995, the nonprofit AIDS Vaccine Advocacy Coalition (AVAC) is dedicated to accelerating the ethical development and global delivery of vaccines for AIDS. AVAC does not accept funding from government or the pharmaceutical industry. This publication and AVAC's continuous policy, advocacy, and outreach work is made possible by the dedicated labor of AVAC advocates and support from Broadway Cares/Equity Fights AIDS, the Ford Foundation, the Bill & Melinda Gates Foundation, the International AIDS Vaccine Initiative, The Overbrook Foundation, Until There's A Cure Foundation, the WHO-UNAIDS HIV Vaccine Initiative, and many generous individuals who have become AVAC members. AVAC is an IRS-certified 501(c)3 tax exempt organization, and donations are tax deductible.

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