

VAX

AN IAVI REPORT
BULLETIN

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VAX is a monthly bulletin featuring shorter, non-technical versions of articles from the *IAVI Report*, the newsletter on AIDS vaccine research published by the International AIDS Vaccine Initiative. VAX is currently available in English, French, German, Spanish and Portuguese as a pdf (www.iavi.org/iavireport) or an e-mail bulletin. If you would like to receive VAX by e-mail, please send a request including language preference to: VAX@iavi.org

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SPECIAL REPORT:

◆ XV International AIDS Conference, Bangkok

In July more than 19,000 people from around the world gathered in Bangkok, Thailand for the XV International AIDS Conference. As in years past, this meeting was colorful, chaotic and at times controversial, as well as an opportunity to reflect on signs of progress and challenges in the global response to HIV/AIDS

OVERVIEW

◆ A tale of two timeframes: Short- and long-term agendas for the response to AIDS

At times, the XV International AIDS Conference in Bangkok (11-16 July 2004) crackled with the outrage and activism that enlivened the 2000 meeting in Durban; at other moments it echoed the 2002 Barcelona conference where there was frustration at how little progress there had been in making life-saving antiretroviral (ARV) drugs available in many parts of the world. Ultimately, however, the Bangkok gathering moved beyond both of these meetings and was the first of its kind to take place since many developing countries launched ARV treatment programs with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR), the World Bank and other sources. The conference provided a first glimpse of both the inspiring possibilities and the significant shortcomings of the first efforts now underway to "scale-up" ARV treatment in the world's resource-poor countries.

With its packed program and diverse array of participants, Bangkok also provided a first indication of ways that the relationship between prevention and treatment efforts may change in the era of treatment scale-up. The overall message was clear: as treatment programs roll out, prevention is as important as

ever. "Without a greatly expanded prevention effort, treatment is simply not sustainable," said Peter Piot, head of UNAIDS, during the conference's closing ceremony. Released at the conference, the most recent UNAIDS statistics underscore this point: in 2003 the number of HIV infections was higher than ever—five million new HIV infections worldwide.

How should this expanded prevention effort be developed? Many speakers emphasized the importance of expanding access to available, proven prevention strategies such as condoms and clean needles while also continuing research on other interventions which could provide additional protection, like vaccines, microbicides and pre-exposure prophylaxis with drugs.

However Bangkok also highlighted some of the challenges to merging the treatment and prevention agendas. Perhaps more than any other previous world AIDS conference, this year's in Bangkok illuminated the contrast between the timeframes for short-term responses (such as treatment scale-up and expansion of existing prevention programs) and long-term responses, which largely focus on developing and testing new technologies like AIDS vaccines and microbicides.

When it comes to short-term goals, the overwhelming opinion is that the deadline for action passed long ago: the slogan "Time's Up" was stamped on the side of a giant blue balloon that bounced above thousands of people who took part in a march for treatment access hours

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[The Newsletter of the International AIDS Vaccine Initiative]

before the opening ceremony. The urgency was also voiced by global leaders who warned that greater investments of funding, political will and human resources are needed to meet targets for expanded treatment programs, such as the “3 by 5” program of the World Health Organization (WHO) that aims to have 3 million HIV-infected individuals on treatment by 2005. With that deadline only 15 months away, WHO AIDS director Jim Kim said, “By these measures of human life, the ones that really matter, we have failed. And we have failed miserably to do enough in the precious time that has passed since Barcelona.”

Yet while the treatment field is thinking in terms of months, the AIDS vaccine field is preparing for an effort that will take many years, if not a decade or more. “The development of an HIV vaccine represents one of the most difficult challenges that modern biomedical science is confronting,” said Jose Esparza, Senior Advisor on HIV Vaccines at the Bill & Melinda Gates Foundation in his plenary speech on AIDS vaccines. Esparza’s comments echoed the assessment of IAVI’s 2004 Scientific Blueprint for AIDS vaccine research, which was released at the conference and stated that, “The progress of the past few years is outweighed by critical scientific, operational and resource challenges.” The Blueprint also noted that the field will not know whether the current vaccine candidates being tested will provide any protection until “late 2007 at the earliest.”

The microbicide field is working on a similar timeframe. As many as six large-scale trials involving five candidates could start by the end of 2004, and early results from these studies will be available two to three years after they begin.

Can the world muster the necessary resources and political will to address both long- and short-term agendas? Bangkok provided mixed answers to this question. On the one hand, AIDS vaccines received relatively little attention outside of non-vaccine related sessions and—for the first time in some years—were not mentioned at all during the confer-

ence’s opening ceremony. On the other hand, many speakers made strong forward-looking statements that addressed research along with treatment and prevention. In a speech at the closing ceremony, Sonia Gandhi, chair of India’s National Advisory Council, said, “We are aware that vaccines will not be available for quite some time, but we realize their enormous potential.”

The need to balance short- and long-term priorities was at the heart of “AIDS Vaccines: Global Progress, Global Challenges,” a “Meet the Leaders” panel discussion where UN Special Envoy on AIDS in Africa Stephen Lewis observed that the field had “failed to make AIDS vaccines a central issue” in the global response to HIV/AIDS.

Global spending on AIDS vaccine research is still less than one percent of all health product research and development, a fact still far from common knowledge. During this session’s discussion, a 23-year-old audience member raised his concerns saying, “For the last 15 years I’ve been hearing about AIDS and HIV and for all those years, I’ve been thinking ‘Where is a vaccine?’ It is not until this morning that I realized why we don’t have a vaccine—that only US\$600 million a year is being spent on AIDS vaccine research. It is appalling.”

Maintaining and expanding momentum among communities and politicians is also important. South African treatment activist Zackie Achmat, another panelist at the “Meet the Leaders Session”, urged the vaccine field to build better bridges with the treatment access movement saying, “I think most of us have felt mystified by what an AIDS vaccine is or how to find it. The most important challenge is to de-mystify vaccines.”

Another key element is increased coordination within the various groups involved in AIDS vaccine research and advocacy. “This is about a nonpartisan, business-like approach to a candidate [vaccine] regardless of who is developing them and where they are being developed. Let’s steer away from funding tied to certain institutions,”

said Dutch HIV/AIDS ambassador Laetitia van den Assum.

Ultimately, the ability to meet both long- and short-term goals will depend on strengthening collaborations between treatment and prevention programs and between groups involved in scale-up and research sites in developing countries, said IAVI President and CEO Seth Berkley. “The AIDS vaccine agenda needs to be owned by the members of the broader global AIDS community because they are the ones who have to take the lead on this.”

■ *For more information: see IAVI’s Scientific Blueprint 2004 at: www.iavi.org*

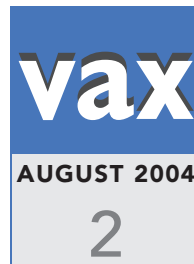
CONFERENCE HIGHLIGHTS

◆ Recruitment reports from around the world

Bangkok brought frontline reports from many sites that have recently launched AIDS vaccine trials and are using innovative approaches to enrollment. But it was also clear that recruitment is a time-consuming process that often does not proceed as rapidly as planned and can require trial teams to revise original recruitment strategies.

Perhaps the most dramatic example comes from the ongoing Phase III “Prime-Boost” trial in Thailand. Principal Investigator Supachai Rerks-Ngarm gave an update on enrollment for the study, which aims to recruit 16,000 volunteers in the provinces of Rayong and Chon Buri. The trial is enrolling a “community-based” cohort, meaning that all trial activities are integrated into existing health facilities and that all adult residents of these provinces are eligible to enroll.

Recruitment began in late September 2003 and, as of June 2004, 2,571 volunteers had enrolled in the trial, fewer than originally anticipated. The enrollment will be extended by another year. “We are



confident that we will achieve enough volunteers after this extension," said Dr. Rerks-Ngarm.

Another report came from the vaccine trials unit in Soweto, South Africa, where the country's first two AIDS vaccine trials began in 2003. The site used community-based voluntary counseling and testing (VCT) centers as the "entry point" for recruitment. All HIV-uninfected adults were invited to join monthly "vaccine discussion groups" and individuals who attended more than two sessions were then invited to be screened for trial participation. This approach led to a 10:1 ratio of screening to enrollment, a typical ratio that illustrates the effort and resources required for trial recruitment, even at experienced sites.

Other posters also described recruitment, retention and media outreach strategies in settings like Botswana, Brazil, Kenya and the UK, and examined key issues such as the enrollment of women into trials and the level of health care that should be provided to volunteers and surrounding communities.

Trial preparation also starts long before the first volunteers are screened. IAVI Medical Director-India, Jean-Louis Excler, discussed ongoing efforts to prepare for India's first AIDS vaccine trials, which could start as soon as late 2004. Excler described intensive coalition-building work on a national level and in six of India's high-prevalence states, including outreach to AIDS NGOs, women's groups and political leaders.

■ *For more information: A searchable database of conference abstracts can be found online at: www.aids2004.org*

◆ Adolescents and trial participation

South African researcher Ann Strode (University of Kwa Zulu Natal) highlighted the complexities of enrolling adolescents into AIDS vaccine trials. Young women aged 15-24 are particularly vulnerable to HIV infection—in South Africa, for example, 25% of women are HIV-infected by the time they are 22 years old. To prevent HIV infection

in this age group it will be important to vaccinate adolescents or, possibly, pre-pubescent girls who have not yet become sexually active. Most licensed vaccines for other diseases have been tested in children (after preliminary safety tests in adults), since children are the primary recipient of these protective vaccinations. But AIDS vaccines will be tested in adults before they are evaluated in adolescents or children. If a vaccine shows efficacy in adults it will be necessary to show that the vaccine has the same immune and safety profile in adolescents and that the effects last for several years.

There are many challenges involved in enrolling young people in trials of AIDS prevention strategies. One overarching issue is that many countries have varied or conflicting regulations regarding young people's participation in trials. South Africa is one example of a country where "children have limited but evolving legal capacity," Strode reported. For example, young people can obtain contraceptives at the age of 14 without parental consent, they can have sex at 16, and young women are allowed to terminate a pregnancy at any age. However, Strode noted, South Africa has "no independent age for [children to] consent to research."

Strode recommended that countries develop national systems to recruit adolescents for AIDS prevention trials and that research and human rights groups work together on advocacy for legal and ethical reform of age of consent laws. She also recommended further research on children's ability to understand the risks and benefits of trial participation.

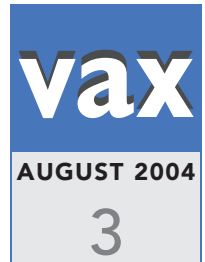
■ *For more information: "Adolescents: The Missing Cohort" in AIDS Vaccine Advocacy Coalition Annual Report 2004 at: www.avac.org*

◆ A new coalition between advocates

Bangkok saw the launch of a new global initiative to strengthen joint advocacy on HIV/AIDS microbicides, treatment and vaccines. The

"MTV" initiative grew out of a series of meetings convened by the Canadian HIV/AIDS Legal Network (CHLN) to identify opportunities for collaboration between these fields, which have often pursued separate advocacy and community organizing strategies. A coalition of groups, including IAVI, the Global Campaign for Microbicides and the CHLN launched a statement of commitment for building a comprehensive response. A companion "Plan of Action" was designed as a framework for the future.

■ *For more information: www.aidslaw.ca/Maincontent/issues/vaccines.htm*



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IAVI is a global organization working to speed the development and distribution of preventive AIDS vaccines—the world's best hope for ending the AIDS epidemic. IAVI focuses on four areas: mobilizing support through advocacy and education, accelerating scientific progress, encouraging industrial participation in AIDS vaccine development and assuring global access.

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SNAPSHOTS FROM BANGKOK 2004

Treatment strategies will not succeed if prevention efforts are failing, as there will always be more people requiring treatment. Prevention strategies will not succeed if treatments are not accessible. Where treatments are accessible, the nexus between AIDS and death is broken. Hope is generated and stigma is reduced. As a result, people are more willing to come forward for testing and more likely to access prevention services.

Statement of Commitment to Building a Comprehensive Global HIV/AIDS Response, released by the coalition for Joint Advocacy on HIV/AIDS, Treatments, Microbicides and Vaccines at Bangkok, 2004

Failure number one is the lack of political will shared by the North and the South... Currently there is just USD\$650 million being spent on AIDS vaccine research each year and close to 60 percent of those funds are coming from the United States. This effort is under-resourced.

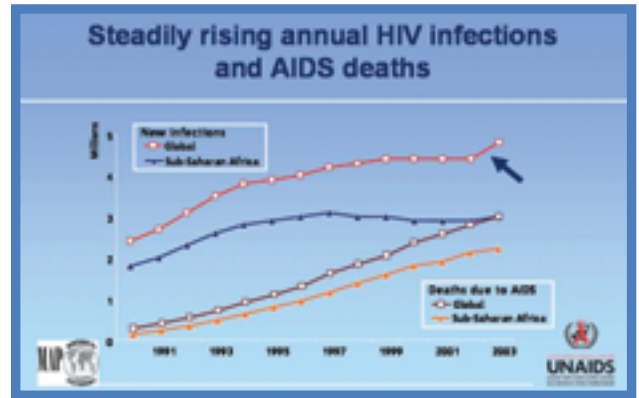
Chrispus Kiyonga, Minister without Portfolio, Uganda (former chair of the Global Fund to Fight AIDS, Tuberculosis and Malaria), at Meet the Leaders Session on AIDS Vaccines, July 15 2004

More doctors leave Ethiopia each year than are being trained in their medical schools; there are more Guyanan nurses working in the UK National Health Service than in Guyana. In easing our own [developed country] capacity constraints, we are adding to theirs. AIDS needs an emergency response, but this response should be complemented by investment in the human and physical needs of the health sectors of the developing country.

Princess Mabel van Oranje, Open Society Institute, plenary speech, July 12 2004

I cannot help but feel, given the current levels of new infections, that the quest for a vaccine must lie at the heart of this response. The massive assault [of the epidemic] on women has to be one of the ways that leaders are driven to their senses and finance a vaccine with the understanding that...for women this is the ultimate salvation.

Stephen Lewis, UN Special Envoy on HIV/AIDS in Africa at Meet the Leaders Session on AIDS Vaccines, July 15 2004



The day after tomorrow, the 18th of July, will be the day I turn 86. There could be no better gift than knowing that there is renewed commitment from leaders in every sector of society to take real and urgent action against AIDS. We know what needs to be done—all that is missing is the will to do it. Allow me to enjoy my retirement by showing that you can rise to the challenge.

Nelson Mandela, speech at closing ceremony, July 16 2004

The three currently available prevention approaches—abstinence, being faithful, and using condoms—while incredibly important are just not enough. Married women or women who do not have control over if they have sex cannot choose abstinence.

Zeda Rosenberg, Chief Executive Officer of the International Partnership for Microbicides, plenary speech, July 15 2004

When I can work in safe and fair conditions I am free of discrimination, when I am free of labels like: "immoral" or "victim of trafficking", when I am free from unethical researchers, when I am free to do my job without harassment, violence or breaking the law, when sex work is recognized as work, when we have safety, unity, respect, and our rights, when I am free to choose my own way then I am free to protect myself and others from HIV.

Community Statement, People to People Messages, closing ceremony, July 16 2004

