

## Speech



## **Microbicides 2008**

## **Closing plenary speech**

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Friends, colleagues, I'm very pleased to be here with you today.

This meeting comes at a difficult time for biomedical research on HIV prevention. There was encouraging news this time last year about the potential for male circumcision to reduce sexual transmission of HIV to men. But this wasn't enough to balance the disappointments around the cellulose sulphate trials and the Merck vaccine. We all heard what David Baltimore had to say about "depression" among the vaccine community at the American Association for the Advancement of Science meeting which I attended earlier this month.

Setbacks like these should not surprise us: microbicide and HIV vaccine development is a new field. Reference points are limited and the challenges are daunting. But this is the nature of the work involved. Remember, it took 50 years to develop an effective polio vaccine and 40 years of clinical trials to come up with effective treatment for paediatric leukaemia. And we still don't have truly effective vaccines for tuberculosis or cholera

Like David, I believe that we must remain optimistic. The fact that the Carraguard trial ran its full course without any safety concerns is itself an achievement. The search for an effective microbicide is a vital and valid one - and I am fully committed to supporting it.

But I want to start by stepping back a little and taking a wider look at the epidemic and our response to it. As you all know, two years ago, the world's governments committed to scale up towards universal access to HIV prevention, treatment, care and support by 2010.

What seems less well known is that we are beginning to see some real progress. We hear too much these days about lack of progress. This gives a false impression that nothing is happening.

On the contrary, a lot is happening. Not everywhere, to be sure. But in many places we are seeing a clear return on AIDS investments.

First, the roll-out of antiretroviral treatment is well under way. Botswana, Thailand, and a number of countries in Latin America and the Caribbean are already providing

universal access to HIV treatment. Given the rates of scale up in previous years, it seems safe to estimate that by the end of 2007, some 3 million people in developing countries were on antiretroviral therapy – up from 230,000 in 2001. A few countries, including India, are beginning to provide second-line drugs.

Second, there has been some progress on prevention of mother-to-child transmission of HIV. Some countries are providing universal access to services to prevent mother to child transmission today. Others have a long way to go: overall access to services to prevent mother to child transmission of HIV developing countries stands at around 11 per cent.

Third, HIV prevalence is beginning to fall - in many parts of southern and eastern Africa, Latin America and here in some areas of India. Reports of changed sexual behaviour from countries such as Haiti, Malawi, and Rwanda show that HIV prevention interventions are beginning to have impact.

Our task now is to sustain and expand on these gains.

This is no mean challenge. It's one thing to get three million people on treatment. It's another to keep them there. At the same time, we have to get antiretrovirals to the 6 million people who still can't access them, and ensure that new regimens become available to those who need them.

We must also move urgently to improve HIV prevention. To be honest, we are still only scratching the surface of the prevention issue. This, obviously, is where microbicides come in. We all know that effective HIV prevention requires a comprehensive approach, what has often been called combination prevention. People need a range of options to choose from. The development of new technologies is vital to increasing the choices available.

Colleagues, I want to pay tribute to all of you for your leadership, for putting microbicides on agendas where they have never been before and for the advances you've made in research. This evening I want to highlight four areas where I believe particular progress has been made.

First, there are more resources for microbicide research than ever before – investment from public and philanthropic sectors almost tripled between 2000 and

2006. In 2006, \$217m was spent on microbicide research and development – though this was over \$100 million less than what was called for.

Second, there are more research facilities. As well as boosting microbicide research capacity, this brings two other benefits to the countries where they've been established. One is that biomedical research capacity has increased generally – through the creation of laboratories and trained personnel, and also through training and participation in data analysis and interpretation. Another is that sites for large-scale community-based clinical trials make an important contribution to local health infrastructure in places where it is badly needed. They not only build capacity to provide HIV treatment and care during trials and afterwards, they also strengthen basic reproductive health care and primary care.

Third, we are learning a lot of lessons about methodologies and developing new principles around prevention research. Many of you have heard me say that AIDS often highlights problems that have gone unnoticed – or undealt with. Take, for example, concerns about community engagement in HIV trials. These prompted UNAIDS and the AIDS Vaccine Advocacy Coalition to publish "Good Participatory Practice – guidelines for biomedical HIV prevention trials. Concern about ethical aspects led to UNAIDS and WHO to revise the document on "Ethical considerations in biomedical HIV prevention trials" last year. And the need to assure the safety of women – and their foetuses, breastfed infants and partners – resulted in UNAIDS and the Global Coalition on Women and AIDS launching a new initiative to put women at the heart of clinical trials.

Fourth, largely thanks to the Quick Working Group, there is a growing movement to harmonize and rationalise research. Reducing unnecessary duplication makes microbicide money work more efficiently and effectively. It is also good to see more pooling of data between researchers.

This brings me to a couple of suggestions about ways we might further enhance microbicide research.

Looking at the series of halted trials, I wonder if there should be more rigour in deciding which products go through to the next stage of trials. Businesses use what

they call "down selection" processes to eliminate all but the most promising looking products early on. There may be lessons to be learnt from this approach.

Second, as many of you have been saying, we need to re-think the way we communicate about trials. I worry sometimes that we set ourselves up unnecessarily for "failure", by over-hyping what we hope to achieve, and by not doing enough to explore and share what can be learnt through the trial. For example, it would be good to look more deeply at the four trials that ended recently and to mine and combine the data to answer questions we may not have anticipated.

Colleagues, we are at a crossroads. We are at a point where we can act on important lessons from what's happened already – both the successes and the failures. We are also at a point where we must start to look at AIDS as a long-wave event, and draw up a strategic plan for the future.

The task is complex.

First, it requires us to sustain political will and leadership on AIDS. This will not be easy. But the progress made on AIDS so far came about because the epidemic is on the political agenda. It is vital that it remains there.

Second, we must find new impetus to address structural factors – the inequalities and human rights issues that that fuel the spread of the epidemic, and intensify its impact. We must push for social change to eliminate the gender inequalities that make it so difficult for women to protect themselves from HIV infection.

Third, we must sustain and increase funding for the AIDS response – to keep paying for what's working now and for scaling it up. And we must work out who's going to be paying AIDS bills in low and middle income countries 25-30 years from now.

Fourth, we must work to reduce costs and make HIV treatment, care and support affordable to those who need it.

Fifth, we have to mobilize a constituency that demands HIV prevention. One of the major differences between scaling up treatment and scaling up prevention is that there is massive demand for treatment. There is relatively little demand for prevention – something that obviously has to be overcome if microbicides are to fulfil their potential.

Sixth, we must accelerate investment in research and development of new treatment drugs and biomedical tools to prevent infection. Even if we could prove tomorrow that one of the microbicides on trial was effective, we'd still have to find serious levels of funding to manufacture and distribute it. At the same time we'd need to keep investing to sustain development of improved next generation candidates.

I know fundraising's a challenge. It reminds me of the early days of AIDS when it was hard to raise money because it was hard to see results. That changed with the discovery of combination antiretroviral therapy. Suddenly there was something real to invest in: success breeds success.

But until this happens, we must focus both on attracting new sources of funding and ensuring that a proportion of money going into HIV prevention is channeled into development and introduction of new prevention technologies.

And we must do this because developing an effective microbicide will be a critical step forward in the AIDS response. To provide women with HIV prevention technology they can use themselves will be nothing short of revolutionary.