

## Spotlight

### Waiting for a breakthrough



#### An Interview with Stephen Lewis

*Stephen Lewis is the Special Envoy to the United Nations (UN) for HIV/AIDS in Africa. He has served in this capacity for four years and has become an unwavering voice in the battle for women's rights and the development of new prevention technologies like AIDS vaccines and microbicides that could help to slow or end the pandemic. Lewis, a Canadian citizen, lives in Toronto and reports to the UN headquarters in New York. His humanitarian efforts and outstanding skills as a speaker have earned him numerous honors. Earlier this year he was named one of the world's one hundred most influential people by US-based TIME magazine.*

*Prior to his role as envoy, Lewis was the deputy executive director of the UN Children's Fund (UNICEF) and was the Canadian Ambassador to the UN. Lewis*

*spent the early part of his career entrenched in national politics and was a former leader of the New Democratic Party in Ontario, Canada. At 67, Lewis shows no signs of slowing and he travels almost constantly. His wife, a feminist writer from Canada, can barely remember his whereabouts on a daily basis. VAX Science Writer Kristen Jill Kresge recently spoke with Lewis about the current situation with AIDS in Africa and what new initiatives he thinks may help halt the epidemic's unchecked spread there.*

***As envoy for HIV/AIDS in Africa, you are reporting directly to the Secretary General on an entire continent's epidemic. How do you accomplish this and what do you see as your main activities as UN envoy?***

The primary activities of my job are to visit African countries, meet with the political leadership, meet with groups of people living with AIDS, and spend time seeing projects in the field. I've always seen these last two activities as critical so that I can see how the diplomatic community can be of greater use. When I come back to New York I hold a media briefing so that the international media has a sense of what I have found. Then I meet with the Secretary General and discuss with him what I've seen and together we discuss how that might influence the way in which he, and the UN more generally, responds.

In the process I have come to understand that advocacy is also a very important component of the envoy role. I've therefore spent a great deal of time speaking around the world at conferences and meetings in order to convey what is happening in Africa and why it is so desperately important for the world to respond.

#### ***How has the response to the AIDS epidemic in Africa changed in your four years as envoy?***

That's a difficult question. I think that the sense of hope at this moment in time is more alive than at any time during the previous four years. The tremendous efforts by the World Health Organization to put millions of people on treatment and the evidence, although very slight, of increased resources has made people feel glimmers of hope in the midst of pervasive anguish. This pandemic has been going on for over 20 years and we are only now, literally at this moment in time, beginning to come to grips with it. Unfortunately on the ground things are as painful as they've always been because people are dying in such vast numbers.

#### ***How has your attitude changed during your tenure as envoy? Do you find it difficult not to get discouraged?***

When I started as envoy I was swamped with despair. Now I live in a perpetual rage. I feel an even greater sense of urgency four years into it. At first I heard all these numbers about the situation in Africa and I was lost in the data. Now when I travel I just want to save individual lives. Instead of get-

## In This Issue

### Spotlight

- **Waiting for a breakthrough**  
**An Interview with Stephen Lewis**

### Global News

- **Microbicides and AIDS vaccines on the agenda at the UN**
- **GSK collaborates with IAVI in research on new AIDS vaccine vectors**
- **Indian doctors to be trained to administer ARVs**

### Primer

- **Understanding Informed Consent**

ting discouraged I get angry because when you are surrounded by death you can't get over it.

***AIDS is now disproportionately affecting women. What is the situation like in Africa?***

I feel more deeply now than I ever did before that the vulnerability of women is possibly the most terrifying component of the pandemic and about which the world is doing almost nothing. This is true in Africa, as well as in other regions of the world. The women are the core of the society—they do the farming, they carry the burden of care—yet they are really under siege. The disproportionate number of infections is huge and women are suffering so extensively.

***Is there any progress towards building a women's movement in Africa?***

I see very little change on the ground. There is little progress in building a legal infrastructure and getting laws in place to protect the property and inheritance rights of women. We need the toughest laws imaginable against sexual violence and marital rape, and we need ways to enforce them. But I just can't get over how slowly this is happening. What we have is an absolute vindication of the feminist analysis: when you're dealing with the inability of men to relinquish power and authority, then you are in real trouble.

***So what do you think can be done to alter the course of the epidemic in women?***

I've come to the conclusion that we must have an international women's agency rooted in the UN. There is a United Nations Fund for Women (UNIFEM) and it has a budget of around US\$20 million a year for the whole world. In comparison, UNICEF has a budget of over \$1 billion and the United Nations Development Program (UNDP) has a budget of nearly \$2 billion. So half of the world's population gets a pittance of support from within the UN system. This is not the fault of the UN; it's the fault of the member states. And maybe you could get away with that until the dramatic expansion of the pandemic in women, but now there must be an international agency for women. This is the single most

important reform that could happen within the UN as far as I'm concerned. UNAIDS (the Joint United Nations Programme on HIV/AIDS) must also take on AIDS as a women's issue as though there were no tomorrow, because for the women of Africa, there is no tomorrow.

***"I hope that vaccines and microbicides will receive a boost at the G8 meeting and that there will be a new sense that we haven't done enough and we had better do it now."***

***Research into new preventive technologies like AIDS vaccines and microbicides is seen as a critical way for women to become empowered and be able to protect themselves from HIV infection. Do you think there is enough political action into the search for an AIDS vaccine?***

I remember the first time I met Seth Berkley of the International AIDS Vaccine Initiative (IAVI). He said to me the most obvious thing in the world—a vaccine is the ultimate answer. It's really strange that we don't integrate that into absolutely everything we say and do because it is the ultimate answer for women, and for everyone. But this urgency has not gripped everyone yet, and we're still not putting enough money, or energy, into it.

***Do you think this might change with the initiatives that have recently been announced, including the upcoming meeting of the G8 nations in Scotland?***

I think the British are very much engaged in vaccines but I don't know whether we're going to be able to convert the G8 summit into something that can confront the pandemic in a serious way. If they cancel the debt and raise a

good deal of money from Europe then it will be an excellent meeting. But it won't be the dramatic turn-around everyone hopes for unless the US makes a dramatic shift in the amount of foreign aid.

***The UN general assembly recently held its special session on HIV/AIDS in New York. Were AIDS vaccines or microbicides high on the agenda? Was there discussion on the pressing needs of women?***

I sat in on the so-called session on gender and AIDS and that meeting was meaningless, and I don't care who is offended by that. There was nothing in that meeting that would galvanize a response by governments to what is happening to women. This is symptomatic of what's happening—we're not responding.

In the materials on prevention produced for the meeting there was absolutely no mention about AIDS vaccines or microbicides. How is it humanly possible that the people who are responsible for setting out the details on prevention forget these important technologies? It just isn't rooted in the minds of those who have to respond.

I hope that vaccines and microbicides will receive a boost at the G8 meeting and that there will be a new sense that we haven't done enough and we had better do it now. We have to fight like hell on both fronts simultaneously.

***You have become such a strong voice for women's rights that I wonder how your wife has influenced your work.***

My wife, Michele Landsberg, has been one of the strongest feminist voices in print in Canada for a quarter of a century and the feminist analysis has very much become part of my own ideology because of her influence. She's been an absolutely extraordinary and uncompromising voice and she has shaped me. The power and force of her ideas has been unquestionably the greatest influence on my life. I also inherited a lot from family, of course, and was deeply engaged in politics for a while, but in terms of what I think is and isn't important in this world, the benchmark for me has been my wife.

## How do you get the world to realize the consequences of this pandemic and mount a suitable response?

You have to keep at it relentlessly by driving home your arguments, trying to persuade people, and never allowing your voice to be silenced. We know that we can save lives because we have

generic antiretroviral drugs at a low enough cost that they should be available to everyone. But even though treatment is now being rolled out it's happening too slow, too late, and too incrementally. That drives me crazy. The criminal negligence on the part of the Western world has lasted for so

long that we'll never be able to compensate for the deaths that have occurred. But you have to continue fighting, and one day, unexpectedly, you break through. That's what I'm waiting for.

## Global News

### Microbicides and AIDS vaccines on the agenda at the UN

The International AIDS Vaccine Initiative (IAVI) and the International Partnership for Microbicides (IPM) were joined recently by prominent world leaders during the United Nations General Assembly's Special Session on HIV/AIDS to emphasize the need for new preventive technologies to curb the pandemic's spread. The non-profit organizations called on governments to double efforts and funding into the development of AIDS vaccines and microbicides.

"It's important that we look for innovative options, especially for women," said Secretary General Kofi Annan, who attended the IAVI and IPM-sponsored luncheon held during the special session meetings. "It's not going to happen tomorrow, but we need to look for long term approaches."

Gareth Thomas, MP of the UK's Department for International Development spoke about the need to accelerate the efforts to overcome the scientific obstacles in developing vaccines and microbicides. This requires effectively using the funding currently available as well as seeking additional resources. The UK is hosting the summit of the G8 nations in July where it is hoped that the leaders of the world's richest nations will have development issues, including AIDS vaccines, high on the agenda.

### GSK collaborates with IAVI in research on new AIDS vaccine vectors

GlaxoSmithKline Biologicals (GSK) is partnering with IAVI to conduct pre-clinical development of a viral vector to be used for future AIDS vaccine candidates. IAVI will be working with GSK to

develop the new vector, which uses a chimpanzee version of adenovirus to deliver a non-infectious fragment of HIV. Vaccine candidates using a human adenovirus vector have already been tested in several trials in humans and a larger Phase IIb trial is now ongoing.

The collaboration between Europe's largest pharmaceutical company and a non-profit international health organization is the first of its kinds in the AIDS vaccine field. Such public-private partnerships are already in place for other diseases like tuberculosis. Both GSK and IAVI are committed to making an effective AIDS vaccine available in developing countries at an affordable price.

### Indian doctors to be trained to administer ARVs

The Clinton Foundation established by former US president Bill Clinton and the UK's Department for International Development will help the National AIDS Control Organization in India train 150,000 of the country's doctors to administer antiretroviral (ARV) drugs. Training physicians is a necessary component of the roll out of life-saving ARVs.

The Indian government has been the subject of criticism by Richard Feachem, executive director of the Global Fund to fight HIV/AIDS, Tuberculosis, and Malaria, for failing to supply their own citizens with drugs that are manufactured in India. The Clinton Foundation views the training of doctors as the first step in assuring that India's estimated 5.1 million HIV-infected citizens will have access to affordable treatments.

Soon after this announcement the Indian pharmaceutical company Ranbaxy received tentative approval from the US Food and Drug Administration (FDA) for one of its generic ARVs. The FDA also granted

tentative approval to Ranbaxy and another Indian company, Aurobindo Pharma, to produce copies of the ARV nevirapine.



#### Editor

Simon Noble, PhD

#### Senior Science Writer

Philip Cohen, PhD

#### Science Writer

Kristen Jill Kresge

#### Web Editor

Roberto Fernandez-Larsson, PhD

All articles written by Kristen Jill Kresge.

VAX is a project managed by Kristen Jill Kresge.



VAX is a monthly bulletin from *IAVI Report*, the newsletter on AIDS vaccine research published by the International AIDS Vaccine Initiative (IAVI). It is currently available in English, French, German, Spanish and Portuguese as a downloadable pdf file ([www.iavireport.org](http://www.iavireport.org)) 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](mailto:vax@iavi.org)

IAVI is a global not-for-profit organization working to speed the search for a vaccine to prevent HIV infection and AIDS. Founded in 1996 and operational in 23 countries, IAVI and its network of partners research and develop vaccine candidates. IAVI also advocates for a vaccine to be a global priority and works to assure that a future vaccine will be accessible to all who need it.

Copyright © 2005

## How does the informed consent process work in vaccine trials?

AIDS vaccine candidates must be tested in human volunteers to evaluate their safety and efficacy. A vaccine trial can only be successful if people in the community are willing to volunteer for the trial, receive the vaccination, and return to the trial site for follow-up visits. An essential part of running ethical research is assuring that the rights of these volunteers are protected.

To ensure that the volunteer enrollment in vaccine trials meets high ethical standards there is a process known as informed consent. During this process trial investigators must fully explain the details of the trial and the vaccine candidate that will be tested, make sure that the volunteer understands the information, and allow the potential volunteer to freely decide if they wish to participate. The informed consent process must be completed for each person before he or she can enter the screening process for the trial. During the screening process all volunteers undergo research voluntary counseling and testing (see April *Primer on Understanding Research Voluntary Counseling and Testing*) for HIV infection because only people who are not infected with HIV can enroll in a preventive vaccine trial.

At the end of the informed consent process, everyone who chooses to join the trial is asked to sign the informed consent document that has all this information in writing. The document shows that they want to participate in the trial, but informed consent involves much more than simply signing a paper. The United Nations Joint Programme on HIV/AIDS (UNAIDS) established a set of guidelines that recommends cooperation between researchers, community representatives in the form of Community Advisory Boards (see May *Primer on Understanding Community Advisory Boards*), and regulatory bodies to design and implement the informed consent process at AIDS vaccine trial sites throughout the world. The protocol for a vaccine trial, including the informed consent document, must receive approval from a local ethics committee and national regulatory authorities before that trial can begin.

### Information

Community outreach is the first step of the informed consent process and aims to prepare a community for a vaccine trial. Educational materials about HIV and AIDS vaccines are a necessary first step in getting people informed and

interested in participating in a trial. This general information includes what HIV is, how it is transmitted, and how an AIDS vaccine might work. When members of the community who may be interested in volunteering come to the trial site, they are educated about the trial and the vaccine candidate being tested.

The nurse or counselor at the trial site begins by explaining any general background information about HIV and then explains why the vaccine candidate is being tested, what participation in the trial involves, and how the trial is being conducted. For example in some trials, not every person in the trial will receive the vaccine candidate. Some volunteers will receive an inactive substance known as placebo, so that the researchers can compare the vaccine being tested to something they know will have no effect. In most trials, neither the volunteers nor the researchers will know who receives the vaccine candidate or placebo until the end of the trial (this is called a “double blinded” study). The nurse or counselor explains that the person can’t be infected with HIV from the vaccine candidate and also emphasizes that the vaccine being tested may not provide any protection against HIV infection and so all volunteers must avoid risk behaviors.

The information provided also includes specifics about the trial process, including the length of the trial, the number of visits to the site, and what medical tests (such as the collection of blood samples) will be required. Potential volunteers will also be informed about the type of general healthcare provided during the trial, any reimbursement they will receive for traveling to the site, and most importantly, their right to leave the trial at any time.

The way this information is provided varies based on the trial site, but informed consent documents used in developing and developed countries are very similar. At some sites the informed consent process can extend over several visits, allowing the volunteers to take the information home and discuss it with their family. Once the trial site staff are trained, it is their responsibility to carry out informed consent process according to international and local standards.

Researchers may use videos or flip charts to explain complex issues like the benefits and risks of participation in the trial. The possible benefits include the medical attention that volunteers receive, as well as the rewarding feeling of participating in research that will benefit the community. Potential risks of participating in a vaccine trial include the possibility of side

effects of the vaccine candidate or the possibility of temporarily having a false positive HIV test in the future, even though they are not HIV infected. A false positive can occur because the vaccine may cause the person’s immune system to make antibodies to HIV, which is what the standard tests measure.

### Cultural considerations

Investigators at the site do their best to explain terms in a way that is easy for the individual to understand and should try to answer all questions to the best of their ability. This is an important part of obtaining “true” informed consent. Researchers must be able to explain complicated terms to potential volunteers in a way that is relevant to the community and can easily be understood, sometimes even in languages that have no translations for these words.

The local ethics board as well as Community Advisory Boards have input into the informed consent process before the trial protocol is implemented and can therefore influence this process. Leaders in the community can provide the investigators with culturally-specific ways to explain key concepts. But it is still very important that researchers uphold the standards of the informed consent process, while trying to make it more sensitive to the beliefs of the community.

### Understanding

The final step of the informed consent process involves ensuring that each individual fully understands the information provided. At some sites investigators may use written tests to verify their understanding. The investigators also try to ensure that each person’s decision to participate is truly voluntary. The potential volunteer must not be pressured into enrolling by anyone at the trial site, or anyone in their family or community. This can be difficult in some cultures where, for example, women are unable to make decisions without consulting their husbands or community leaders. The nurses or counselors at the trial site should do their best to find out if each person’s decision was made independently and was based on a firm understanding of the trial.

Once these criteria are met, the informed consent document can be signed. If the volunteer cannot write, he or she may be identified in another way, such as a thumbprint. Volunteers that complete this step can enter the screening process, where they are examined and tested to see if they are eligible for the trial.