



## Spotlight

### Spreading the word

*Using public health campaigns to raise awareness about HIV/AIDS*

A high-school student turns away from three male friends and says, “Sex can wait.” This is just one image featured on posters and billboards in Malawi—part of a public health campaign to draw attention to HIV/AIDS. In Thailand, posters depicting stick figures in various sexual positions illustrate when to use condoms. A Swiss campaign features two naked people fencing with the message, “No action without protection.”

Such public health campaigns are an essential part of HIV prevention efforts and are used around the world to relay messages that encourage people to modify their behaviors or address some of the stigma surrounding HIV/AIDS. Their substance can vary greatly, from racy to rather staid images, but the message is always the same. These posters, billboards, or media campaigns provide much-needed facts to the general public, help dispel myths and misconceptions about HIV/AIDS, and empower people to take control of their lives.

In some countries these campaigns have been outstanding success stories—in Uganda and Thailand, for instance, many credit public health campaigns with making progress in reducing the number of new HIV infections. But the consistently high prevalence and incidence rates of HIV in many regions of the world indicate that public health campaigns still have a long way to go in getting the message out about HIV/AIDS and how infection can

be prevented. In India, which may have more HIV-infected people than anywhere else on the planet, 43% of women have never even heard of HIV. Even in the media-saturated US, misconceptions abound. One study showed that roughly 47% of African Americans believe an AIDS vaccine is available but is being purposely withheld.

These are significant challenges for the organizations that are creating and disseminating these public health messages, including those targeting potential volunteers for AIDS vaccine trials. These campaigns must balance the desire to be thought-provoking with the need to remain culturally sensitive. Discussing sexual behaviors adds an additional layer of complexity. But past campaigns have shown that creating messages within the population and having support from national leaders are critical to success.

#### Change from within

All successful public health campaigns follow certain principles. These include conducting research to identify the target population, pre-testing messages, and conducting follow-up research to analyze the impact and benefit. A truly effective campaign, however, requires local involvement, national leadership, use of the right sort of media to reach people, and a sense that the campaign originates within the culture rather than being imposed by outsiders. “It is tempting to think that behavior change is just an impossible goal,” says Tony Barnett, an economic and social researcher at the London School of Economics. “That is not true. People’s cultures are very variable and changeable. However, they are more changeable from within than from without.”

A Zimbabwean campaign to reduce stigma illustrates how involving local people can make a difference in how the message of the campaign is received, says Devora Joseph, acting director of AIDSMark, a program engaged in the social marketing of HIV prevention products and services run by the non-profit organization Population Services International (PSI). PSI and its local partners identified HIV-infected people willing to talk about their experience and featured them in radio and television ads and on posters as part of the campaign, “Don’t Be Negative About Being Positive.” PSI’s research indicated that people who had heard the campaign’s messages were more accepting of people living with HIV/AIDS.

Strong national leadership can also pay off. Many credit Uganda’s president, Yoweri Museveni, for his role in the success of the country’s campaigns to reduce HIV transmission—prevalence fell from about 15% in the early 1990s to roughly 6.7% in 2005. While debate has simmered over which prevention methods (whether abstinence, being faithful, or condoms) contributed most to this decline, Museveni’s leadership is widely praised. For example, Museveni urged men and women to become more sexually responsible through an ongoing series of AIDS radio messages. Each one began with the beating of a drum, the traditional

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instrument used to transmit urgent warnings among villages, a cultural reminder that helped people recognize the importance of his message.

In Thailand the 100% condom campaign, which required that all sex workers use a condom during every sex act, was strongly endorsed by the national government and identified in the public consciousness with health minister Mechai Viravaidya, who became affectionately known as “Mr Condom.” The program involved distributing condoms, educating sex workers and their clients, and closing venues that didn’t comply. The policy is credited by the United Nations Development Programme with reducing new infections from 140,000 in 1991 to 19,000 in 2003. The World Bank estimates that use of effective prevention campaigns in Thailand averted 6.7 million new HIV infections in the country.

Another important element is choosing the right form of media. With a subject as complex as sexual behavior, billboards, posters, and other mass media cannot be the only outlets utilized. In rural areas people often live miles from the nearest television, radio, or even billboard. Instead educators combine media campaigns with other interventions such as counseling, support groups, peer educators, or even traveling-theatre groups. Campaigns have been forced to become creative. In many parts of Africa, health educators stage local soccer matches that draw people from the surrounding villages and use the event as an opportunity to convey messages about HIV/AIDS. In these settings, interpersonal communication is especially effective. “Thinking that one can just put up a billboard and say ‘use a condom’ is often-times not adequate,” says Joseph.

### **One size does not fit all**

Without a sense of ownership and strong local leadership, public health campaigns can actually be counterproductive. For the 2002-2003 World AIDS Campaign, UNAIDS commissioned a series of posters designed to illustrate AIDS-related stigma for use in places as diverse as Africa and India. But afterwards an analysis by researchers at McGill University, Canada found that many people actually thought the posters were condoning stigma, rather than discouraging it.

Sometimes the same campaign doesn’t work everywhere even within a coun-

try’s borders, says Kwaku Yeboah, director of prevention at the nonprofit health organization Family Health International. City-dwellers in most developing countries often embrace modern lifestyles, while others in rural villages get much of their information from elders and traditional healers. “It is absolutely important to have that local participation to guide you in understanding people’s thinking processes,” says Yeboah.

In 1988 the government of Botswana initiated a campaign that was highly influenced by Western ideas to educate people about HIV/AIDS and promote condom use. In rural areas the campaign was met with disbelief and condoms became associated with promiscuity and a breakdown of traditional values. As a result many people began to believe that

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## ***Effective prevention campaigns in Thailand averted 6.7 million new HIV infections***

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AIDS was a disease brought on by immoral behavior. People therefore considered the disease as something that couldn’t happen to them and saw no reason to change their own behavior.

There are many examples that illustrate just how difficult it is to create public health campaigns around sensitive issues like sexual behavior. “We don’t know much about human sexual behavior in general,” says Barnett, “let alone cross-culturally.” Therefore Barnett contends that it is impractical to think it is easy for people to start using condoms or that abstinence is a simple choice.

Finding out why people engage in the sexual practices that they do is essential for designing campaigns that can deliver on the promise of reducing HIV transmission rates. The cultural meaning of sex can vary not only between countries but between social groups within a country. Sexual choices are influenced by cultural, social, and economic factors. This is especially true

among women. “Whether or not people have sex with each other may be less to do with culture and much more to do with decisions that people make in order to survive, particularly where women are concerned,” says Barnett.

In many regions of the world, women are often economically dependent on men, lack the power to demand fidelity or condom use, and are more likely to live under threat of violence from an intimate partner. As a result, particularly in resource-poor settings, transactional sex is often a necessary means of survival. This is one reason why women are increasingly bearing the brunt of the HIV/AIDS epidemic.

The age-old concept of women who seek sex with older ‘sugar daddies’ as a way to improve their economic status also poses new threats. These young women are at greater risk of acquiring HIV since, on average, older men are more likely to have had multiple sexual partners. To combat this trend, PSI has developed campaigns in Uganda, Cameroon, Kenya, and Mozambique that appeal to parents, young women, and their male partners.

Other programs encourage men to treat women more respectfully. A campaign aimed at seasonal farm workers in South Africa teaches supervisors not to abuse their position of authority by sexually harassing or exploiting female workers.

Future campaigns may be modeled on more innovative approaches like a recent one in South Africa. The Intervention with Microfinance for AIDS and Gender Equity (IMAGE) study showed that empowering women economically—through small loans that allowed them to start retail businesses—and training them on HIV/AIDS and gender issues, reduced their risk of interpersonal violence.

The strength of this type of intervention, says Barnett, is that it doesn’t try to alter people’s behavior by telling them what they should or should not do. Rather it gives women economic opportunity that they would not otherwise have and with it the potential to change their decision-making around sex.

### **AIDS vaccine campaigns**

The developing world has no monopoly on misunderstandings about HIV and AIDS. In the US misconceptions are common among the very populations in which the epidemic is growing fastest—AIDS diagnoses among African Americans have

grown from 25% of cases diagnosed in 1985 to 50% in 2005. Lack of accurate knowledge about HIV/AIDS among African Americans and Latinos is affecting not only transmission rates, but also recruitment of participants in vaccine trials.

Only about 17% of people enrolling in AIDS vaccine trials in the US are African American or Latino, according to Cornelius Baker at the Academy for Educational Development (AED), an organization that designs public health campaigns. AED is the recipient of a five-year contract from

the National Institute of Allergy and Infectious Diseases (NIAID) to encourage participation in AIDS vaccine trials.

One of the first steps is educating target populations. The history of medical injustice towards African Americans in the US has left a legacy of distrust. AED is currently studying how to penetrate groups that harbor misconceptions about HIV despite being exposed to mass media. In keeping with the need for locally-grown campaigns, Baker says AED will distribute the money to local organizations to create

campaigns or work within existing outreach groups, rather than design a national campaign.

As difficult as it is now to design effective public health messaging for HIV/AIDS, it will undoubtedly become more complex with the availability of new HIV interventions, such as male circumcision, AIDS vaccines, microbicides, diaphragms, or pre-exposure prophylaxis (PrEP), which could all one day require new messages that must be designed for, and disseminated to, a wide range of people.

## Global News

### New AIDS envoy appointed

Elizabeth Mataka, the executive director of the Zambia National AIDS Network (ZNAN) and the vice-chair of the board for the Global Fund to Fight AIDS, Tuberculosis, and Malaria, was recently appointed to the position of Special Envoy for AIDS in Africa by Ban Ki-moon, the Secretary General of the United Nations (UN). Mataka is a native of Botswana and has been involved with HIV/AIDS prevention, treatment, and care for the past 16 years. She succeeds Stephen Lewis, who left the post after five years when previous Secretary General Kofi Annan retired at the end of 2006.

During his time as Special envoy Lewis spoke passionately about the devastation that HIV/AIDS is causing in Africa and he became one of the most outspoken and well-known advocates for the rights of women on the continent. The appointment of Mataka fulfills Lewis's request that his replacement be an African woman. She is the first African to hold the position of Special Envoy at the UN and, as she assumes the post, the situation facing African women has never been more dire. As HIV continues to spread in sub-Saharan Africa, women are increasingly becoming infected. It is estimated that 4.6% of young women in sub-Saharan Africa are currently living with HIV, compared to 1.7% of young men.

### Phase I AIDS vaccine trial begins

The Vaccine Research Center (VRC) at the US National Institute of Allergy

and Infectious Diseases in partnership with the US company GenVec recently began a Phase I clinical trial to evaluate the safety and immunogenicity of a novel adenovirus serotype 35 (Ad35)-based AIDS vaccine candidate in 15 volunteers. Adenovirus can cause some forms of the common cold and there are several serotypes circulating worldwide. Another adenovirus serotype, known as Ad5, is already being used as a vector in other AIDS vaccine candidates to deliver pieces of HIV to the immune system (see September 2004 *Primer on Understanding Viral Vectors*). Ad5-based vaccine candidates are now being tested in a series of Phase II trials by the VRC and in two large Phase IIb trials by the US company Merck. However one possible drawback to candidates that use Ad5 as a vector is the high prevalence of the virus in certain parts of the world. People who have been previously exposed to Ad5 may have pre-existing immunity towards the viral vector, and that could hinder their immune responses to the AIDS vaccine candidate. The potential advantage of using Ad35 is that it has a much lower prevalence globally.

This two-part trial is the first to test another serotype of adenovirus in clinical trials. The first part will evaluate the safety of an intramuscular injection of the vaccine candidate at three different doses. Once the safety data is reviewed researchers will evaluate the safety and immunogenicity of the candidate when administered in combination with the VRC's Ad5 candidate. The Ad35 vaccine candidate was developed by the VRC and GenVec.



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VAX is a monthly bulletin from *IAVI Report*, the publication 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.

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 24 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. For more information, go to [www.iavi.org](http://www.iavi.org).

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## How do DSMBs monitor ongoing clinical trials?

Several different groups oversee the ethical standards of clinical trials, including those testing AIDS vaccine candidates. These committees are set up for each new trial to ensure they are performed safely, the rights of the volunteers are protected, and that the basis of the study is scientifically credible. Before a trial begins, the overarching plans for the trial or protocol is reviewed by an independent ethics committee called an institutional review board (IRB). This group is primarily responsible for reviewing the study design and all the trial-related materials, such as informed-consent documents and informational brochures (see June 2005 *Primer on Understanding Informed Consent*). A clinical trial can not start without approval from the IRB.

Another external committee known as a data safety monitoring board (DSMB) is responsible for monitoring the safety and progress of the trial once it is underway. DSMBs were first established in the 1960s as a way to assist organizations sponsoring medical research with data analysis, but now their most important role is to continually assess risk and monitor safety for volunteers throughout the course of a trial. A DSMB is an independent committee that can advise the trial sponsors, funding agencies, and investigators. After analyzing the safety and efficacy data the DSMB determines if the trial should continue unchanged or with modification, or if it should be terminated. This group also monitors the scientific merit of the study in light of results from other trials or advances in the field.

### The function of a DSMB

A DSMB is comprised of 3 to 10 members and usually includes researchers, clinicians, biostatisticians, and community members or advocates. Members are typically independent experts, either working in the same field or in a related discipline, who have no personal or professional ties to the intervention being tested and are therefore unbiased.

Not every clinical trial requires a DSMB and different regulatory agencies, like the US Food and Drug Administration or the European Agency for Evaluation of Medical Products (EMA), have different standards. Generally they are utilized for double-blind studies where trial sponsors and investigators don't know who is receiving the active product or placebo, whenever there is a potential risk to the study participants, or when a trial is conducted at multiple clinical trial sites. A DSMB is especially important for large, multi-center trials that take place in different countries or on multiple continents because often the principal investigators only have access to data generated at their individual sites. The DSMB, however, can monitor the safety and efficacy data accumulated from all sites to make a decision regarding the continuation of the trial.

DSMBs have several important duties. First they periodically review the safety data from the trial and analyze the risk/benefit profile of the intervention being tested and any adverse events that occur. They also regularly examine the efficacy data that is accumulated throughout the course of the trial. For example, if the trial is testing a microbicide or an AIDS vaccine candidate that is designed to prevent HIV infection, a DSMB would review the number of volunteers who become incidentally infected with HIV through risk behaviors during the course of the study to see if more of these infections are occurring in the placebo group than in the group receiving the experimental intervention, or vice versa. This can help the DSMB determine if the experimental intervention is beneficial or possibly causing harm.

The DSMB also closely watches the progress and conduct of the trial and evaluates whether or not the study protocol is being followed. This includes reviewing the number of volunteers recruited and retained, the type of volunteers (for example women versus men), the performance of the trial sites, and the integrity of the data being reported by the sites. The progress of the trial, as well as the safety and effi-

cacy data, are reviewed by DSMB members at pre-defined intervals and their findings are reported back to the IRB.

### Altering a trial

There are several possible scenarios where a DSMB might suggest modifications to a trial protocol. For example, if the DSMB determines that there are not enough volunteers being recruited to properly determine the efficacy of the product, they might recommend that the target enrollment be increased.

In many cases the DSMB might also suggest that a trial be closed. The cost and time required to run a clinical trial are significant and it is a serious decision when one is stopped midway. However, protecting the personal safety of the volunteers and ensuring the ethical conduct of the trial are the DSMB's principal concerns. A DSMB may recommend terminating a trial when the intervention being tested appears to possibly be harmful. Recently an HIV prevention trial testing the ability of the microbicide candidate cellulose sulfate to prevent HIV infection in women was stopped early by the DSMB because more new HIV infections occurred in the volunteers using the microbicide gel than in those who received an inactive placebo gel. Evaluation is now underway to determine if the microbicide candidate was actually responsible for this increase in infection.

A DSMB may also stop a study that is in progress if the intervention offers a clear benefit and is so effective that it would be unethical to continue with a placebo group. This happened recently in two randomized, controlled trials of male circumcision. The DSMB members observed such a strikingly positive effect of male circumcision on the risk of HIV infection in men that they stopped the trial and also offered the surgical procedure to the uncircumcised men.

Another reason a DSMB may stop a trial is if it is unlikely to provide conclusive results. This is known as stopping a trial for futility and it can happen when the number of incidental HIV infections in a trial is too low to actually determine if the AIDS vaccine or microbicide candidate is effectively stopping infection.