Testing, testing, 1, 2, 3

The routine HIV testing model first adopted in some African countries is now being recommended in the US in an effort to finally reduce the spread of HIV

By Kristen Jill Kresge

Only a few years ago Botswana had one of the highest HIV prevalence rates in the world. In 2002 the government started a national treatment program to provide free antiretrovirals (ARVs) to all HIV-infected individuals in need, but very few people were benefiting. By 2004 only 17,500 of the estimated 110,000 people in need—a mere 16%—were receiving treatment. The reason for the poor uptake was that most people didn’t even know they were infected with HIV (PLoS Med. 3, 7, 2006).

Researchers have observed that the number of people willing to undergo HIV testing is higher when treatment programs are available. This stands to reason since without life-saving medicines an HIV/AIDS diagnosis is, for most people, the notification of an early death. Fortunately, as ARVs are increasingly available in developing countries, more and more people are being tested for HIV infection. In South Africa the number of people undergoing voluntary counseling and testing (VCT) doubled between 2004 and 2005 when the government’s treatment program was introduced. Other African countries, including Lesotho and Malawi, are also expanding their VCT efforts.

But in Botswana this “if you build it, they will come” treatment and testing scenario did not seem to be working. Despite a national treatment program, only 70,000 HIV tests were performed in a country of 1.7 million people through mid-2003. In response President Festus Gontebanye launched a routine HIV testing initiative in January 2004 that meant everyone seeking healthcare received an HIV test unless they specifically refused.

There was hope this approach would encourage more people to be tested by erasing some of the stigma associated with the disease, which is one of the main barriers to HIV testing in developing countries. Making testing more commonplace also helps prepare communities for HIV prevention trials, like those for vaccines and microbicides, where volunteers must first be screened for HIV infection.

In Botswana, more testing also meant healthcare workers could link HIV-infected individuals in need to the national treatment program. In just two years this initiative spurred

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Stemming the flow

Health worker brain drain to industrialized nations has been receiving attention, but less often discussed is the depletion of developing country research talent

By Sheri Fink

Several years ago, Dr. Veronica Mulenga, a Zambian physician, was offered a two-year research training fellowship at Miami University. She gained her research skills in well-run, state of the art facilities. The situation when she returned home was markedly different. “A lack of equipment, erratic supplies of reagents, even drugs,” says Mulenga, now a consultant pediatrician at the University Teaching Hospital in Lusaka, where she conducts clinical research on critically important treatment parameters in HIV-infected children. While Mulenga has toughed it out in less-than-ideal conditions, she says many of her colleagues have made a different decision: they are no longer working in the country. “They become frustrated with the systems they come back to—poor administration, poor objectives,” she says. “Quite a lot of people return and then leave again because of frustration.”

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significant progress and Shelia Tlou, the country’s health minister, reports that now 70% of those who need ARVs are receiving them from the government. Studies also indicate that routine testing is widely supported by the citizens of Botswana (PLoS Med. 3, 261, 2006).

This dramatic turnaround was hailed as a great achievement by public health experts and many started touting Botswana as a model for other African countries. The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) modified their HIV testing guidelines to recommend that other countries with high HIV infection rates follow Botswana’s lead.

Now a similar routine testing paradigm for HIV, known as opt-out testing, is also being recommended by the Centers for Disease Control and Prevention (CDC) in the US, where it is estimated a quarter of a million people are currently HIV infected and don’t know it (MMWR Recomm. Rep. 55, 1, 2006). This major shift away from the VCT model that was created for HIV has provoked both praise and criticism, but more than anything it has raised many questions. “We’re pleased to see that there’s been a lot of open dialogue about this,” says Bernard Branson of the Division of HIV/AIDS Prevention at the CDC.

Everyone agrees that conducting more HIV testing will have many benefits, the most obvious of which is identifying those who are HIV infected and promptly referring them to treatment and care services. Most researchers also concur that people who know their HIV status will be more likely to change their behaviors to protect either their partners or themselves from future infection. Such behavioral modification should result in fewer new infections. But many researchers, clinicians, and activists are carefully considering the legal and human rights issues involved in routine testing, the use of HIV prevention counseling, and whether there is enough money and manpower to ensure that the HIV-infected individuals identified through widespread testing will be connected with treatment programs. “We have to measure our success not just on the number of tests or diagnoses, but on how many people receive care and treatment,” says Jeffrey Levi, executive director of the public policy association, Trust for America’s Health.

**Success stories**

Botswana’s routine testing program was not the first of its kind. The model was adopted much earlier in the HIV epidemic by many developed countries—including several states in the US—as a way to identify HIV-infected pregnant women. This initiative has resulted in more women being placed on treatment during pregnancy and has helped dramatically lower the number of HIV-infected infants born in developed countries.

There is also evidence from some testing initiatives in the US, adopted on a state-by-state basis, that routine testing is an effective way to eliminate barriers to HIV testing. New York City started an HIV testing initiative in public hospitals that serve 1.3 million people in the metropolitan area that increased testing rates by 57% and doubled the number of new HIV diagnoses. Similar initiatives have also occurred in Texas and Colorado.

Washington, DC also launched a new testing campaign in June called ‘Come together DC, get screened for HIV’ that included several initiatives to expand access to testing, with plans to eventually make it routine in all healthcare settings. Marsha Martin, senior director of HIV/AIDS administration for the district’s department of health, calls routine testing “the best of public health.” As of September this program has tested more than 16,000 people for HIV, a 300% increase over the previous year.

**Taking action**

Over the past two years the number of people with AIDS has increased in every region of the world, according to the annual report on the global epidemic issued in December by UNAIDS and WHO (www.unaids.org/en/HIV_data/epi2006/). In the US there are still 40,000 people newly infected with HIV each year and, despite sustained HIV prevention efforts and public health campaigns, the number of new infections has not declined at all over the past 15 years.

Moreover many of these new infections are being discovered late—40% of people in the US progress to AIDS within a year after discovering they are infected with HIV. The progression from initial infection to an AIDS diagnosis typically takes about a decade, so it is possible that these people are transmitting HIV to others for many years unknowingly.

Mike Saca is a professor of medicine at the University of Alabama in Birmingham.

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and directs an AIDS clinic there. A quarter of the people who test positive for HIV infection at his clinic are already in deteriorating health and have fewer than 200 CD4+ T cells/ml blood, which means they have already reached the clinical definition of AIDS and therefore require ARV treatment. These so-called late testers are more often adolescents, an age group where the epidemic is rapidly expanding. “Routine opt-out testing is clearly needed,” says Saag, to reach this demographic.

To that end the CDC has revised their guidelines on HIV testing, now recommending that all people between the ages of 13 and 64 should be tested at least once for HIV infection as part of receiving general healthcare, regardless of their perceived risk or the HIV prevalence in that area. Those who are considered at high risk of infection, including men who have sex with men and injection-drug users, should be tested annually, and heterosexual men and women should be retested each time they change their sexual partner or if their partner changes partners.

If these recommendations are adopted—which in most cases would require changing individual state laws that oversee infectious disease testing—the informed consent process specific to HIV testing that was adopted in the 1980s and the VCT approach would be largely eliminated. All individuals visiting a doctor’s office, health clinic, or hospital would be informed that they will receive an HIV test unless they expressly decline or opt out. The HIV test would be administered along with other regular tests and a single consent form, signed by the patient, would cover all medical care.

Another reason for introducing a routine testing paradigm now is that testing more people has never been easier or cheaper. The advent of rapid HIV tests, many of which only require a drop of blood or a small sample of saliva, has made it easier for clinics to conduct more HIV tests and results can be provided much more quickly, sometimes in only about 20 minutes. Rochelle Walensky and her colleagues at the Epidemiology and Outcomes Research Group at the Harvard Center for AIDS Research have shown that introducing routine HIV testing is now a cost-effective approach in all areas that have an HIV prevalence greater than 0.1%, which is true throughout the US (Am. J. Med. 118, 292, 2005). “HIV testing is more cost effective than testing for breast cancer, colon cancer, or screening for diabetes, tests that are routinely conducted in the US,” she says.

The CDC’s goal is to mainstream HIV testing so that it becomes as common as a cholesterol check. Lumping together a test for what was once an untreatable and highly stigmatizing viral infection with the routine battery of medical tests reflects how far AIDS treatment has progressed in

Vials of blood collected for HIV testing. Samples are bar coded to protect the anonymity of the individuals being tested.
Bernard Branson

HIV infection eventually declares itself. People need treatment whether or not they’re diagnosed.

wealthy countries over the last 25 years. Although taking ARVs is still difficult because of unpleasant side effects, drug regimens are now much simpler and have, for the fortunate minority who can afford therapy or gain access through treatment programs, turned AIDS into a chronic disease. Public health workers are hopeful that treating the diagnosis of HIV/AIDS like other chronic diseases will help remove some of the stigma associated with the virus.

Others argue that this is an invalid comparison. “This conveys a real misunderstanding about what living with HIV in America is like today,” says David Ernesto Munar, associate director for policy and communications at the AIDS Foundation of Chicago. “The emotional and psychological issues are so great. It’s nothing like a cholesterol test.”

Need for counseling?

In the 1980s AIDS activists demanded that HIV testing be conducted differently because of the pervasive stigma associated with a sexually-transmitted infection that affected mostly white, homosexual men. This brought about several unique initiatives, including the VCT approach that is still in practice today that emphasizes pre- and post-test counseling and HIV-specific education, regardless of whether a person tests positive or negative. But in the CDC’s new guidelines, counseling in conjunction with an HIV test “is not required,” and this has become one point of contention.

Some argue that without pre-test counseling a person will be ill-prepared for the consequences of an HIV diagnosis and, since post-test counseling will probably only be provided to those who test positive for HIV infection, people who are not already infected would receive little education on how to reduce their risk in the future. Branson says the CDC’s goal is to initially target those who stand to benefit the most from HIV counseling. Research studies show the positive effect HIV counseling has on individual risk behaviors and therefore the HIV transmission rates in those who test positive. The CDC itself conducted one study in 1998, known as project RESPECT, which found that consistent use of condoms was more likely in groups that received pre- and post-test counseling and that this group also had a marked decline in the rate of sexually-transmitted diseases. This study, however, didn’t look at behavior differences between those who tested positive or negative for HIV infection. “It’s very hard to find studies that look at the impact of counseling in people who test negative for HIV,” says David Holtgrave, professor in the department of health, behavior, and society at Johns Hopkins University.

If the prevention landscape changes and new options—such as pre-exposure prophylaxis—become available, the CDC will consider changing their recommendations on counseling to also include those who are uninfected, says Branson.

Reactions

Evidence from limited research studies suggests that having more people who know their HIV serostatus will result in fewer new HIV infections. Data indicates that HIV transmission rates among those who are aware of their HIV status are around 2%, compared to 9-11% amongst people who are unaware they are infected. Based on this the idea of routine testing has won praise by many in the public health field as a way to not only connect people to treatment and care services but also to improve HIV prevention efforts. “This certainly isn’t happening too soon,” says professor Lawrence Gostin, of the Center for Law and the Public’s Health at Georgetown University Law Center.

But many civil and human rights advocates are opposed to routine testing. They say it creates a situation where an individual is less likely to decline a test because of the power imbalance between the patient and healthcare provider, making testing involuntary. Groups like the American Civil Liberties Union and Lambda Legal say opt-out testing is in violation of basic human rights and that it is a slippery slope from this to mandatory testing. Gostin admits that there will be some individuals whose informed consent will be compromised with routine testing but argues that policies that benefit the most people must prevail when dealing with such an insidious epidemic. “Personal autonomy can no longer trump overall public health when dealing with this epidemic,” says Gostin, who authored an article questioning the conflict between public health and civil liberties (JAMA 296, 2023, 2006).
Branson says that people do opt out of testing and that the CDC will be continually assessing whether or not people feel comfortable refusing an HIV test. There are also several anti-discrimination laws in the US that offer protections, many specifically tailored to HIV-infected individuals.

**Treatment access**

Ultimately, as in Botswana, the success of the CDC’s routine testing initiative will be measured by how many people are linked to treatment and care services. But many question whether clinics and the current funding systems in the US, like the Ryan White Care Act and the AIDS Drug Assistance Programs, are prepared to handle an influx of HIV-infected people. Statistics indicate that the majority of people with HIV are considered low income and are less likely to have private insurance, which might cover the yearly cost of ARV treatment—around US$12,000 to $15,000.

“We have a problem already,” says Levi. “We already have a lot of people diagnosed with HIV who aren’t receiving care.” He estimates that about 250,000 individuals in the US, who are known to be infected, aren’t receiving treatment. Adding another quarter of a million HIV-infected people into the system, many of whom may need treatment immediately, would require significantly more capacity and funding. The CDC argues that just identifying HIV-infected individuals isn’t in itself adding to the problem. “HIV infection eventually declares itself,” says Branson. “People need treatment whether or not they’re diagnosed.”

Physicians like Saag still maintain that their clinics are already at capacity and that a dramatic increase in federal or state funding would be needed for them to provide the complex treatment and care services to more HIV-infected patients. Yet in 2006 the approved budget for the Ryan White Care Act—federal legislation that provides funding for the medical care of people living with HIV/AIDS—actually decreased. “The idea that the funding pie is fixed is wrong,” says Saag. “If you have a growing epidemic, you have to pay for it.”

Without more funding researchers worry that the connection between testing and treatment will not be made and so more testing will do little to stem the number of new infections. “We shouldn’t be looking for the needles in the haystack if we’re only going to throw them back in,” says Walensky.

Many of these issues will continue to be discussed and debated in the future. If routine testing is widely adopted critics will be closely monitoring how many HIV-infected individuals end up actually accessing treatment, which they say is the only way to truly measure the success of the initiative and was the key to Botswana’s dramatic turnaround.

But it remains to be seen how many states will adopt the new CDC guidelines. In most cases implementing routine testing programs will require altering individual state laws, meaning state officials will have to navigate through murky territory and come up with testing policies that aren’t in violation of their existing privacy, consent, and human rights laws. For now, the agency’s recommendations remain just that. “Everything that comes out of the CDC is a recommendation,” says Branson. “It’s not the FDA [US Food and Drug Administration]; we’re not a regulatory organization.”

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