Rapid Test Time

The new 20-minute HIV tests are being trumpeted as prevention's much-needed magic bullet. But will HIVers pay high anxiety for neggies' comfort?

February 1, 2003 By Kai Wright

It's Thursday night and the crew's camped out in one of Baltimore's neglected concrete pastures, the same spot where it parks every Thursday. Nearby, there's a couple of gay bars popular among black men, and the lot itself hosts a gaggle of small-time pushers. Add the "meat rack" around the corner where hustlers stroll, and you've got an ideal rolling laboratory for an HIV testing and outreach experiment. That's why HERO, or Health Education Resource Organization, the city's oldest and largest AIDS service group, is here.

David (not his real name) pulls his new ride alongside HERO's RV. He hops out, bass pulsing from his windows, and bounds into the van, jonesing for the results from his STD tests. The dapper young man jokes about his new girlfriend and flaunts a casual excitement more like that of a game-show contestant awaiting his prize than someone learning whether he's contracted a potentially fatal virus. He chills long enough to slip a discreet question to Kontar Mosi -- the lead outreach worker who, himself a boyish 28, is David's peer. Mosi whispers back something about lubricant and the gay bookstore. When tallying the number of men the staff saw having sex tonight, he'll include David.

David's syphilis test comes up negative -- "I'm legal, kid!" he giddily proclaims, giving a pal a celebratory pound -- but his HIV test isn't ready yet. David doesn't know it, but that's bad news. A wait of more than one week probably means the lab is double-checking a positive result. Mosi hopes David will show up to find that out next week, but the odds aren't great: More than 40 percent of his clients don't return for results. That's standard when it comes to mobile-testing programs. In fact, it's a reality even in more clinical settings. According to the Centers for Disease Control and Prevention (CDC), one-third of the 2 million people who take HIV tests each year disappear before learning the outcome. As a result, a quarter of all positive results go undelivered.

These are blasphemous numbers to the "know your status" church of HIV prevention, in which getting tested is the doorway to both living with the virus and stopping its spread. Indeed, the CDC's brave new prevention strategy turns on testing 30,000 more people annually. But the problem is especially serious when the client is a guy like David. The prevention message just doesn't seem to be connecting with young black men who have sex with men -- whether they identify as gay, bisexual, same-gender-loving or none of the above. And studies show not only that infection rates among these men are exponentially higher than both their white and their

heterosexual counterparts', but also that their at-risk self-perception is moving in the opposite direction. Last summer, the CDC reported new data from an oft-cited survey of 5,700 young gay and bi guys in which 10 percent were positive: A stunning 93 percent of the HIV positive black men didn't know they had HIV. Baltimore was one of the six cities in the study.

But as POZ went to press, the Food and Drug Administration (FDA) was poised to release what many consider a silver bullet: a rapid test for HIV. Widely used around the world, rapid tests have yet to break into the U.S. market. But earlier this year, the feds notified two diagnostics companies that their rapid-test applications were "approvable" -- clinical trials have shown the tests to be safe and effective. All that remained was the agency's license.

Both tests can spit out results in as few as 20 minutes (see "Truth or Dare" below). And as prevention experts awaited the FDA announcement, they wondered whether the feds would limit the settings in which the tests can be performed; if given a "waived" classification, the tests could be performed outside of a lab -- say, in a van like Mosi's. "If this test is categorized as waived," says the CDC's Bernard Branson, MD, "it's going to make a huge difference."

Branson arrived in Atlanta at the CDC in 1990 after spending the '80s on the frontline of Baltimore's epidemic, in private practice and as medical director of HERO. During his 12 years in Atlanta, Branson has tirelessly pushed rapid tests, so his cheerleading is to be expected. But many in the much-beleaguered prevention establishment are equally energized.

Former CDC honcho Helene Gayle, MD, who helped craft the agency's know-your-status campaign, says she's "hugely excited about it." The Presidential Advisory Council on HIV/AIDS (PACHA) focused much of a recent meeting on rapid testing and voted to recommend outside-lab application. The new year, it seemed, would mark the dawn of an HIV-testing revolution. "We lose a lot of people," says Ron Simmons, MD, the pioneering head of Washington, DC's Us Helping Us, a 17-year-old ASO targeting black men. "Rapid testing would help."

Lee Savoy, however, is less enthused. A hulking man with a long beard and cleanly shaven scalp, Savoy plays up his cranky-academic manner. He views his testing and counseling gig at HERO as a sort of patient evangelism, and when asked about the promise of rapid testing, he offers a belly laugh. "If we go to bars and rapid-test everybody," Savoy says, waving his hand over imagined swarms of the newly tested, "and tell everybody their result, the negative people will jump up and shout hallelujah -- and then five minutes later say, 'OK, let's see who I can have sex with to celebrate the news,' and not worry about condoms."

Savoy is sitting in Baltimore's gay community center, where he handles drop-in testing and counseling before heading out with Mosi and company on the van. A client -- relaxed, professional-looking -- interrupts to ask for his results. This demographic is what Savoy sees primarily at the center -- white men in their late 20s and 30s who get tested regularly as part of their health maintenance. Few would disagree that this group will balloon with rapid testing on the market. Even better, according to the CDC, rapid testing will boost the number of hospital patients who get their results and also allow for reliable HIV screening in emergency situations.

The dispute over prevention's rapid-testing revolution turns on the presumed goal of "behavior change." Savoy and other skeptics question the prevailing "know your status" mantra for the hardest-to-reach and most-at-risk people, for whom the obstacles to harm reduction -- starting with condoms -- far outstrip the barriers a speedy test can remove. Knowledge, they argue, isn't necessarily power. Carlton Smith, a black gay HIVer and longtime Baltimore activist, puts it this way: "Getting tested is one thing, knowing your status is another, and living your status is still another."

To Smith, the challenge is more complex than simply getting people to take an HIV test. The plight of prevention, he says, is to persuade high-risk but low-access folks not only that HIV is a serious threat but that they can both protect themselves against it or, if they have it, get treatment. A potentially fatal yet slow-progressing disease just doesn't register as worth confronting when weighed against the immediate crises that many such people face. Mosi says he meets this attitude every time he tries to round up testing volunteers. "They say, 'If I got it, I don't want to know,'" he says. "Is it fatalism? Is it an esteem issue? Or is it just that they see it as a reality of life?" If the skeptics are right, effective prevention isn't about how quickly you move positive and negative people through the testing process, but, oddly, the opposite: how long you hold them in a conversation about the disease.

Chaos in the Baltimore van on any given night raises another set of issues. As a gentleman finishes up giving blood in one of two private stalls (while loudly assuring everyone he is a staunch heterosexual), a string of young men poke their heads in the van hesitantly. Some enter to sit down. It's a small space, and the vibe is more communal than private. Everyone is either in the middle of -- or on the way out for -- a night on the town. And it's hard to imagine a worse setting to tell someone they have HIV.

"You have your agenda of going to the store or to cop drugs or going to get some cocktails or whatever, somebody out there persuades you to have a test and tells you you're positive. I think that's rough," Savoy says. "When we give you a week or two turnaround, you have time to prepare." Those who don't come back probably weren't ready to deal. Simmons agrees. "There is no guarantee that just because you know your status you're going to wake up a new person," he says. "You might wake up a basket case."

While Simmons shares these doubts about a dramatic revolution -- "Getting your results back in five minutes isn't going to get people to test who wouldn't anyway because they're afraid" -- but he's still thrilled about anything that may get more HIVers into treatment. Helene Gayle, who now heads the AIDS program at the Bill and Melinda Gates Foundation, strikes a similar note. "Anybody who thinks knowing your status is the final answer doesn't know anything about prevention," she says. "Knowing your status is a gateway [to treatment and prevention]."

According to Thomas Coates, PhD, director of the Center for AIDS Prevention Studies at University of California at San Francisco, it's a gateway with tremendous potential. "The lion's share of studies show that people who test positive for HIV do reduce risk behavior," he says flatly, "and that's an important accomplishment." Though behavior change is less pronounced for those who

test negative, he says, they, too, practice more risk reduction than the untested. And a waived test could extend the benefit: “Studies in Africa show that by taking testing out into the field more high-risk people get their results,” Coates says.

Given such data, Branson is infuriated by naysaying about rapid testing. “You only get HIV from a person who is infected,” he says. “I’m interested in preventing disease.” The best way to do that? Disentangle counseling and testing and simply apply the “screen and treat” model used with other STDs. Since there was no treatment for HIV when screening tests first emerged in 1985, counseling was indispensable. Now, Branson argues, the advent of treatment options means “the role of testing itself -- with or without counseling -- is more important.” The bottom line? He insists that the more people who know their status, positive or negative, the fewer transmissions that will occur.

Truth or Dare

Dozens of rapid tests are used worldwide, but only one, Abbott’s SUDS (Single Use Diagnostic System), is available in the U.S. -- and SUDS is used sparingly because it requires a technician and lab. But last year the FDA also rated OraSure’s OraQuick test safe and effective for domestic use. OraQuick screens single blood samples for HIV antibodies -- not the virus itself -- using a finger stick, a reading device similar to a pregnancy test -- oh, and a technician. Working in partnership with Abbott, the company won a license to market the test in November. At presstime, Canada-based MedMira was awaiting an FDA stamp of approval for Reveal, a techie-free finger-stick test.

Studies show that the 20-minute OraQuick is as reliable as the classic ELISA/Western Blot, which -- as many of us remember all too well -- takes one to two weeks. The 10-minute Reveal has proved slightly less accurate, but still 99 percent error-free. The problem is that all three tests give a few false positives. As a result, each requires further confirmation (usually by Western Blot). This means that HIVers -- and those rare false positives -- must endure a nerve-racking week waiting for their second results. The CDC is already huddling with advocates to craft safeguards for confirming positive results. If the test is FDA-OK’d for nonclinical settings such as HERO’s van, a new protocol will have to be carefully hammered out for the test’s “speed” to be of any value.

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All this fast talk about fast testing has left unmentioned one significant detail: a positive result using the rapid-screening method requires a second test to confirm that it is not a false positive. This second test takes a week to complete. “In other words,” says longtime treatment activist and HIVer Tim Horn, “some poor SOB will get tested and wait half an hour only to be told that he ’may’ have HIV and that additional blood tests are needed. Talk about anxiety.” Or as Bob Huff, editor of Gay Men’s Health Crisis’ (GMHC) Treatment Issues, asked in a February 2002 piece: “If a simple finger-prick device can give a result within 15 minutes, how does a test-provider deal with a positive result? One way is to tell individuals that they have had an inconclusive result, then draw more blood to send to a lab for the conventional test and confirmation process. So while a single rapid test may be fine for alleviating the anxiety of the uninfected, it may not be the best solution for someone who really has HIV.” The fast test, then, is “fast” only for those who test negative.

While this may meet the goal of the “know your status” school to get as many people tested as possible, and may even successfully change the risk behavior of the uninfected, it remains to be seen what effect it will have on those who test positive -- who see their lives turned upside-down in a half hour and then are sent away to wait, hope against hope.

So far, the chasm between the optimism of folks like Branson and the reticence of the Baltimore crew suggests an increasingly familiar story. It is, once again, the tale of two realities: one for the positive, another for the negative. But it is also two epidemics in another sense. For people who value (and have access to) health care, the key moment bridging a person with HIV and treatment, between risky behavior and responsible safety, is knowledge of having HIV -- that is, getting tested. But for others, such as the folks at our Baltimore parking lot, that seemingly empowering information has far less meaning. “The key is understanding why young black men don’t know their status,” says Columbia University scholar Richard Elovich, the GMHC’s former prevention director, ticking off a list of intangible factors like stigma and sexual identity. “You may be able to deliver a rapid test in front of a club, but you can’t deal with these issues in front of a club.”

Elovich worries that it is our reluctance to confront such complex challenges that draws us to the quick technological fix of rapid testing. In that light, the "HIV results in minutes!" pitch is only as useful as the strategies we use to deploy it. And if we use it, however unwittingly, as a kind of intellectual condom to block out prevention’s genuine difficulties, the numbers of people tested may rise, but the rates of unsafe sex and infection likely will, too.

Still, consumers want the rapid test. And while HERO staff may be skeptical, every client on the van says he’d rather get results now than later. David, too, is thrilled about the idea -- sort of. “If I got it, just don’t tell me, ’cause I’ll go off,” he says -- a flip remark that he repeats several times. So Mosi and company are taking it seriously and will prepare for a tough counseling session should David show next week. That’s something they wouldn’t have been able to do had they informed him of the results just 20 minutes after administering the test.

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