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THE IMPORTANCE OF RAPID HIV TESTING IN AFRICA'S RESOURCE-CONSTRAINED SETTINGS

JURGENS DE LANGE

SUMMARY

- Accurately and quickly diagnosing HIV status in Africa's resource-constrained testing environments is an important, but poorly implemented facet of the overall fight against HIV/AIDS.
- Existing rapid tests are proven to be reliable in lab settings, but lack the required sensitivity and specificity when applied in the field. Further research on test accuracy and standardization should be done in concert with African countries.
- Access to clinical trials in the field and improved training of test administrators are key to improving the efficacy of rapid results.

BACKGROUND

One of the largest problems facing the HIV/AIDS epidemic is diagnosing HIV status. As a disease with multiple transmission routes and widespread prevalence amongst resource-constrained communities, it is critical to develop inexpensive, rapid and reliable methods to conduct testing. Ineffective HIV testing has particularly grave repercussions that extend beyond the patient's healthcare to the general population.

In January 2012, the South African government released a new National and Strategic Plan (NSP) for infectious diseases. One of their objectives is to test every South African for HIV at least once a year, meaning that more than 50 million HIV tests would have to be administered annually (South African National AIDS Council, 2012). In order to meet these ambitious objectives in a resource-constrained environment, the speed, accuracy and cost of HIV tests become key factors.

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Jurgens de Lange is a master's student in theoretical chemistry at the University of Pretoria, South Africa. Currently he is investigating the structure and reactivity of bisphosphonates, a class of drugs involved in the diagnosis and treatment of bone cancer.

This backgrounder explores the current state of research on rapid HIV testing from an African perspective. The pros and cons of different tests are presented and the discrepancy between lab results and applications in the field are shown. It offers a critical look at the problems HIV tests are facing and possible solutions to improve their effectiveness.

DEFINITIONS

Sensitivity and specificity: the sensitivity of a test is defined as the proportion of subjects who are correctly diagnosed positively, whereas the specificity of a test is defined as the proportion of subjects who are correctly tested negatively (The Gale Group, 2008). As an example, a test with a sensitivity of 85 percent will declare 15 out of a 100 people with HIV to be incorrectly HIV negative (false negative), while a test with a specificity of 90 percent will diagnose 10 out of a 100 people living without HIV to be HIV positive (false positive).

Window period: the window period is defined as the time interval after initial HIV infection but before a specific test can draw a conclusive result. This is dependent on the nature of the specific test, and is subject to variability due to differing environmental conditions and genetics.

Rapid testing: testing methodology consists of at least two tests: screening assays or supplemental/confirmatory assays. Screening assays are considerably cheaper and faster than confirmatory assays, but less accurate. Positive results from these tests are confirmed using a suitable confirmatory assay, whereas negative results are usually accepted as such, depending on the history of the community, patient and clinic (World Health Organization, 2009).

DIFFERENT CLASSES OF HIV TESTS

HIV tests differ fundamentally by which molecules they target. Tests can detect the genetic sequence of the virus by targeting specific nucleic acid sequences, detect gene-products in the form of antigens or measure the hosts' immune response against the virus in the form of antibodies. Combinations have evolved over time since the discovery of the HIV virus into a rich and diverse field of specific and unique tests (World Health Organization, 2004). Each test has specific conditions, from the amount of

sample preparation needed to the window period for detection, sensitivities and more. The result is that a specific test or combination of tests can cater to a specific purpose or community.

The three most important factors for consideration in Africa are the sensitivity, specificity and cost of an HIV test. Health leaders, whether at the national, regional or community level, must find an equilibrium between these variables. South Africa, for example, has only just started to show an increase in the amount of people tested annually, with seven million receiving tests in 2009 (World Health Organization, 2010). However, if a test has a sensitivity of even 99 percent, 70,000 people living with HIV would receive a false negative result. The situation is even worse for over 40 million South Africans who are not sure if they have HIV or not, as a false negative result (for those who do test) can lead to increased transmission rates through subsequent unprotected sexual activity and blood donation. The problem can be avoided by using double or triple screening, but for most African communities this is not a resource effective solution.

ATTAINING CONCLUSIVE RESULTS IN DEVELOPING COUNTRIES

According to the WHO, the minimum required specificity and sensitivity for a HIV rapid-test is 98 percent and 99 percent, respectively (World Health Organization, 2007). Since this proclamation in [insert year], there hasn't been a new product released that did not meet these standards in a lab setting. In fact, since 2000, most laboratories have reported specificities and sensitivities of 100 percent. Even still, rapid tests are only supposed to be used for screening, with positive results requiring confirmation from a more reliable method. The WHO suggests, however, that rapid tests be used conclusively in areas where communities do not have laboratories to confirm positive results (World Health Organization, 2004).

In recent years, studies emerging from Africa have seriously challenged the accuracy of rapid tests when applied outside lab settings. For example, a team of researchers based at the Nelson R. Mandela School of Medicine at the University of KwaZulu-Natal tested four HIV rapid tests in 2008 and found sensitivity and specificity in the ranges of 93-97 percent and 97-98 percent respectively (Moodley, Moodley, Ndabandaba, & Esterhuizen, 2008). In a laboratory the same tests scored 100 percent, but in the field

they were administered by relatively untrained nurses and counselors in KwaZulu-Natal province, South Africa. The same types of results for HIV rapid tests have been noted across the continent — performing well in laboratory settings, but showing high variability in the field (Phili & Vardas, 2002; Awazu, Abeti, Ewang, Ghogomu, Asobo, & al, 2000; Dessie, Abera, Walle, Wolday, & Tamene, 2008; Gray, Makumbi, Serwadda, Lutalo, Nalugoda, & al., 2007).

Generally, these studies were not critical of the tests themselves, but rather of the lack of training and quality control in their application. A 2012 study by another team based in South Africa conducted performance trials using similar tests as those conducted in 2008, but followed rigorous quality control procedures. This trial achieved sensitivity and specificity values between 99-100 percent — close to laboratory tested values (von Knorring, Gafos, Ramokonupi, Jentsch, & Team, 2012).

In addition to the direct negative effects of inaccurate testing, there are secondary effects as well. The first is a possible over-estimation of HIV incidence within certain areas of South Africa (and possibly elsewhere), due to low specificity in the tests frequently used in the field (Black, Osih, Rees, & Chersich, 2009). There is an ongoing debate on the subject, but the general consensus is that better testing methods and stricter clinical controls are needed. Incorrect reporting of incidence and prevalence statistics can have long-reaching effects, and can negatively affect policy-making. Secondly, the array of different tests and methodologies makes comparison of results and staff training extremely difficult. Thirdly, certain tests are susceptible to different HIV strains and host genetics. This is a relatively unexplored area, but clinical and laboratory trails are often conducted in countries with different epidemiological, viriological and genetic profiles than countries in Africa. Consequently, it should be expected that tests developed outside of Africa will perform differently in Africa.

CONCLUSIONS

HIV testing is a critically important part of the overall fight against the HIV/AIDS epidemic. At the individual level, inaccurate testing can lead to a false positive or negative result, both of which impact the health and mental well-being of the patient and entire communities. In addition, large-scale

inaccuracies lead to false reporting of epidemiological data, which can affect expenditure and policy decisions.

Results from African countries indicate that rapid tests themselves are adequate, but the personnel conducting them are undertrained. Training staff in the use of specific, standardized tests should be facilitated by governmental health policies, which currently do not cover HIV rapid tests in many African countries. There is also a need for up-to-date international research on currently available rapid tests and methodologies. Specifically, more field tests within different settings and populations are required in order to determine whether it is necessary to focus on researching new tests or training staff to use old ones. Ideally, this would be done with African countries playing a larger role in the development of new tests, both in terms of field trials and user input to improve ease-of-use. Rapid point-of-care tests developed for resource-constrained settings will continue to make undervalued contributions to fighting HIV/AIDS if they are developed in resource-rich environment.

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ABOUT THE AFRICA PORTAL

The Africa Portal is an online knowledge resource for policy-related issues on Africa. An undertaking by the Centre for International Governance Innovation (CIGI), Makerere University (MAK), and the South African Institute of International Affairs (SAIIA), the Africa Portal offers open access to a suite of features including an online library collection; a resource for opinion and analysis; an experts directory; an international events calendar; and a mobile technology component—all aimed to equip users with research and information on Africa's current policy issues.

A key feature to the Africa Portal is the online library collection holding over 3,500 books, journals, and digital documents related to African policy issues. The entire online repository is open access and available for free full-text download. A portion of the digital documents housed in the library have been digitized for the first time as an undertaking of the Africa Portal project. Facilitating new digitization projects is a core feature of the Africa Portal, which aims to improve access and visibility for African research.

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AFRICA INITIATIVE

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