Ensuring the Quality of HIV Rapid Testing in Resource-Poor Countries Using a Systematic Approach to Training

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Abstract

HIV rapid testing is a key tool in the fight against the HIV/AIDS epidemic; it enables the rapid expansion of prevention and treatment programs in resource-limited countries. Meeting the goals of these programs means that millions of people will need testing annually. Accuracy and reliability of these tests are critical to the success of these programs. Given the enormous number of rapid tests that are performed each year, even a low error rate of 0.5% applied to 100 million people will result in 500,000 erroneous results. Ensuring the quality of HIV rapid testing presents unique challenges in that testing is often performed in various settings by personnel without formal laboratory training. This article describes the development and implementation of a generic HIV rapid test training package using a systems approach in an effort to standardize training and ensure the quality of rapid tests. It also highlights achievements from Uganda, Haiti, and Botswana.

According to the joint United Nations program on AIDS, in 2008, 33.4 million people were living with HIV worldwide, including 2.7 million who became infected that year. About 2 million died.1 Sub-Saharan Africa remains the most affected region in the epidemic, where 10% of the world’s population accounts for 67% of adults and nearly 90% of children infected with HIV.2 During the last several years, there has been a concerted effort worldwide, especially from the Global Fund for AIDS, Tuberculosis and Malaria; The US President’s Emergency Plan for AIDS Relief (PEPFAR); the World Bank Global AIDS Program; and others to prevent, treat, and care for patients with HIV or AIDS in Africa.3-7 Although an estimated 4 million HIV-infected persons are already receiving treatment in developing countries,2 millions more will need to be counseled and tested to meet the global goal for universal treatment. Such large-scale testing is unprecedented in the history of infectious diseases. For instance, Tanzania planned to treat about 500,000 HIV-infected persons with antiretroviral treatment (ART) by the end of 2008.8 Given its HIV prevalence of 6.5% and ART eligibility criteria, Tanzania had to test 25 million people to reach its treatment target.9 It was estimated also that 8,000 testers and 2,000 test sites would be needed to reach the targeted goal.

Efforts to expand the service, however, have been challenged, partly owing to the limited number of qualified personnel to perform accurate HIV diagnosis. Traditionally, these tests are done in a laboratory by highly trained technicians using relatively sophisticated technology such as the enzyme-linked immunosorbent assay. The introduction of HIV rapid tests has moved testing outside the traditional laboratory and into settings such as point-of-care sites for ART, prevention of mother-to-child transmission, and volunteering counseling and...
testing sites, tuberculosis clinics, and sexually transmitted diseases clinics. It has also allowed non-laboratory staff, such as nurses and community counselors, to perform HIV rapid tests. This is consistent with the World Health Organization (WHO) recommendations on task shifting in support of universal access to HIV and AIDS prevention, treatment, and care.\textsuperscript{10,11}

Regardless of the setting or the personnel who perform the tests, the accuracy and reliability of diagnostics must be maintained for the success of HIV/AIDS programs. To date, more than 86 million people have received counseling and testing for HIV from PEPFAR-supported programs. Assuming an error rate of 0.5%, 430,000 people will have received erroneous results. To ensure reliability and minimize errors, quality assurance measures must be in place to address all aspects of testing as rapid testing expands into nontraditional settings where testing is conducted by people without a laboratory background or formal healthcare training.

There was an urgent need to train a critical mass of personnel to meet program goals. To standardize and ensure the quality of training, the US Centers for Disease Control and Prevention (CDC) and WHO, with funding from PEPFAR, used a systematic approach to developing and implementing tools to help resource-poor countries train nonlaboratory personnel in HIV rapid testing.\textsuperscript{12,13} This article describes the tools and global training strategy to implement high-quality HIV rapid testing in multiple countries.

### Using a Systematic Approach: Development of an HIV Rapid Test Training Package

The CDC/WHO HIV Rapid Test Training Package is competency-based, comprehensive, and adaptable to support country-specific policies and testing algorithms. It allows modifications to address different target audiences: laboratory staff, nurses and health care workers, and community counselors. The package is organized into 16 modules, only 4 of which are directly related to the actual performance of rapid testing. Other modules address various aspects of quality assurance such as safety, inventory management, equipment use and care, quality control, external quality assessment, and documents and record keeping.

To maximize the effect of the training package, CDC and WHO developed a framework Table I to guide ministries of health and their partners to systematically plan and execute the rollout of the training program nationwide. This framework prescribes 5 phases: (1) direction setting, (2) alignment, (3) readiness, (4) implementation, and (5) monitoring and evaluation. It also includes a template to guide the planning process through the 5 phases.

### Global Training Strategy

To meet the varying needs of countries, the training package contains elements requiring country customization in addition to core and universal content. Detailed instructions are provided on adapting the package and preparing for the practical and didactic sessions. Furthermore, this package is built with the “workshop-in-a-box” concept to make it portable with multiple components: training video, presentation slides, trainer’s guide, participant’s manual, and laminated job aides for obtaining blood specimens and performing individual tests.

These tools were launched in 2005 in Dar es Salaam, Tanzania, and the CDC has provided consultation to several countries on rollout planning and curriculum customization.

**Table I**

Framework for Systematic Training Rollout

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<thead>
<tr>
<th>Phase</th>
<th>Purpose</th>
<th>Result</th>
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<tr>
<td>Direction setting</td>
<td>Defines training goal in support of a country’s scale-up plan to achieve its care, treatment, and prevention targets</td>
<td>Linkage to country’s or program’s goal and strategy; clearly defined training goal that specifies the target audience, the total number of people to train, geographic and programmatic coverage, and the time frame</td>
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<td>Alignment</td>
<td>Builds key stakeholder consensus and commitment to ensure training success</td>
<td>Appropriate policy in place; funding/resources secured; consensus achieved; roles and responsibilities defined; coordinated effort; more efficient use of limited resources</td>
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<td>Readiness</td>
<td>Ensures system readiness for training rollout</td>
<td>Learner readiness; trainer readiness; training tool readiness; training infrastructure readiness; workplace readiness</td>
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<tr>
<td>Implementation</td>
<td>Implements training systematically on a national scale</td>
<td>A national training calendar specifying the number of training workshops, when and where training will take place, training-of-trainers activities, and follow-up supervisory visits; a training budget</td>
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<tr>
<td>Monitoring and evaluation</td>
<td>Ensures quality, improves process, and measures success</td>
<td>(1) Has training been implemented according to plan? (2) Have we achieved the training targets/coverage? (3) Are trained health care workers providing quality service on the job?</td>
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Uganda and Trinidad and Tobago began their national rollouts quickly and later served as models for other countries. In December 2006, the CDC held a workshop in Atlanta and trained program managers and trainers from 11 PEPFAR-supported countries (Côte d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, Tanzania, and Zambia) on rollout planning and training skills. In 2007, the CDC supported 4 countries (Botswana, Ethiopia, Tanzania, and Zambia) to conduct training-of-trainers (TOT) workshops that resulted in 116 trainers.

**Outcome**

Different countries are at different stages of using the tools for training. Remarkable progress has been made in terms of expanded testing capacity, increased number of trainers, improved quality of testing, and reliability of test results. Herein we highlight challenges and achievements by 3 countries: Uganda, Haiti, and Botswana [Table 2].

**Observation**

We learned several lessons from our multicountry rollout experiences.

*Non–laboratory staff, if properly trained, can perform rapid testing as well as laboratory personnel.* Evidence from Uganda indicates that nonlaboratory workers perform as well as people with a laboratory background based on results of practical examinations or follow-up proficiency tests (Table 2). One possible explanation is that they may be more receptive to learning new procedures outside of their routines.

*Curriculum customization requires a lot of time and staff.* Many countries initially underestimated the amount of effort required for adapting the training package. Early attempts to do this on a part-time basis often failed. Dedicated staff and intensive meetings away from the office seemed more productive. Botswana found it helpful to have an outside consultant coordinate the effort. The large amount of content in the training package seemed to overwhelm many people. They needed a lot of guidance on customizing the package to their specific settings. Programs such as tuberculosis,

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<td><strong>Country</strong></td>
<td><strong>Description of Experience</strong></td>
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<td>Uganda</td>
<td>To date, Uganda has trained a total of 3,325 service providers. Of the service providers trained, 43.9% were laboratory personnel, and 56.1% were nonlaboratory personnel. Furthermore, Uganda had implemented follow-up visits to all trained personnel to identify challenges and provide posttraining support and supervision. Each participant received a panel of 20 samples to test as part of the certification requirements. Based on the data from follow-up visits the following findings were noted: (1) All test providers who were regularly supervised performed well throughout the testing process (preanalytical, analytical, and postanalytical). (2) Test providers who were not performing tests routinely were noticeably slow in performing the task. (3) Although nurses were slow in recording results, they performed well and met all certification requirements. (4) Some trainees were unable to perform tests owing to shortages of necessary supplies. The Uganda experience demonstrated that nonlaboratory staff members were equally able to correctly identify the HIV status as laboratory personnel during the practical examination and 3 months later, on site. Their experience also highlighted follow-up visits as an essential part of any training and a strategic tool for promoting quality assurance. Uganda has also been working to establish a nationwide quality assurance scheme for routine monitoring of rapid testing.</td>
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<tr>
<td>Botswana</td>
<td>By 2008, Botswana had conducted 37 workshops and trained a total of 400 lay counselors, midwives, and nurses from all districts using a national standard curriculum customized from the Centers for Disease Control and Prevention–World Health Organization generic package. All participants performed well at the final examination using PT panels. The success was attributed to the emphasis on hands-on training. Trainees who performed poorly during hands-on sessions received individual coaching and practiced on more specimens. To monitor posttraining performance of the test providers, Botswana established a quality control program for HIV rapid tests. The National Health Reference Laboratory sends out PT panels to all trained personnel twice a year. Since the start of the program in late 2007, 30 facilities and 65 test providers have participated. Results from the first round of the PT program showed that 40% of the participants scored 100% and 55% scored 85%, while 5% could not be scored because expired kits were used to test the PT specimens. They also found that lay counselors did not perform as well as other nonlaboratory staff in the PT program, indicating the need for more on-site supervision. sites with poor PT performance were followed up by the National Quality Assurance Laboratory with on-site supervision visits. A checklist was used to identify areas requiring improvement. Additional hands-on training was provided with emphasis on timing of the reaction and reading and interpretation of the results. The visit concluded with another PT for evaluation.</td>
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<tr>
<td>Haiti</td>
<td>Following the December 2006 training-of-trainers workshop in Atlanta, GA, the Haiti delegation immediately briefed key stakeholders and formed the national laboratory training team. The team customized and translated the training package and conducted a training-of-trainers workshop. In early 2007, Haiti established 2 training laboratories at the national laboratory and procured laboratory supplies to get ready for the national rollout. Training was implemented as part of the national laboratory QA program for HIV rapid testing. Other QA components included implementing a standardized log book for testing, proficiency testing, regular site assessment, and retesting of samples at newly established sites. By the end of 2007, the national laboratory had conducted 21 workshops and trained 430 health care workers, including 38 physicians, 207 nurses, 84 auxiliary nurses, 88 laboratory technicians, 7 psychologists, and 6 social workers.</td>
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PT, proficiency testing; QA, quality assurance.
preventing mother-to-child transmission, and counseling and testing asked for a much scaled-down version to plug into their existing curricula to train nonlaboratory personnel. To address this need, the CDC convened a workgroup in late 2007 and devised a simplified package for integration into other curricula that target nonlaboratory personnel.

The shift of HIV testing to nonlaboratory settings has vast implications on test strategy, procurement, quality assurance, and training. When HIV rapid tests are performed outside the laboratory setting, they are usually done one patient at a time (vs batch testing), using whole blood collected from fingers (vs venipuncture). These changes require new thinking on appropriate test algorithms, procurement of laboratory supplies, workload of test providers, and training, as distinguished from tests that are done in a laboratory.

Because most rapid tests involve finger stick, a device is required to transfer the specimen from the finger to the test. Some test kits (eg, Determine HIV 1/2/O, Inverness Medical Innovations, Princeton, NJ) do not come with a blood transfer device. Countries have to procure such devices separately or leave it up to the sites to improvise. We found cases where the test protocol called for clients to drop finger blood directly into the test kit, rendering sample volume difficult to control.

On the other hand, when blood-drawing devices are part of the kits, different kits use different devices: pipettes, loops, droppers, and others. This complicates training, especially for nonlaboratory personnel. Some countries have contemplated streamlining blood-drawing devices for ease of training and operations but were concerned about deviating from manufacturers’ standard operating procedures (SOPs).

Furthermore, to ensure correct sample volume to the test kits, some countries devised complicated protocols to transfer blood from a finger to the test device using capillary tubes and parafilm (or a slide) as middle steps. All of these devices need to be procured, and personnel need to be trained in all these skills. The use of capillary tubes and slides also requires measures for sharps disposal.

Finally, many countries use a serial testing algorithm. That is, only clients with a positive result on the first test are tested on the second. This has a lot of complications in high-burden areas. One is the higher likelihood of having to prick the client’s finger more than once. It also takes longer to perform serial testing than parallel testing (performing 2 tests at the same time). With serial testing, a community counselor can see an average of only 5 clients a day. A client being called back for a confirmatory test also poses a confidentiality issue.

The availability of tests using oral fluid may simplify many of the aforementioned issues. They require no blood transfer devices, and there is no need to worry about sample volume or sharps disposal. Evaluation of these test kits is underway in several countries.

Recommendations

Several critical aspects must be addressed for successful training and service expansion. Factors such as policy development, stock availability, and test site work process are critical and must be addressed for training to achieve its desired effect. For example, it is not unusual that a country started curriculum customization and training before the appropriate national policy was in place. As a result, it had to revise the package later to reflect the new policy. Uganda found that many trained personnel were unable to provide service because of test kit stock-out. Tanzania could not obtain the confirmatory test kits from the manufacturer on the eve of its planned launch of the new test algorithm and training. At counseling and testing sites in South Africa, blood drawing and test result reading were disjointed; as a result, the incubation time could not be controlled. Without redesigning the work process, skilled test providers will not be able to provide accurate test results.

Countries should pilot-test the customized curriculum before launching it nationwide. To support rapid program expansion, some countries skipped the crucial step of pilot-testing the newly customized materials. Pilots provide the opportunity to identify weaknesses and address gaps in the curriculum. One country printed hundreds of highly polished training manuals without a pilot and later had to face a second round of customization and reprinting costs. It is important that countries test the customized curriculum on the target audiences (HIV rapid test providers) and revise and finalize the materials based on feedback from the pilot before printing large quantities of the manuals and conducting TOT workshops.

Like laboratory SOPs, training SOPs are important during training rollout. Many countries use the TOT model to quickly build up the training capacity to reach the district and community levels. Typically, they train a group of master trainers, and the master trainers, in turn, train more trainers. As training is cascaded downstream, standardization of how to teach the curriculum becomes crucial in ensuring quality and consistency. This is particularly important when teaching practical sessions such as finger pricking and rapid testing procedures. Some laboratory staff we observed in the TOT workshops were unaware of their own deficiencies in laboratory practices. Therefore, they are likely to transfer those habits, albeit unintentionally, to the test providers they would train in the future. To better assurance quality of training during scale-up, it is important to standardize how the laboratory procedures are demonstrated and taught. These SOPs can be used during TOT and in subsequent training rollout.

A national quality assurance program must exist to sustain results achieved through training. A key factor in the success achieved by Botswana, Haiti, and Uganda is that training was implemented as part of a national quality assurance program (Table 2). This program ensures routine monitoring.
of rapid testing through on-site supervision, proficiency testing programs, and use of a standardized log book. Training should not be treated as a stand-alone intervention but should be part of a larger quality assurance strategy to sustain the performance of the trained test providers.

Conclusions

Tremendous progress has been made since we first launched the HIV Rapid Test Training Package in 2005 in Dar es Salaam. Undoubtedly there is still much to do. Consistent monitoring and follow-up of trained personnel are hard to sustain unless a national quality assurance system is put in place by the government. However, we believe that the lessons we have gained from multicountry training rollout are transferable to any training programs in resource-poor countries, such as the President’s Malaria Initiative, and should be shared broadly.

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References