Malawi is a landlocked country in Southern Africa with a population estimated to be around 14 million (NSO, 2008). According to the Antiretroviral Treatment program quarterly report (2009) about 200,000 people are tested every three months and 16% of these test HIV positive. Of the HIV positive about 77% are referred to the Antiretroviral Treatment (ART) program and 20% are pregnant women and referred to Prevention of Mother To Child Transmission (PMTCT) program. Malawi utilises mostly non-medical professionals in HIV rapid testing and there has been efforts to bring HIV testing closer to the communities which has led to increase in HIV Testing and Counselling Sites (HTC).

The HTC sites range from static, outreach, mobile vans, door to door and introduction of each of them poses a challenge in maintaining standards and quality. The sites increased from 300 in 2006 to 984 in 2009 making provision of quality HIV testing in support of prevention and care a national priority.

To address this challenge the National HIV reference laboratory (NHRL) was mandated by the Ministry of Health to establish a HIV rapid testing Quality Assurance Program (QAP). The aim of the QAP was to ensure that HIV rapid testing in Malawi is done with standards and quality despite the volumes testing and use of non-laboratory and in many cases non-health professionals. At the time of reporting there were almost 3000 people trained to perform HIV rapid testing in various communities in Malawi and this posed a challenge in ensuring quality of testing.

Intervention: The HIV QA program provided QC, PT, site assessments through the district focal points using standardized protocols. HIV positive and negative quality control plasma samples were prepared at the NHRL and distributed to the testing sites every quarter since November 2006 to December 2009. Proficiency testing (PT) samples consisting of 5 panels were prepared and distributed by the NHRL to the District Focal points referred to as Quality Assurance Referral Laboratories (QARLs) and these subsequently distributed to the HTC sites. Quarterly site assessments were conducted and proficiency testing feedback with scores was provided with suggestions for corrective action. District, central and other faith based hospital laboratories were used as the QARLs to ensure distribution of QC materials and supervision of the HTC sites as shown in the diagram in Figure 1.

Figure 1: HIV QA program flow chart
Standardized checklists and forms were used in the assessments and reports were sent back to the NHRL. Quality assurance trainings were conducted to refresh all staff involved, supervisors and new personnel joining at various levels described in the above diagram. Those classified to have passed the site assessment had at least partially fulfilled all the sections of the checklist. For the PT the individual tester should have followed the algorithm, provided correct results and correct interpretation. HTC sites were followed up all the HTC sites that underperformed and in turn the NHRL followed up all underperforming districts.

Results:

The PT results were not blinded for other years from November 2006 to March 2008. From June 2008 PT results were blinded and documentation had improved after receiving feedback from users and international assessors. Marked competency improvement in HIV testing from 67% to 97% (p<0.001) of testers getting a 100% pass rate was noted from June 2008 to September.

Figure 2: HTC sites and testers performances

The graph shows HTC testers performances from June 2008 to September 2009 on three key QA indicators – Use of quality controls, use of standard algorithm and PT performances. Use of quality controls improved from ~55% to 93% over the period. Interventions done were to ensure that all testers have QC materials available, were checked that they perform the quality control weekly and keep records of the quality control in the HTC log book. Availability of algorithm improved from 40% to 97%. Interventions done were printing and laminating the national HIV testing algorithm on A4 and these were distributed to all HTC sites in Nov 2008 to ensure standardization of HIV testing. PT improved from 67% to 97% for testers achieving 100% pass rate. There were efforts in identifying testers who fail and ensuring that their reasons of failing were identified and corrected. The most common reasons for failing identified included:

- Not waiting for incubation time as they would read and interpret once control line appears. There was emphasis on adhering to the standard operating procedures and use of stop watch to ensure interpretation is done after the recommended incubation times.
- Problems in identifying weak positives. Some testers were lacking confidence in interpreting a faint line as a positive.

Lessons:

Lessons learnt

- Constant supervision and provision of PT samples can help to improve quality of HIV rapid testing even in remote areas.
• Provision of Quality Assurance materials from the one central coordinating unit can help in standardising HIV rapid testing.

• Combining PT and site assessments is key in identifying problems and taking corrective action for continuous quality improvement.

The following challenges were noted;

• A number of HTC sites still fall short of required standards and performances

• Coverage of all sites and testers has not yet reached the maximum

• Tracking of testers in ensuring that the non-performers are assisted before serving clients.

• Ensuring availability of test kits, thermometers, stopwatches and fridges for QC material storage.

• Inadequacy of funds to address the challenges in a timely manner.

There were recommendations and plans to;

• Pilot and roll-out Dried Tube Specimen (DTS) technology for HIV quality control preparation to address challenges in storage and transportation. This has proven to be cost-effective as it has already been piloted in other countries.

• Introduce HTC tester individual log book and unique identification number to assist in tracking site assessment, PT performance and training.

• Revisit the training curriculum to ensure the practical component is strengthened, HIV quality assurance is emphasized and competence assessed before certification to practice. Training of HTC testers can also be coordinated through the HIV QA program to standardize the training and ensure quality of the training product.

• Integrate the HIV rapid test Quality Assurance program with other QA programs to mobilize resources and strengthen the laboratory system.
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