Effect of On-Site Support on Laboratory Practice for Human Immunodeficiency Virus, Tuberculosis, and Malaria Testing

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ABSTRACT

Objectives: To evaluate the effect of on-site support in improving human immunodeficiency virus (HIV) rapid testing, tuberculosis (TB) sputum microscopy, and malaria microscopy among laboratory staff in a low-resource setting.

Methods: This cluster randomized trial was conducted at 36 health facilities in Uganda. From April to December 2010, laboratory staff at 18 facilities participated in monthly on-site visits, and 18 served as control facilities. After intervention, 128 laboratory staff were observed performing 587 laboratory tests across three diseases: HIV rapid testing, TB sputum microscopy, and malaria microscopy. Outcomes were the proportion of laboratory procedures correctly completed for the three laboratory tests.

Results: Laboratory staff in the intervention arm performed significantly better than the control arm in correctly completing laboratory procedures for all three laboratory tests, with an adjusted relative risk (95% confidence interval) of 1.18 (1.10-1.26) for HIV rapid testing, 1.29 (1.21-1.40) for TB sputum microscopy, and 1.19 (1.11-1.27) for malaria microscopy.

Conclusions: On-site support significantly improved laboratory practices in conducting HIV rapid testing, TB sputum microscopy, and malaria microscopy. It could be an effective method for improving laboratory practice, without taking limited laboratory staff away from health facilities for training.

In sub-Saharan Africa, more than half of all deaths are due to infectious diseases, such as human immunodeficiency virus (HIV), tuberculosis (TB), and malaria.1 While efforts to address infectious diseases in Africa have increased substantially,2 global infectious disease programs have primarily focused on clinical training in prevention and treatment, with limited attention to other aspects of health care. Strong laboratory practices are necessary to ensure reliable test results that lead to appropriate diagnosis and treatment. Despite documentation of poor-quality laboratory practices, insufficient resources have been directed towards their improvement.2-5

Within laboratories, quality management practices such as standard operating procedures are key tools to ensure high quality and consistent laboratory testing.6 Improving adherence to these procedures increases the quality of laboratory testing and leads to more accurate patient diagnoses.7 Without access to high-quality laboratories, patients will continue to be misdiagnosed, leading to inappropriate treatment and increased mortality.3

Recent randomized control trials and reviews have shown that on-site support can effectively improve clinical skills, leading to improved patient quality of care in resource-limited settings.6-13 A similar approach could be applied to build laboratory capacity. Past studies of laboratory capacity building have primarily used pre-post designs and focused on training programs14-17 or training mixed with on-site support,18,19 usually addressing laboratory tests for a single disease.
The Integrated Infectious Disease Capacity-Building Evaluation (IDCAP) was a cluster-randomized trial that aimed to test the effect of training and on-site support (OSS) on clinical competence, clinician practice, facility performance, and population-based mortality of children younger than 5 years. The OSS intervention involved all staff at the IDCAP intervention facilities, including laboratory staff. As a secondary outcome, laboratory staff practice in conducting laboratory tests for three leading causes of mortality in Uganda (HIV, TB, and malaria) was measured. We evaluated the effectiveness of on-site support in improving HIV rapid testing, TB sputum microscopy, and malaria microscopy testing processes among laboratory staff.

Materials and Methods

Evaluation Design

This evaluation of laboratory practice used a cluster-randomized design. The clusters were 36 health centers IV (HCIVs), comparable private health centers, and small hospitals in Uganda, randomized (1:1) to parallel intervention and control arms. HCIVs act as the highest health care referral point for health subdistricts and provide preventive and curative outpatient services to a population of about 100,000 people. They offer emergency, surgical, and obstetric procedures accompanied by limited inpatient wards, as well as referral to district hospitals. HCIVs provide daytime laboratory services, while hospitals provide overnight laboratory services through an on-call system. Observations of laboratory staff were conducted at the health facilities between December 2010 and March 2011. The full trial protocol is available as Protocol S1 in Weaver et al.

Participants and Eligibility

The 18 health facilities were drawn from all major regions of Uganda. Facility inclusion criteria have been described previously. One inclusion criterion relevant for this analysis was that each facility was required to have a functional laboratory that could conduct the following six investigations: HIV rapid test, malaria blood smear, TB sputum smear, urinalysis, stool analysis, and hemoglobin estimation. All laboratory staff at each facility were eligible and invited to participate in OSS.

Interventions

OSS visits took place between April and December 2010 and were conducted once a month for 9 consecutive months. OSS included four components: multidisciplinary team training, breakout sessions by cadre, one-on-one mentoring, and continuous quality improvement. Each visit focused on a specific topic (ie, HIV, TB, malaria), as well as follow-up on topics from previous visits. The sequence of topics was reported in Naikoba et al. The OSS visits were 2 days each and implemented by a four-person mobile team: a medical officer, clinical officer, laboratory technologist, and registered nurse. The laboratory technologist is the highest level of training for laboratory professionals in Uganda. Before each OSS visit, the mobile teams were oriented to the OSS training materials designed for that visit. Each mobile team visited the same set of health facilities throughout the 9 months to ensure continuity of the OSS intervention.

During each visit, laboratory staff attended the didactic multidisciplinary team training with the other clinical staff at the health facility. Following the training, the mobile team laboratory technologist would lead breakout training sessions focused on building laboratory capacity. The content for the laboratory breakout sessions was adapted from the Infectious Diseases Institute’s 10-day “HIV Laboratory Techniques and Good Laboratory Practices” training to include laboratory techniques for TB sputum and malaria microscopy. The malaria microscopy content was adapted from the laboratory training portion of the Joint Uganda Malaria Program, which has been shown to successfully improve the practice of laboratory diagnosis of malaria. Table I describes the core competencies included in the breakout sessions.

During mentoring sessions, the mobile team laboratory technologist demonstrated correct laboratory procedures, observed and coached laboratory staff as they conducted the procedures, and provided guidance on infrastructure and equipment.
systems issues such as the organization of the laboratory and the development of laboratory standard operating procedures. They used the observation checklist to assess the skills of the laboratory staff for the tests that were the focus of the OSS visit. Laboratory staff also participated in the continuous quality improvement teams at their facilities. These teams met during OSS to review facility performance indicators and develop and implement action plans to improve performance.

Outcomes

The laboratory practice measures were the proportion of laboratory procedures correctly completed for HIV rapid tests, TB sputum microscopy, and malaria microscopy. A standardized observation tool was used to assess laboratory staff practice in carrying out the three laboratory tests. Each test had 12 to 20 items to assess proficiency. Each item was phrased as a question, and observers were prompted to check a “yes” or “no” as to whether the laboratory staff being observed correctly performed the step. The number of steps done correctly was totaled for each test to produce the proportion of laboratory procedures correctly completed during each observation.

Sample Size

Sample size calculations were based on facility performance indicators, such as the proportion of malaria suspects with a malaria test recorded, rather than laboratory practice measures. A convenience sample of the laboratory staff who were available on the day of the observation at each of the 36 facilities was observed.

Ethical Considerations

The IDCAP protocol was reviewed and approved by the School of Medicine Research and Ethics Committee of Makerere University (reference number 2009-175) and the Uganda National Committee on Science and Technology (reference number HS-722). The University of Washington Human Subjects Division determined that it did not meet the regulatory definition of research under 45 CFR 46.102(d).

Written informed consent was obtained from the observed laboratory staff for secondary analysis of the Infectious Disease Institute’s training program data, including the laboratory observations.

Data Collection

Observations were carried out by the mobile team laboratory technologists between December 2010 and March 2011. Each mobile team was assigned to a region that included intervention and control facilities. In the intervention arm, the observations were conducted by the laboratory technologist who provided OSS at the facility. In the control arm, they were conducted by the laboratory technologist who was assigned to the same region. For each of the three laboratory tests, the observer watched as the facility laboratory staff conducted the test and recorded whether each step on the observation tool was done correctly. The laboratory technologists observed up to seven tests of each type, subject to patient availability.

Data on the total number of laboratory staff at each facility were collected from the facility managers during the first OSS visit. Laboratory staff participation in OSS was collected during each visit.

Data Analysis

All observations were double entered in EpiInfo3.2 (Centers for Disease Control and Prevention, Atlanta, GA), cleaned, and validated. All analyses were performed with Stata 11 (StataCorp, College Station, TX). Descriptive statistics on laboratory staff’s cadre and participation in OSS were summarized.

To test the effect of OSS on laboratory staff practice on each outcome, we used a multilevel mixed-effects linear regression model, with each observation as the unit of analysis, controlling for the effect of the laboratory qualification or cadre and clustering on health facility. The main effect was arm, with cadre (laboratory assistant, technician, or technologist) as the covariate.

Results

Participant Flow

The flow of facilities and the laboratory participants is shown in Figure 1. Of 36 health facilities, 31 were HCIVs and five were hospitals. Four of the five hospitals were randomly assigned to the control arm. There was no attrition among the 36 enrolled facilities. Of the 128 laboratory staff, 64 (50%) were observed. All laboratory staff on duty during that day were observed. Table 3 also shows participation in OSS in the intervention arm by cadre as a percentage of total laboratory staff and the observed staff as a percentage of total laboratory staff.

Recruitment

The facilities and their staff were recruited between March and September 2009. Consent for the use of the training program data for this evaluation was carried out between January and March 2011. OSS recruitment and registration began in April 2010 and continued throughout the
intervention. All staff were encouraged to attend OSS regardless of previous attendance.

Outcomes and Estimation

Item Analysis

For HIV rapid testing, nine (75%) of 12 checklist items were done correctly for more than 80% of the observations in the intervention arm compared with 5 (42%) in the control arm (Table 2). The intervention arm performed more than 20% better than the control arm in three steps: assembling required materials, timing the procedure, and following Ministry of Health algorithms for HIV testing. In 80% or more of the observations in both arms, laboratory staff wore gloves, drew the right volume of blood, and followed...
safety and infection control procedures for HIV rapid testing. In 100% of observations across both arms, laboratory staff interpreted HIV rapid test results correctly. In less than 40% of observations in both arms, laboratory staff checked for kit lot numbers and expiry dates and timed the procedure.

For TB sputum microscopy, 16 (84%) of 19 items were done correctly for more than 80% of the observations in the intervention arm compared with seven (37%) in the control arm. The intervention arm performed more than 20% better than the control arm in 11 steps, such as explaining to the patient how to avoid contamination of the exterior of the sputum container and using a quality control stain with known positive and negative smears. In more than 93% of observations in both arms, laboratory staff followed all steps in the sputum staining. In less than 40% of observations in both arms, laboratory staff explained the importance of the sputum examination to the patient.

For malaria microscopy, 11 (85%) of 13 items were done correctly for more than 80% of the observations in the intervention arm compared with five (26%) in the control arm. The intervention arm performed more than 20% better in seven steps. Only one indicator, wiping away the first drop of blood, was below 50% in both arms.

Focusing on reporting practices, both arms reported HIV rapid tests legibly as shown in HIV rapid test item 10 (99% intervention arm and 100% control arm) in Table 2. Both arms reported 100% of TB sputum results according to
World Health Organization (WHO) criteria (item 17). The intervention arm reported 99% of malaria test results according to WHO criteria compared with 63% in the control group (item 12). There was no register review or documentation of changes in recording completeness over time.

Comparing Intervention and Control Arms

Laboratory staff in the intervention arm performed 18% to 29% higher than the control on all three laboratory tests, with mean scores all above 80% (Table 5 and Table 6). The intervention arm performed 18% higher in HIV rapid testing (adjusted relative risk [aRR], 1.18; 95% confidence interval [CI], 1.10-1.26), 29% higher in TB sputum microscopy (aRR, 1.29; 95% CI, 1.21-1.40), and 19% higher in malaria microscopy (aRR, 1.19; 95% CI, 1.11-1.27) compared with the control arm. Laboratory technicians did not perform significantly better than laboratory assistants in any of the tests, with an aRR (95% CI) of 1.02 (0.99-1.05) for HIV rapid testing, 0.97 (0.92-1.03) for TB sputum microscopy, and 1.01 (0.97-1.06) for malaria microscopy.

Discussion

OSS significantly improved the practice of laboratory staff in conducting HIV rapid testing, TB sputum microscopy, and malaria microscopy.
microscopy, and malaria microscopy. While several studies have documented the effect of OSS on clinical skills, this is one of the first studies to demonstrate the effects of OSS alone on laboratory practice across multiple tests and diseases.\textsuperscript{8} Several key processes in the preparation of laboratory samples, including explaining to patients how to produce good sputum for TB testing, following the algorithms for testing, and correctly dispensing the blood on test strips for HIV testing, and recording results according to WHO criteria for malaria testing were substantially higher in the intervention arm.

Both laboratory assistants and laboratory technicians took part in OSS. There was no significant difference in the practice of laboratory assistants and laboratory technicians in any of the three tests, demonstrating that OSS can improve laboratory skills regardless of cadre. A study in Ghana showed improved diagnostic accuracy among laboratory assistants after establishing a national supervision program, corroborating findings.\textsuperscript{19}

This OSS intervention was carried out for 2 days a month over 9 months and covered HIV, TB, and malaria testing. By integrating testing for these three diseases, the program was able to improve laboratory practice on multiple tests as part of a single intervention. This is similar to the findings in Sarkinfada et al.,\textsuperscript{24} in which a quality assurance program in Nigeria that integrated TB and malaria showed significant improvement across both diseases.

Only 50\% of the eligible laboratory staff were observed. A similar level of attendance was seen throughout the intervention, as eligible laboratory staff (Tables 3 and 4) observed. A similar level of attendance was seen throughout the intervention. The lack of routinely collected slides as part of an external quality assurance data from national data sources for HIV and TB was reflected in facility performance data.\textsuperscript{8,18} Further research is needed to determine how such interventions affect laboratory skills and appropriate use of laboratory results.

While we originally planned to collect external quality assurance data from national data sources for HIV and TB testing and conduct on-site blinded slide rechecking for malaria microscopy throughout the intervention, these samples were not consistently collected by facility laboratory staff or available at the national laboratory bodies. The lack of routinely collected slides as part of an external quality assurance program demonstrates, in part, weaknesses within the national laboratory supervision programs at the time of the intervention. Previous studies have also documented similar challenges in establishing and maintaining robust national external quality assurance.

Present on a given facility visit and that 60\% of these absences were approved for attending trainings, seminars, or another official mission.\textsuperscript{25} Despite low attendance, 90\% of laboratory staff in the intervention arm benefited from at least one OSS visit. Given high absence rates, OSS could be a powerful tool for building laboratory capacity without further contributing to absences. When planning future interventions, additional steps could be taken to ensure higher rates of attendance. For IDCAP’s clinical training program, participants were required to attend seven of nine OSS sessions to receive a certificate of completion, and the average attendance among this subgroup of clinicians was seven of nine sessions.\textsuperscript{8} A similar requirement could be introduced for laboratory on-site support.

The intervention included four main components: team-based multidisciplinary training, breakout sessions focused on laboratory personnel, one-on-one mentoring, and continuous quality improvement sessions. While our evaluation cannot distinguish the relative value of each component, we hypothesize that breakout sessions and mentoring may have led to the documented improvement in laboratory testing. Multidisciplinary training and continuous quality improvement may lead to increased trust between laboratory staff and clinicians and improved adherence to laboratory results, which was reflected in facility performance data.\textsuperscript{8,18} Further research is needed to determine how such interventions affect laboratory skills and appropriate use of laboratory results.

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HIV Rapid Testing</th>
<th>TB Sputum Microscopy</th>
<th>Malaria Microscopy</th>
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<tbody>
<tr>
<td>Intervention vs. control</td>
<td>1.18 (1.10-1.26)</td>
<td>1.29 (1.21-1.40)</td>
<td>1.19 (1.11-1.27)</td>
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<tr>
<td>Cadre</td>
<td>Reference</td>
<td>Reference</td>
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<tr>
<td>Laboratory assistant</td>
<td>1.02 (0.99-1.05)</td>
<td>0.97 (0.92-1.03)</td>
<td>1.01 (0.97-1.06)</td>
</tr>
<tr>
<td>Laboratory technician</td>
<td>1.02 (0.94-1.10)</td>
<td>1.06 (0.85-1.31)</td>
<td>0.99 (0.87-1.12)</td>
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<tr>
<td>Laboratory assistant</td>
<td>Reference</td>
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<tr>
<td>Other</td>
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CI, confidence interval; HIV, human immunodeficiency virus; NA, not available for observation; RR, relative risk; TB, tuberculosis.
programs for laboratory testing in Africa, including funding and transportation of samples.26,27

As the external quality assurance data were not available, the trial protocol was modified to use a postintervention observation of laboratory staff in both arms. With this change in design, valid baseline data were not available, and we were unable to control for differences between the two arms at baseline. Also, a convenience sample of laboratory staff was observed, which may not have been representative. Finally, the observations were carried out by the laboratory mobile team members who were primarily responsible for providing on-site support, which presented an opportunity to bias results in favor of the intervention facilities.

The health facilities selected for this trial all had laboratories capable of conducting a set of standard examinations. Given that the provision of basic laboratory supplies and equipment in many health facilities in sub-Saharan Africa remains a challenge, our findings may not be generalizable to all facilities.28 In addition to building human resource capacity, which was assessed in this evaluation, OSS may also help address commodity and stock issues through a health system strengthening approach.29 During OSS, supervisors can identify infrastructure gaps and advocate on behalf of the health facilities for the provision of commodities, ensuring that clinicians and laboratory staff have the skills and supplies necessary to provide high-quality care.

Future studies on laboratory capacity building should go beyond assessing the sample preparation and recording process and use blinded slide rechecking or proficiency testing to assess the sensitivity and specificity of laboratory staff readings. Future interventions could also include more advanced diagnostics, such as fluorescence microscopy or Xpert MTB/RIF (Cepheid, Toulouse, France) for TB and malaria rapid diagnostics, which may further reduce error and increase testing in rural facilities.30,31 Finally, studies should be done to determine how such interventions could be taken to scale and integrated into a national laboratory management and support programs that ensure quality across all laboratory tests.

**Conclusion**

OSS significantly improved the practice of laboratory staff in conducting HIV rapid testing, TB sputum microscopy, and malaria microscopy. Integrated on-site support could be an effective method for improving laboratory practice, without taking laboratory staff away from health facilities.

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