Most Clinical Laboratory Testing in Kampala Occurs in High-Volume, High-Quality Laboratories or Low-Volume, Low-Quality Laboratories

A Tale of Two Cities

Timothy K. Amukele, MD,1,2 Lee F. Schroeder, MD,3 J. Brooks Jackson, MD,1,2 and Ali Elbireer, PhD1,2

From 1Makerere University–Johns Hopkins University Clinical Core Laboratory at Infectious Diseases Institute, Kampala, Uganda; 2Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, MD; and 3Stanford University School of Medicine, Stanford, CA.

Key Words: Quality improvement; Point of care; Test utilization; Volume; Uganda; Africa; Laboratory; Global health

ABSTRACT

Objectives: To describe key characteristics (laboratory quality, test volumes, and complexity) of clinical laboratories in Kampala, Uganda (population ~1.7 million).

Methods: Cross-sectional survey using a standard questionnaire to document laboratory type and quality, as well as test menus and volumes. Quality was based on the World Health Organization–Africa Region checklist.

Results: Of the 954 laboratories identified (a density of one laboratory per 1,781 persons), 779 (82%) performed only simple kit tests or light microscope examinations. The 95% (907/954) of laboratories for whom volumes were obtained performed an average aggregate of 13,189 tests daily, for a test utilization rate of around 2 tests per individual per year. Laboratories could be segregated into eight groups based on quality, test volume, and complexity. However, 90% of the testing was performed by just two groups: (1) low-volume (≤100 tests daily), low-quality laboratories performing simple tests or (2) high-volume (>100 tests daily), high-quality laboratories. Each of these two groups did 45% of the daily testing volume (90% combined).

Conclusions: Clinical laboratory density in Kampala (1/1,781 persons) is high, approaching that in the United States (1/1,347 persons). Low-volume/low-quality and high-volume/high-quality laboratories do 90% of the daily aggregate testing. Quality improvement (QI) schemes for Africa must be appropriate to low-volume laboratories as well as to the large laboratories that have been the focus of previous QI efforts.

Key characteristics of clinical laboratories in sub-Saharan African (SSA) communities, such as the daily test volumes and test complexity, are unknown. This information deficit is a detriment to public health because it undermines the impact of capacity-building and quality improvement efforts. For instance, previous work has demonstrated that the laboratories used by SSA communities are of low quality and clinically unreliable.1-3 In response, many national and international initiatives have been deployed to improve the quality of SSA laboratories.4-7 The Strengthening Laboratory Management Towards Accreditation (SLMTA) program,7 an in-depth, 10-module, 50-hour training delivered over a 6- to 12-month period, is currently the most widespread laboratory quality improvement program in sub-Saharan Africa.7 But while such a long-term, hands-on approach may be effective for consolidated, large laboratory systems, is it appropriate for most SSA laboratories that are small, private, and loosely regulated?1,2

Upon completion of this activity you will be able to:

• list key characteristics of clinical laboratories in Kampala, Uganda, such as daily test volumes and laboratory test complexity.
• describe two similarities between the clinical laboratories in Kampala, Uganda, and those in the United States.
• discuss the impact of the rollout of the Clinical Laboratory Improvement Amendments on the use of waived-only testing in physician office laboratories in the United States.

The ASCP is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The ASCP designates this journal-based CME activity for a maximum of 1 AMA PRA Category 1 Credit™ per article. Physicians should claim only the credit commensurate with the extent of their participation in the activity. This activity qualifies as an American Board of Pathology Maintenance of Certification Part II Self-Assessment Module.

The authors of this article and the planning committee members and staff have no relevant financial relationships with commercial interests to disclose. Questions appear on p 149. Exam is located at www.ascp.org/ajcpcme.
To answer this question, we must know the relative amount of clinical laboratory testing done by the large laboratories that SLMTA targets compared with the testing done in small laboratories that SLMTA may not reach. Previous work on clinical laboratories in sub-Saharan Africa does not provide this information because it has been largely descriptive and based on single tests or a few target laboratories. To fill this information gap, the study investigators created a survey for comprehensively identifying and assessing clinical laboratories in large towns and cities in sub-Saharan Africa. The initial rollout of this survey was in the city of Kampala, the capital of Uganda.

The survey was designed to obtain information that reflects the establishments where most individuals in SSA communities actually get their laboratory results rather than research laboratories that meet international quality standards but primarily serve narrowly defined cohorts. The initial implementation of the method in Kampala, as well as a report on the quality of laboratories in this city, was detailed in a recent publication. That publication showed that 95% of laboratories did not meet the lowest quality standards defined by the World Health Organization (WHO). In the current report, we describe the characteristics of the clinical laboratories in Kampala, including the quantity and complexity of testing being performed, as well as laboratory density and test utilization rates per capita in Kampala. To our knowledge, this is the first comprehensive report of the quantity and complexity of tests performed in a major metropolitan city in sub-Saharan Africa.

Materials and Methods

A cross-sectional in-person survey of all clinical laboratories in Kampala, Uganda, was performed during the last quarter of 2011. Clinical laboratories were defined as all establishments where laboratory tests are performed on human specimens for the purpose of health care. They included standalone laboratories (ie, those not associated with a health care establishment), as well as those embedded within health care establishments and identified only by the survey team. The Ministry of Health in Uganda approved and collaborated in the survey.

A modified version of the WHO–Africa Region (WHO-AFRO) Laboratory Strengthening Checklist was used to obtain baseline measures of quality. This WHO-AFRO scheme is based on four core criteria plus 12 quality system essentials (QSEs) that are derived from International Organization for Standardization 15189 standards. The four core criteria are (1) an 80% compliance with stated turnaround times, (2) a sufficient volume of testing to maintain staff competency, (3) performance of daily internal quality controls, and (4) an 80% two-cycle pass rate on external quality control. The 12 QSEs are documents and records, facilities and safety, equipment, purchase and inventory, process control, assessment, personnel, customer service, occurrence management, process improvement, information management, and organization. Conformity to the QSEs are based on a checklist. Checklist scores of 55% to 64%, 65% to 74%, 75% to 84%, 85% to 94%, and more than 95% are ultimately translated into a zero- to five-star scale. Laboratories that do not meet the initial four core criteria are still given a score of zero stars.

Survey questions were administered in person to the “in-charge” or designee at each laboratory facility. Test menus and daily test volumes were documented at each laboratory based on the aforementioned in-person survey interviews. The survey did not distinguish between numbers of individual tests such as albumin and panel-based tests such as a basic metabolic panel, which consists of eight individual tests. However, in Kampala, tests are ordered and billed for individually. Thus, in our analysis, we treated reported laboratory test volumes as those of individual tests, not test panels.

Test utilization rates in Kampala were calculated as the annual test volume divided by the population of Kampala city. Annual test volumes were based on the daily test volumes obtained from the interviews in each laboratory, assuming 250 days per year of operation of the laboratories. For the purposes of our analysis, we defined low-volume laboratories as those performing 100 tests or less per day. In addition, we defined high-quality laboratories as those that met or surpassed the lowest laboratory quality standards defined by the WHO: one star.

Surveyors classified each laboratory as either a point-of-care (POC) laboratory or a moderate/high-complexity laboratory. Laboratories performing only simple kit tests or light microscope examinations of patient samples were classified as POC laboratories. The surveyors also measured other attributes of each laboratory, such as their affiliation (government, private, public, etc), designation (national referral hospital, district hospital, standalone, etc), staff numbers, type, and qualification. Since most private laboratories in Kampala were neither registered nor regulated, it was important for the survey team to categorize each laboratory based on affiliation and type. Laboratory types were defined as follows.

- **Clinic laboratories**: operated by and serving a nonhospital facility in which patients receive medical or surgical care (mostly physician office laboratories)
- **National referral laboratories**: disease-specific reference laboratory for the country to which other laboratories send specimens (eg, the National Tuberculosis reference laboratory)
• Hospital: operated by and serving a hospital facility
• District: owned and/or operated by the government and associated with a regional referral health care center

Laboratory affiliations were defined as follows:
• Public: owned and/or operated by the government
• Private: for-profit laboratories owned by one or a group of individuals
• Academic: primarily carrying out academic research and teaching.
• Nongovernmental organizations (NGOs): owned by legally constituted organizations operating independently from the government
• Religious: owned, funded, or operated by religious foundations or groups

Additional details of the survey, including the training of survey staff, design of the survey instrument, and execution of the survey, have been described in an earlier publication. This article is focused on laboratory type, test quantity, and complexity in laboratories in Kampala.

Results

Laboratory Numbers and Complexity

Of the 954 laboratories identified in Kampala (a population density of 1,781 people per laboratory), 779 (82%) identified by the survey team were classified as POC laboratories. Test volumes and menus were available for 907 (95%) of the laboratories. All subsequent analyses presented in this report are based on the 907 laboratories for which there are both test volumes and test menus. Restricting the analysis to these 907 laboratories with available test volume and menu data did not significantly alter the relative percentage of laboratories of various types or quality ratings.1

Laboratory Test Volumes

The 907 laboratories for which testing data were obtained performed an average aggregate of 13,189 tests daily. In total, 82% (743/907) of the laboratories performed 10 tests or fewer per day. Another 16% (144/907) of laboratories performed between 10 and 100 tests per day, and 2% (20/907) performed between 101 and 2,000 tests per day. Twenty-six (3%) of the laboratories performed 50% of the testing, and 211 (23%) performed 80% of the daily testing.

There were 845 (93.2%) low-volume, low-quality private laboratories; 42 (4.6%) other low-volume laboratories; 16 (1.8%) high-volume, high-quality laboratories; and 4 (0.4%) other high-volume laboratories. Ninety percent (11,900/13,189) of the daily tests performed in Kampala were performed in one of two groups of laboratories. These were low-volume, low-quality private laboratories and high-volume, high-quality laboratories (Figure 2).

Laboratory Number vs Daily Test Volumes

Figure 3 shows the number and testing volume of various laboratory cohorts in Kampala. The cohorts are stratified by quality (zero stars vs one to five stars), type (private vs nonprivate), and affiliation (clinic vs nonclinic laboratories). Higher quality, nonprivate, and nonclinic laboratories accounted for a higher percentage of the daily aggregated testing volume than would be predicted based on their numbers alone. To illustrate, 5% (45/954) of laboratories met or
Figure 3 Number (A, C, E) and testing volume (B, D, F) of laboratories in Kampala stratified by quality (A, B), type (C, D), and affiliation (E, F).

exceeded the lowest quality standards of the WHO-AFRO laboratory checklist rating: one star. These 5% of laboratories accounted for 45% (5,890/13,189) of the daily aggregate testing volume. Four percent (40/953) of the laboratories were nonprivate, accounting for 35% (4,677/13,189) of the daily aggregate testing volume. Six percent (57/953) of the laboratories were nonclinic laboratories, accounting for 48% (6,334/13,189) of the daily aggregate testing volume. Only 953 laboratories are listed because one of the 954 laboratories was not assigned to any of the six designated laboratory types or four designated affiliations.

Table 1 shows additional characteristics of the large (>100 tests/d) and small (≤100 tests/d) laboratories in Kampala. The large laboratories were more likely to be of higher quality, more likely to be nonprivate, and more
likely to perform more complex testing than the small laboratories. To illustrate, even though only 5% of laboratories (45/954) overall met the one-star WHO-AFRO laboratory quality standard, 80% of the 20 high-volume laboratories met or surpassed this standard. In addition, only 25% of the 20 high-volume laboratories were private, as opposed to 97% of the small laboratories, and only 35% (7/20) of the higher volume laboratories performed simple POC testing exclusively. The smaller laboratories accounted for most laboratories in Kampala and performed mostly simple POC tests. Only 3% (24/887) met or surpassed the lowest quality standards of the WHO.

Daily Test Volume of Clinical Laboratories Stratified by Type

Table 2 shows the percentage of the daily test volume performed in laboratories of different types. Only 906 laboratories are listed because one of the 907 laboratories with test volume data was not assigned to any of the six designated laboratory types. Test volume data were obtained for 664 physician office clinic laboratories that accounted for 73.3% of all laboratories, 189 twenty-hour clinic laboratories associated with physician offices that accounted for 20.9% of all laboratories, 26 hospital laboratories that made up 2.9% of all laboratories, 16 national referral laboratories that made up 1.8% of all laboratories, eight standalone laboratories that constituted 0.9% of all laboratories, and three district hospital laboratories that constituted 0.3% of all laboratories. However, their aggregate average test volumes were 35.6%, 16.2%, 14.0%, 27.5%, 5.5%, and 1.2% of the daily aggregate test volume, respectively. POC testing as a percentage of total testing volume was 69.0% of clinic, 69.0% of 24-hour clinic, 27.6% of hospital, 20.4% of national referral, 1.4% of standalone, and 54.8% of district hospital laboratories.

Daily Test Volume of Clinical Laboratories Stratified by Affiliation

Table 3 shows the percentage of the daily test volume performed in laboratories of different affiliations. Only 906 laboratories are listed because one of the 907 laboratories with test volume and menu data was not assigned to any of the designated affiliations. Test volume and menu data were obtained for 869 (95.9%) private, 22 (2.4%) public, 13 (1.4%) NGO/religious, and two (0.2%) academic laboratories. These volumes correspond to 95.9%, 2.4%, 1.4%,
Discussion

This article presents data on the quantity, quality, and complexity of testing being performed in Kampala, Uganda, as well as the relationship of these three characteristics to laboratory affiliation and ownership. The results show that clinical laboratories are common and heavily used by the population in Kampala. The density of clinical laboratories in Kampala (1/1,781 persons) is similar to that in the United States (1/1,347 people)\textsuperscript{4,15} and is high relative to that seen in settings with more centralized health care systems. The density of clinical laboratories in Kampala is more than 25 times that seen in the United Kingdom or Australia (~1/50,000 persons).\textsuperscript{16-19}

Ninety percent of the daily aggregate testing occurs in two types of laboratories: 45% is performed in private laboratories, which tend to use only simple kit tests and light microscopy (POC), do a low daily test volume, and perform work with low quality (by WHO standards). Another 45% of testing is performed in large laboratories, by moderate- to high-complexity methods, at high daily test volume, in establishments that test at higher quality (by WHO standards). Not every small or large laboratory had all of the associated characteristics, but more than 60% of the small or large laboratories fit the aforementioned profiles. Most laboratories (81%) among those that fit the profiles were of the private, low-volume, POC, and low-quality variety. The de facto existence of two groups of laboratories persisted whether they were analyzed by affiliation, quality, or type.

This profile of the clinical laboratory in Kampala (two fairly distinct groups of clinical laboratories) is similar to the profile of the clinical laboratory in the United States. In 2006, physician office and other small nonhospital clinical laboratories accounted for around 75% of US clinical laboratories\textsuperscript{20,21} but accounted for only 13% of the test volume. In addition, 63% of their testing was POC testing.\textsuperscript{20,21} On the other hand, US hospital-based laboratories, which represented only 4% of the testing sites, accounted for 55% of the total testing volume.\textsuperscript{20} Similarly, in Kampala, clinic laboratories (physician office laboratories) accounted for 94% of clinical laboratories,\textsuperscript{1} but they accounted for only 52% of the test volume. Of the tests being performed in these clinic laboratories, 69% were simple POC tests. Other nonclinic (nonphysician office) laboratories in Kampala, which represent only 6% of the testing sites, accounted for 48% of the total testing volume.

Our analysis also shows that smaller laboratories, most of which are in physician offices, are of lower quality than higher volume laboratories, which tend to be in other settings such as hospitals, national centers, or so-called standalone laboratories. This begs the following questions: how does one construct a quality assurance system that preserves rapid access to results while being feasible to implement in the challenging financial and technical environments of small laboratories? How do small private laboratories performing simple POC tests without government or donor support maintain high quality when conventional methods of laboratory quality assurance are very expensive?\textsuperscript{22}

The quality assurance framework in the United States could serve as an effective model for clinical laboratories in Kampala or, more broadly, across sub-Saharan Africa. Briefly, the 1988 Clinical Laboratory Improvement Amendments (CLIA) of the US Congress,\textsuperscript{23} which define quality standards for laboratories in the United States, require different levels of regulation depending on laboratory complexity.\textsuperscript{24} Sites that perform only simple POC testing have one major overriding rule: they must use government-approved commercial kits as prescribed by the manufacturer. On the other hand, sites that perform more complex testing have to meet much higher regulatory standards.\textsuperscript{24} In the United States, the implementation of this kind of differential regulatory system has increased overall laboratory quality while preserving access to immediate results in physician offices.\textsuperscript{25-28}

Briefly, in the initial rollout of CLIA, the rates of proficiency testing failure were threefold higher in smaller nonhospital laboratories.\textsuperscript{26} Consequently, in the first 12 years after the rollout, 34% of these smaller laboratories shifted to waived-only testing requiring less oversight.\textsuperscript{26,29} However, this reduction of sites performing complex testing did not appear to reduce access to laboratory services\textsuperscript{28} because these physician office laboratories still had access to waived testing. A 1995 survey of 232 physicians by the Office of the Inspector General showed that physicians were still able to secure in-office laboratory services for their patients.\textsuperscript{28} In addition, the number of laboratory tests paid for by Medicare increased from 232 million in 1988, when CLIA passed, to 403 million in 1995, and much of this testing occurred in office.\textsuperscript{28} In conclusion, low-volume private laboratories perform about half of the daily aggregate testing in Kampala. In order for laboratory quality improvement schemes to affect SSA communities, they must be appropriate for these small private laboratories also.
References