Medical Laboratories in Sub-Saharan Africa That Meet International Quality Standards

Lee F. Schroeder, MD, PhD,[1] and Timothy Amukele, MD, PhD[2]

From [1]Stanford University School of Medicine, Stanford, CA; and the [2]Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, MD.

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ABSTRACT

Objectives: *A recent survey of laboratories in Kampala, Uganda, demonstrated that only 0.3% of laboratories (3/954) met international quality standards. To benchmark laboratory quality throughout the rest of sub-Saharan Africa (SSA), we compiled a list of SSA laboratories meeting international quality standards.*

Methods: *Accrediting bodies were queried via online registries or direct communication in May 2013.*

Results: *There were 380 laboratories accredited to international standards in SSA. Ninety-one percent were in South Africa. Thirty-seven of 49 countries had no laboratories accredited to international quality standards. Accredited laboratory density (per million people) in South Africa, Namibia, and Botswana were similar to those in many European countries. Single variable linear regression showed a correlation between accredited laboratory density and health expenditures per person (adjusted* $R^2 = 0.81$, $P < .001$*).*

Conclusions: *Most SSA countries do not have an accredited clinical laboratory. For those that do, there is a strong correlation between country-specific accredited laboratory density and per-capita health expenditures.*

Poor-quality laboratory testing has a substantial negative impact on health care systems in sub-Saharan Africa (SSA).[1-5] A recent survey of clinical laboratories in Kampala, Uganda, helped to quantify the extent of the quality problem.[6] The survey identified 954 accredited and nonaccredited laboratories in the city, corresponding to a laboratory density of 575 laboratories per million people, similar to the US laboratory density of 761 laboratories per million people.[7] However, only 5% of laboratories in Kampala met even the lowest quality standards defined by the World Health Organization (WHO) and only 0.3% met international accreditation standards.[6] Thus, it can be argued that the population of this large SSA city has good access to laboratories of relatively poor quality. This finding raises two questions. First, does this paucity of high-quality laboratories exist in the rest of SSA? Second, what factors are correlated with the number of high-quality laboratories in a given country?

To address the question of quality in SSA, we used the number of laboratories accredited to internationally recognized standards as a quality metric. There are two widely accepted international accreditation standards for laboratory quality. These are the 1988 Clinical Laboratory Improvement Amendments (CLIA) enacted by the United States Congress[8] and ISO 15189, the clinical laboratory standards of the International Organization for Standardization.[9] As a benchmark in addressing the state of laboratory quality in SSA we compiled a database of laboratories that met either of these laboratory quality standards. The data were analyzed for correlation with country-specific per-capita health care spending and compared with European countries and the United States.

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Materials and Methods

In May 2013 we queried established CLIA and ISO accrediting bodies via online registries and direct communication. The list of CLIA-approved accrediting bodies included The Joint Commission, College of American Pathologists, American Osteopathic Association, American Society for Histocompatibility and Immunogenetics, COLA, and AABB. As there are no ISO-approved accrediting organizations, we relied on the International Laboratory Accreditation Cooperation (ILAC), an international consortium of bodies that accredit laboratories to ISO standards. We queried all ILAC accrediting bodies that had attained full, associate, or affiliate membership and were located in SSA or in countries with strong colonial or trade ties to SSA. Laboratories in SSA meeting CLIA or ISO accreditation standards were labeled as public (government or nonforeign academic, primarily existing to treat patients), private (company or nongovernmental organization, primarily existing to treat patients), or research (generally funded by foreign donors, primarily existing to perform research), depending on their core affiliations.

Including each country in SSA that had at least one accredited laboratory, we performed single variable linear regression, using the least squares method, to evaluate the association of the number of accredited laboratories per million people and country-specific health expenditures per person. The presence of a significant correlation was evaluated using the F statistic. Both the outcome and explanatory variables were logarithmically transformed. Health care expenditures and 2010 population estimates were obtained from The World Bank.[10] A robust variance matrix calculation was performed with Stata 12 (Stata Corp, College Station, TX),[11] thus relaxing the assumption of data homoscedasticity.

Table 1
Number and Type of Laboratories Accredited to Internationally Recognized Quality Standards[a]

	Type of Laboratory			
Country	**Private**	**Public**	**Research**	**Total**
South Africa	276	62	7	345
Kenya	4	0	4	8
Namibia	6	1	0	7
Botswana	2	1	3	6
Uganda	2	0	3	5
Ghana	2	0	0	2
Nigeria	2	0	0	2
Ethiopia	1	0	0	1
Mali	0	0	1	1
Mauritius	1	0	0	1
Tanzania	0	0	1	1
Zimbabwe	0	0	1	1
Total	296	64	20	380

[a] Number and type of laboratories accredited to quality standards of the Clinical Laboratory Improvement Amendments (CLIA) or International Organization for Standardization (ISO). Countries in sub-Saharan Africa without laboratories accredited to these standards are omitted.

Results

There are 49 SSA countries.[10] Thirty-seven of these countries had no clinical laboratories accredited to internationally recognized quality standards. As of May 2013, the remaining 12 countries had 380 accredited clinical laboratories **Table 1**. The majority of accredited laboratories (91%, n = 345) were in South Africa. The other 35 laboratories were broken down by country as follows: Kenya (n = 8), Namibia (n = 7), Botswana (n = 6), Uganda (n = 5), Ghana (n = 2), Nigeria (n = 2), Zimbabwe (n = 1), Tanzania (n = 1), Ethiopia (n = 1), Mali (n = 1), and Mauritius (n = 1).

Of these laboratories, 296 (78%) were private, 64 (17%) were public, and 20 (5%) were research laboratories. Research laboratories comprised 2% of all accredited laboratories in South Africa, but 37% in other SSA countries. Four bodies were responsible for the accreditation of these laboratories: South African National Accreditation System (n = 369), College of American Pathologists (n = 7), Joint Commission International (n = 3), and Kenya Accreditation Service (n = 1).

The locations of accredited laboratories are shown by icons in the map in **Figure 1**. Single variable linear regression showed a significant correlation between the number of accredited laboratories per million people and health expenditures per person in the respective countries (adjusted R^2 = 0.81, $P < .001$) **Figure 2**. The β coefficient on per-person health expenditures was 1.5, so that a 1% increase in per-person health expenditures was correlated with a 1.5% increase in the number of accredited laboratories per million people.

Discussion

This comprehensive evaluation of accredited laboratories in SSA found that 37 of 49 SSA countries had no medical laboratories that met internationally recognized quality standards. In the remaining 12 SSA countries, there were 380 such medical laboratories. South Africa, Botswana, and Namibia had the highest densities, in the range of 1 to 10 accredited laboratories per million people. While population explains some of the disparity between countries in the numbers of accredited laboratories, single variable linear regression shows that a large proportion of the variation in density of accredited laboratories can be explained by per-capita health expenditures (Figure 2). This relationship applies even for several countries that are found some distance from the regression line. For example, the per-capita health

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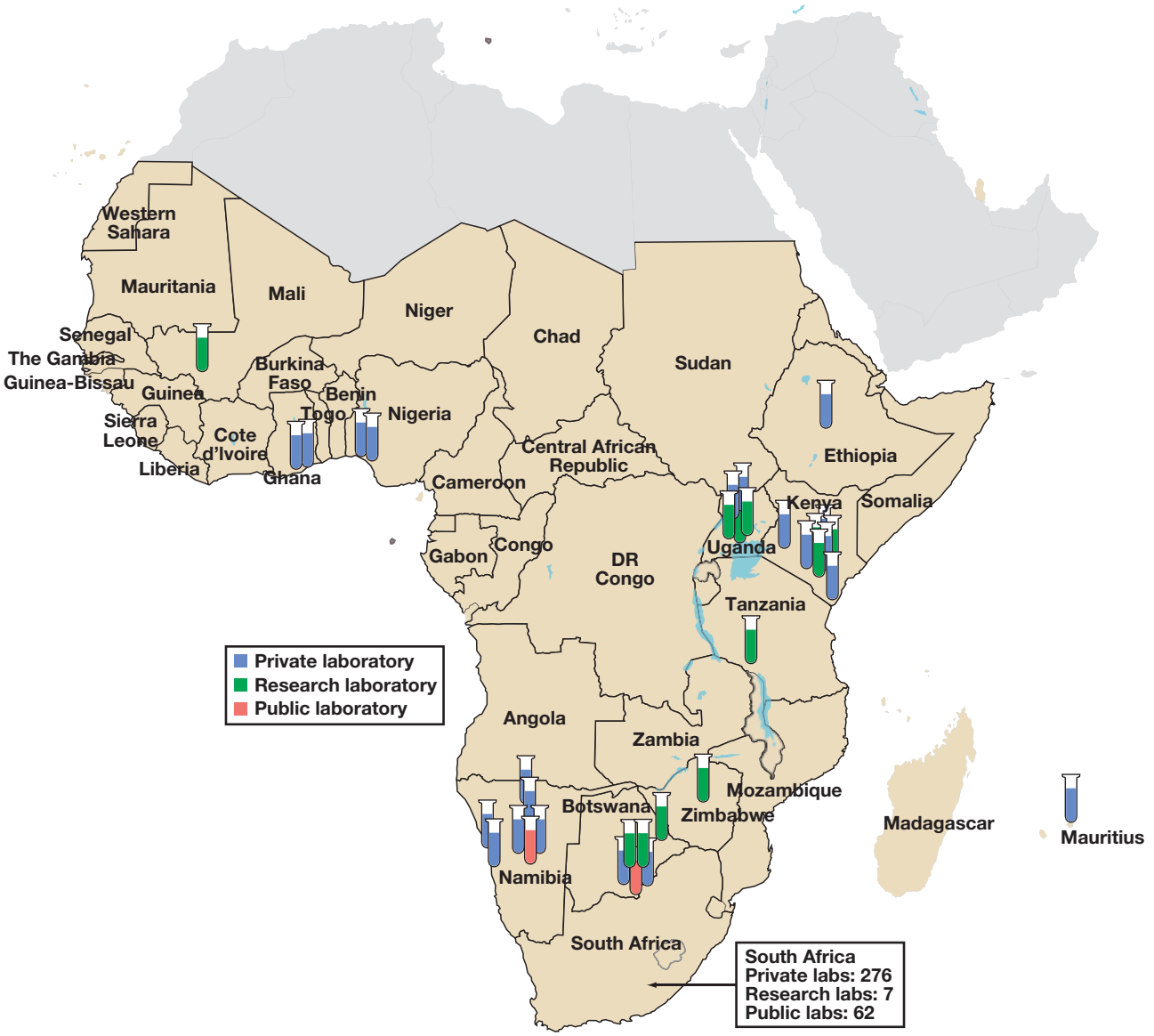

Figure 1 A map showing the location of medical laboratories in sub-Saharan Africa accredited to internationally recognized standards. Because of the large number of such laboratories in South Africa (n = 345), icons in that country were omitted. The type of laboratory is designated by the color of test tube: private (blue), research (green), public (red).

expenditures of Uganda would suggest that the country would have two accredited laboratories, but it has five. However, three of these accredited laboratories are research laboratories. Kenya would also be expected to have two accredited laboratories but has eight. Similarly, four of these accredited laboratories are research laboratories. Likewise, a number of countries would be expected to have fewer than one accredited laboratory given their population and per-capita health expenditures **Table 2**. Most of these countries, perhaps not surprisingly, have none. Other countries (Nigeria, Angola, Sudan, Cameroon, and Cote d'Ivoire) would all be expected to have significantly more numbers of accredited laboratories than they have based on their populations and health care expenditures. These data show that factors in addition to health care spending determine the number of laboratories accredited to internationally recognized standards, such as the culture of the health care system, source of health care dollars, and undoubtedly many others.

How do the densities of accredited laboratories in SSA countries compare with those of other countries? A recent survey conducted by the testing committee of the European cooperation for Accreditation[12] found most European countries had 1 to 10 laboratories per million people accredited to internationally recognized standards (personal communication, Willem Huisman, PhD, European co-operation of Accreditation, December 2012). In June 2013 the United States had 111

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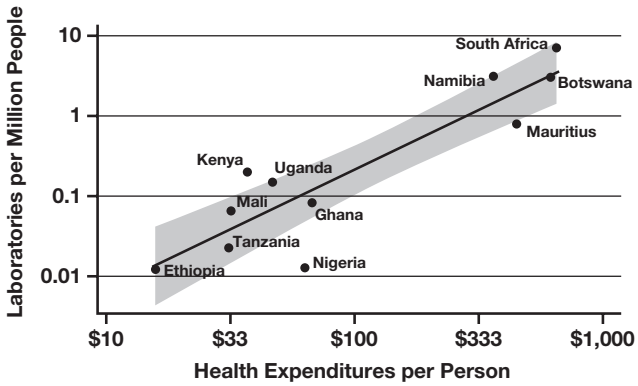

Figure 2 Single variable linear regression was performed on laboratory density accredited to internationally recognized standards (per million people) with health care expenditures per person (derived from World Bank estimates[10]) as the explanatory variable, using the base 10 logarithm for both the outcome and explanatory variable. The shaded region represents the 95% confidence interval. Adjusted $R^2 = 0.81$, $P < .001$. (See "Materials and Methods" section for details of the regression.)

accredited laboratories per million people (counting CLIA certificates of compliance and accreditation of nonexempt laboratories).[7] South Africa, Namibia, and Botswana appear to have a similar number of accredited laboratories per million people as most European countries, though far fewer than the United States. However, these numbers could represent a misleading measure of overall quality. First, the volume of testing per laboratory in various countries could vary substantially. Second, although many European countries do not require all laboratories to be certified to ISO standards, many have rigorous national quality standards that laboratories are required to follow. As such, the number of laboratories per million people in Europe with adequate quality to support health care decision making is likely to be higher than those accredited to international standards as defined in this study.

A similar analysis to that presented herein was conducted in July 2009.[13] The number of laboratories accredited to international standards in SSA has in fact risen from 4 years ago, with the total number of laboratories increasing by 12% (from 340 to 380), and the total number outside South Africa increasing by 25% (from 28 to 35). This may be interpreted as a modest change, given the increasing investment in laboratory infrastructure and quality by the WHO, Centers for Disease Control and Prevention, American Society for Clinical Pathology, Clinical and Laboratory Standards Institute, The World Bank, and others.[13-19] However, the number of high-quality laboratories per million people changes substantially depending on the chosen metric of quality. The metric used in this study was accreditation to internationally recognized standards (ie, CLIA or ISO). Yet previous work has demonstrated that high-quality testing can be achieved without formal accreditation.[20,21] The WHO-Africa regional

Table 2
Country-Specific Demographic and Health Indices

Country	Population	Health Spending Per Person (US$)	Predicted No. of Laboratories[a]	Actual No. of Laboratories	Actual No. of Laboratories Per Million People
South Africa	49,991,300	649	169.4	345	6.90
Nigeria	158,423,182	63	16.5	2	0.01
Botswana	2,006,945	615	6.3	6	2.99
Angola	19,081,912	123	5.4	0	0.00
Sudan	33,603,637	84	5.4	0	0.00
Namibia	2,283,289	361	3.2	7	3.07
Ghana	24,391,823	67	2.8	2	0.08
Mauritius	1,280,924	449	2.5	1	0.78
Uganda	33,424,683	47	2.2	5	0.15
Cameroon	19,598,889	61	2.0	0	0.00
Cote d'Ivoire	19,737,800	60	1.9	0	0.00
Kenya	40,512,682	37	1.9	8	0.20
Tanzania	44,841,226	31	1.6	1	0.02
Ethiopia	82,949,541	16	1.1	1	0.01
Rwanda	10,624,005	56	0.9	0	0.00
DR Congo	65,965,795	16	0.9	0	0.00
Burkina Faso	16,468,714	40	0.9	0	0.00
Mali	15,369,809	32	0.6	1	0.07
Mozambique	23,390,765	21	0.5	0	0.00
Malawi	14,900,841	26	0.4	0	0.00
Niger	15,511,953	18	0.3	0	0.00
Burundi	8,382,849	21	0.2	0	0.00
Gambia	1,728,394	26	0.0	0	0.00
Eritrea	5,253,676	12	0.0	0	0.00

[a] Predictions for the number of accredited laboratories per million people based upon linear regression using health spending per person as the explanatory variable (see Figure 2).

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office (WHO-AFRO) created a stepwise laboratory improvement scheme to measure quality improvements in laboratories that are not yet accredited to internationally recognized standards.[13] A recent city-wide survey in Kampala found 42 laboratories that met the minimum WHO quality criteria.[6] If we use this WHO-AFRO metric as our quality criteria, we obtain 25 quality laboratories per million people in Kampala, rather than the 1.8 laboratories per million people obtained in the city using CLIA or ISO criteria. A reasonable metric for laboratory quality would ideally depend on an evidence base for the efficacy of various accreditation schemes, and targets for that metric should depend on the health care priorities and expenditures in a given country. Both of these warrant further investigation.

Address reprint requests to Dr Schroeder: PO Box 18443, Stanford, CA 94309; lschroed@stanford.edu.

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