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Harmonization of clinical laboratories in Africa: a multidisciplinary approach to identify innovative and sustainable technical solutions

Abstract

Background: In an effective and efficient health system, laboratory medicine should play a critical role. This is not the case in Africa, where there is a lack of demand for diagnostic exams due to mistrust of health laboratory performance. Doctors with Africa CUAMM (Collegio Universitario Aspiranti Medici Missionari) is a non-profit organization, working mainly in sub-Saharan Africa (Angola, Ethiopia, Mozambique, Sierra Leone, South Sudan, Tanzania and Uganda) to help and sustain local health systems. Doctors with Africa CUAMM has advocated the need for a harmonized model for health laboratories to assess and evaluate the performance of the facilities in which they operate.
Methods: In order to develop a harmonized model for African health laboratories, previous attempts at strengthening them through standardization were taken into consideration and reviewed. A survey with four Italian clinicians experienced in the field was then performed to try and understand the actual needs of health facilities. Finally a market survey was conducted to find new technologies able to update the resulting model.
Results: Comparison of actual laboratories with the developed standard – which represents the best setting any African health laboratory could aim for – allowed shortcomings in expected services to be identified and interventions subsequently prioritized. The most appropriate equipment was proposed to perform the envisaged techniques. The suitability of appliances was evaluated in consideration of recognized international recommendations, reported experiences in the field, and the availability of innovative solutions that can be performed on site in rural areas, but require minimal sample preparation and little technical expertise.
Conclusions: The present work has developed a new, up-to-date, harmonized model for African health laboratories. The authors suggest lists of procedures to challenge the major African health problems – HIV/AIDS, malaria, tubercolosis (TB) – at each level of pyramidal health system. This model will hopefully support the non-governmental organization (NGO) Doctors with Africa CUAMM in its activities in sub-Saharan hospitals, providing them with a guideline to programme future interventions.

Keywords: Africa; clinical laboratory; harmonization; technology; sustainability.

DOI 10.1515/dx-2014-0071
Received December 19, 2014; accepted February 23, 2015; previously published online April 14, 2015

Introduction

The majority of African health systems have been inherited from colonial governments and were focused primarily on the healthcare of colonial administrators and expatriates [1]. Local health systems have also been adversely affected by lack of investments, resulting in a general weakening of health infrastructures. Unfortunately foreign aid is unable to solve the issue of the lack of resources, which remain scarce. There are shortages of drugs or medical equipment and human resources are often insufficient in number [2, 3]. Moreover, staff is not always well-trained: the majority of African health workers have mid-level qualifications and only 9.7% have a degree as a medical doctor [2]. The phenomena generally described for health systems affect clinical laboratories

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too. Laboratory medicine should play a critical role in effective and efficient management of healthcare, but this is not the case in Africa [4]. Laboratory expenditure is frequently prohibitive for African health systems, which are adversely affected by corruption. For instance, 95% of financial resources allocated for Ghanaian healthcare are allocated to the individual [5] and thus procurement of medical devices is not guaranteed [6].

According to experience in the field, procedures are not always carried out accurately due to the inadequacy of infrastructures – such as power and water supply networks.

The crucial role of health laboratories in diagnosing and treating pathologies has also recently been recognized within the African framework, as demonstrated by World Health Organization (WHO) Resolution number AFR/RC58/R2 [7] and the Maputo consultation [8]. Several efforts have accordingly been made to fill the gaps in laboratory medicine. For instance, some governments and associations, such as the African Society for Laboratory Medicine (ASLM), are working on strengthening the laboratory workforce – by training and certifying laboratory professionals through standardized frameworks – and on enrolling laboratories in quality improvement programmes to achieve accreditation by international standards [9].

Recently several authors have demonstrated that harmonization [10] of laboratory activities is a critical step in developing health systems. Specifically, it allows more accurate understanding and planning of facility needs, which in turn would avoid, for example, the expiry of medicines and consumables and the consequent wastage of resources. The aim of this work was to follow this initiative and to sustain the activity of Doctors with Africa-CUAMM, an Italian NGO whose mission is to develop sub-Saharan health services. CUAMM needed a ground plan to manage the health laboratories they would help, by structuring their activities, procedures and resources and prioritizing investments. To fulfil this requirement, a new, up-to-date, harmonized model for African health laboratories has been developed. To address the major health problems, this work proposes lists of procedures for each level of the pyramidal network of health laboratories. An evaluation was made to select and suggests the most appropriate equipment. The suitability of appliances was assessed in accordance with recognized international recommendations, reported experiences in the field, and the availability of innovative solutions that can be implemented on site in rural areas, while requiring minimal sample preparation and little technical expertise. The effectiveness of the developed standard was tested by evaluating the performance of four different healthcare facilities managed by CUAMM and by submitting it to clinicians with experience in the field. Comparison between actual and theoretical conditions allowed gaps to be identified in the service offered and to programme future interventions, taking into account the major health problems of local communities.

Materials and methods

The reported analysis began with the assessment of previous attempts at harmonization of laboratory medicine [8, 11–14]. The WHO archive was the major source of data and one of its documents represents the cornerstone of the proposed standard [13]. It was established that each new publication about laboratory medicine must consider all the most recent discoveries in the field and each innovative procedure or technology. More recent publications on health laboratory services have also been taken into account: the most relevant concerns the work of the Maputo Conference (22–24 July 2008) [8], where international attention focused on the diagnostic tests required at each level of the tiered health laboratory network.

However, since the aim of the present work was to support CUAMM's interventions in sub-Saharan Africa, a survey was performed to understand the actual needs of the local health workforce, with the help of four clinicians experienced in the field, working with Doctors with Africa. Attention was specifically directed at four case studies, which were compared with the developed standard to assess performance. All the evaluated health facilities serve district hospitals, in Aber (Uganda), Lui, Yirol (South Sudan) and Pujehun (Sierra Leone), respectively (Figure 1). CUAMM's reports provided data on the effective workload of the four case studies and also on the current workforce. Finally, a market survey was conducted to include the most recent scientific and technological innovations that allow CUAMM to perform all envisaged laboratory procedures, avoiding wastage of resources and taking advantage of available, but relatively unqualified staff.

A review of previous works on laboratory harmonization showed that the health laboratory system could only be strengthened through harmonization of laboratory activities and equipment [3, 10]. In the present model, laboratory procedures have been proposed for four theoretical levels of the tiered health laboratory network, in accordance with the Maputo Meeting Report [8]. The lowest level is defined as the primary laboratory level and consists of all laboratory units serving health centres and rural hospitals. This level also includes mobile units and microscopy centers.

Above the first level are the district laboratories connected to hospitals of the same name. The third level of the network is represented by provincial or regional facilities while the national laboratories stand at the top of the network. The present work did not establish or propose a standard model for the uppermost level of the network because facilities at this level are strictly governed at the national level, with their own national programmes, guidelines and ad hoc standards – or are connected with academic institutions interested in specific research fields.

The first step was to propose a list of health problems that each of the above-reported levels must be able to treat. Primary health laboratories should manage HIV/AIDS, malaria, tuberculosis (TB) [15], syphilis, various infections, noncommunicable diseases, endemic

Figure 1: A photographic overview of evaluated district laboratories.

diseases such as human African trypanosomiasis, and pregnancy. It is also deemed necessary for primary facilities to implement diagnostic techniques for clinical chemistry and hematology.

According to the present standard, district laboratories should treat the same pathological and physiological conditions managed at the primary level in addition to handling hepatitis B and C and inpatient monitoring.

Provincial laboratories have to manage all the previous states in the same way as Western facilities.

Results and discussion

A brief summary of the activities envisaged for primary and district health laboratories in Africa is reported in Table 1. It has been suggested to implement rapid diagnostic tests (RDTs) because they are generally less expensive than traditional methods, and are readily usable and understandable, even by less qualified personnel. RDTs would mainly be used not only for diagnosing and/or screening main diseases (such as HIV/AIDS, malaria or syphilis) but also for less common ones, as human African trypanosomiasis (Figure 2).

A new method to detect tuberculosis and drug resistance has been implemented by Xpert® MTB/RIF. It has been demonstrated that the MTB/RIF test is less dependent on user skills, and can be utilized by staff with minimal training. Turnaround time is also short since the test simultaneously detects tuberculosis and rifampin

Table 1: Standardized panel of activities for primary and district African health laboratories.

Pathologies/conditions	Suggested procedures	
	Primary labs	District labs
HIV/AIDS	RDTs	RDTs and EIA; CD4 counts; cryptococcal antigen
Malaria	RDTs; microscopy (thick and thin film)	RDTs; microscopy (thick and thin film)
Tuberculosis	Microscopy (Ziehl-Neelsen)	Microscopy (Ziehl-Neelsen); Xpert® MTB/RIF
Syphilis	RDTs	RPR (I); TPPA/TPHA (II)
Clinical chemistry	Dry chemistry analyser or traditional techniques [glucose; ALT(III); creatinine]	Wet chemistry analyzer (complete chemistry panel)
Hepatitis B and C	Not envisaged	HbsAg(IV) and HCV(V); EIA
Hematology	Hemoglobinometer or Drabkin's solution method [HGB (VI)]	Haemoglobinometer or Hct (VII) estimation (HGB); blood cell counts; type and crossmatch
Other	Not envisaged	CSF(VIII) chemistry and cell counts; procedures for endemic diseases [CATT(IX), Widal test, etc.]

(I) RPR, Rapid plasma reagin; (II) TPPA/TPHA, Treponema Pallidum Hemoagglutination Assay/Treponema Pallidum Particle Assay; (III) ALT, alanine transaminase; (IV) HbsAg, hepatitis B surface antigen; (V) HCV, hepatitis C virus; (VI) HGB, hemoglobin; (VII) Hct, hematocrit; (VIII) CSF, cerebrospinal fluid; (IX) CATT, Card Agglutination Test for Trypanosomiasis.

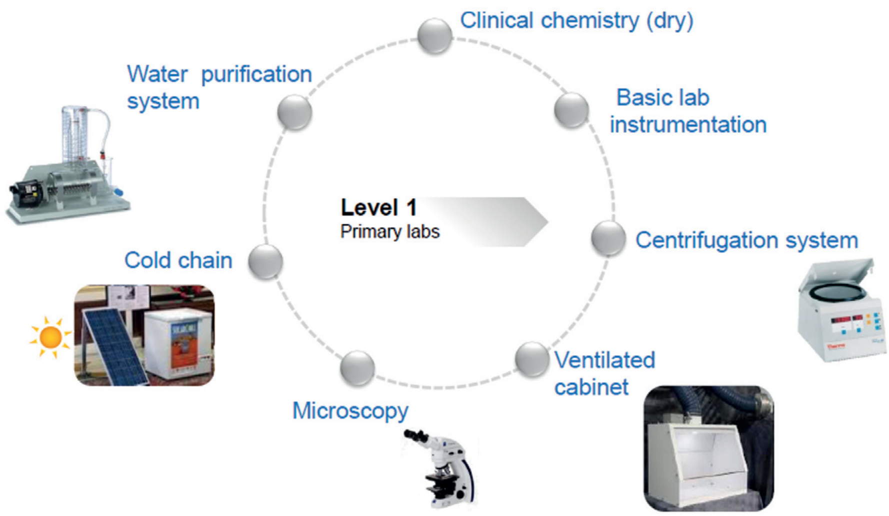

Figure 2: Standard instrumental equipment proposed for primary laboratories.

resistance in <3 h [16]. Moreover, Xpert® MTB/RIF permits TB to be diagnosed with the advantages of dry chemistry: i.e., reagents can be stored at room temperature; no large amounts of water are required; there is no need for additional plumbing; basic servicing activities suffice; and no staff with specific skills are needed. This equipment is also recommended in part because of its price: following WHO negotiation, laboratories in endemic countries can procure it at a fair rate [17].

Table 1 clarifies a few points. Analysis of thin film samples for malaria diagnosis in primary laboratories can only be performed if adequate safety devices are available for workers. The same applies to samples of cerebrospinal fluid (CSF), which can only be tested if a lumbar puncture is performed and personnel able to perform one are available.

The present model takes into account that some facilities are seriously underdeveloped. Accordingly, dry clinical chemistry techniques can also be considered acceptable in district laboratories, although wet chemistry remains the best solution (Figure 3). As noted in Table 1, the introduction of enzyme immunoassay (EIA) techniques in district laboratories is pivotal because the same instrumentation can be used to carefully diagnose both HIV/AIDS and hepatitis (although different kits are obviously needed).

Provincial laboratories can perform the same panel of activities as district ones, in addition to carrying out nucleic acid tests for HIV/AIDS; acid-fast bacilli (AFB) smears, culture, identification and susceptibility for tuberculosis; cell cultures and polymerase chain reaction (PCR) techniques as supplementary tests.

Concerning standardized technologies and equipment, the present model suggests that primary laboratories must have at least a scale for weighing products and reagents; a hot plate or equivalent; a mixer; a Bunsen burner; a pH meter; a bench centrifuge; a microscope; a colorimeter; a hemoglobinometer; a glucometer or dry chemistry analyser; a laboratory refrigerator; a water purification system; and a ventilated workstation. The latest technology was introduced to protect health workers from the use of dangerous substances, such as ethanol or HCl, and particularly during the Ziehl-Neelsen procedure, which requires adequate aeration. A feasible option is the model developed by the Global Laboratory Initiative [18] which provides instructions on how to produce a cheap, effective ventilated workstation with the option of mounting a HEPA (high efficiency particulate air) filter.

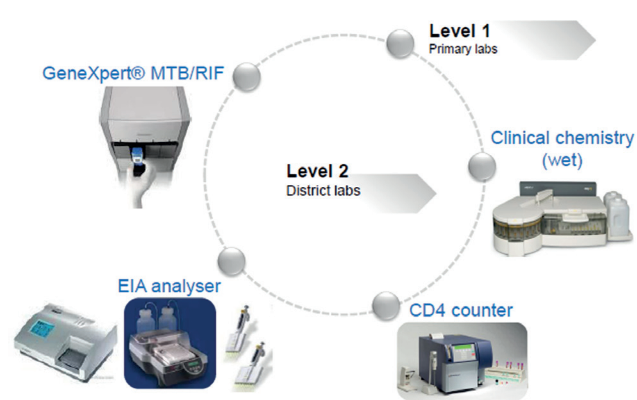

Figure 3: Standard instrumental equipment proposed for district laboratories.

The SolarChill battery-free unit represents an interesting alternative to traditional refrigerators [19]. Only devices for vaccines have been developed to date, but they can also be appropriately used for the present standard, while waiting for a specific one.

Relevant initiatives have also been taken for traditional instruments as the microscope. The Foundation for Innovative New Diagnostics (FIND) has effectively negotiated with Carl Zeiss over the price of a special microscope, the PrimoStar iLED [20], which works both as a simple microscope but also in fluorescence – essential for special techniques that have recently been recommended by WHO to diagnose TB.

District laboratories must have the same equipment as primary ones; in addition they should have cell counters; CD4 counters, in accordance with Westerman et al. [21]; EIA analyzers; a wet chemistry analyzer; a laboratory freezer; and Xpert® MTB/RIF. Lastly, provincial laboratories should also have a CO_2 incubator and biosafety cabinet for cell cultures.

A comparison was then made between the developed standardized model and the four case studies managed by Doctors with Africa CUAMM. The facilities at Aber, Lui, Pujehun and Yirol are all district laboratories. First, panels of laboratory activities were compared with the standard; the results are shown in Table 2. Comparing the standardized model with actual performance in selected case studies permitted gaps to be identified in the expected health service. In particular it was observed that it is frequently difficult to perform thin film analysis for malaria diagnosis. This prevents the *Plasmodium* causing the disease from being clearly identified, so treatments are often not focused. Similarly EIA techniques, CD4 counts and cryptococcal antigen tests are not performed; Xpert® MTB/RIF has not yet been introduced into African laboratories, despite WHO recommendations. Another relevant question concerns clinical chemistry, which is fundamental in addressing the expected increase in noncommunicable diseases in the African region over the coming years.

Comparison of the inventory of theoretically and actually available technology has highlighted several shortages, strictly connected to the items missing from the panel of procedures. As shown in Table 3, there is an insufficient number of ventilated cabinets, clinical chemistry analyzers and no EIA analyzer or Xpert® MTB/RIF have yet been purchased. Using the standardized model as a guideline has also highlighted the scarcity of data about basic laboratory instrumentation, as mixers, thermostatic baths, weighing scales and other similar devices. This should prompt recommendation of a more accurate collection of information on these technologies in order to establish a solid investment plan. If the lack of basic instrumentation is confirmed, priority must be given to

Table 2: Number of case studies complying with requirements of standard for district laboratory activities.

Procedure	No. of case studies completely complying with requirements of standard
RDTs for HIV/AIDS	4
EIA for HIV/AIDS	0
Microscopy for malaria	0
AFB(I) for TB	4
Xpert® MTB/RIF	0
RPR, TPPA/TPHA for syphilis	1
Pregnancy test	4
Hemoglobinometry	2
Clinical chemistry	1
Type and cross match	3
ESR(II)	3
HCV and HbsAg	3
Cell count	1
CD4 count	1
Cryptococcal antigen test	0
CSF microscopy	2
Microscopy	3
Tests for endemic diseases	4

(I)AFB, Acid fast bacilli; (II)ESR, erythrocyte sedimentation rate.

Table 3: Number of case studies complying with requirements of standard for district laboratory equipment.

Equipment	No. of case studies completely complying with requirements of standard
Mixer	Data not available
Clinical chemistry analyzer	1
Thermostatic bath	1
Weighing scales	Data not available
Ventilated cabinet	1
Centrifuge	4
Microhematocrit centrifuge	2
Colorimeter/spectrophotometer	1
Cell counter	1
CD4 counter	2
Hemoglobinometer	4
Blood bank	1
Refrigerator	3
Incubator	Data not available
Microscope	4
EIA analyzer	0
Xpert® MTRB/RIF	0
Water purification system	1
Other	2 (Glucometer)

rectifying the situation before procuring any other equipment, as EIA analyzers.

It is worth highlighting that even where a technology is present, it is often not well-maintained or functional. For instance, there is a CD4 counter at the Lui laboratory but workers cannot adopt it because it is located in a crumbling, dark room, making it useless. A similar situation exists at Pujehun laboratory, where microscopists must use an obsolete microscope-with damaged lenses – because there is not sufficient power to support the newly purchased one. Clearly, in this latter case an adequate, correctly sized, reliable power system – possibly based on solar energy, will have to be provided.

The finished model was then submitted to clinicians working with Doctors with Africa CUAMM, who accepted and validated it.

Considering that the model developed in this work represents the best setting any African health laboratory could aim for, it has been demonstrated that comparing the performance of actual laboratories with the standard allows deficits to be identified in the expected service and interventions to be subsequently prioritized. The model is also designed to evaluate the amount of financial resources to invest in order of priority: starting with basic, essential equipment and moving on to other specialized technologies [22].

However, to improve the quality of health laboratory services, other cornerstones need to be taken into account and developed [23]. First, it is fundamental to focus on staff training: nowadays laboratories are understaffed and there is an insufficient number of qualified personnel. Petti et al., reported that only 26% of 693 Ghanaian laboratory staff had a recognized degree [24] and, as reported by CUAMM, this situation is widespread in Africa. Hence the authors suggest that NGOs should support educational institutions in training laboratory technicians, assistants and technologists in the improvement of quality management systems and in accelerating laboratory accreditation [25]. In the near future, hospitals and laboratories could take advantage of "task shifting" practice: personnel such as nurses and midwives could be trained in some specific laboratory activities, thereby guaranteeing a basic health laboratory service [25].

The present work has highlighted the considerable difficulties encountered in tracking laboratory activities and their equipment inventory. Several efforts have to be made to file and manage data because it becomes very hard to programme interventions at health laboratories without correct, current information.

Procuring appliances and consumables – such as cuvettes, cartridges, and so on – is still a difficult issue: territorial geography, viability and transportation conditions, and poor stock management often cause discontinuities in health laboratory services. Hence interventions are needed in this field to avoid further wastage of resources.

Lastly, NGOs and institutions should collaborate to improve disinfection, sterilization and waste disposal procedures because current practices – e.g., recycling cuvettes and slides for different patients and burying contaminated materials – are not acceptable at hospital units.

Several authors have recently proposed to establish a pathway towards accreditation of health laboratories in limited settings [25]. This is chiefly based on the common idea that accredited facilities have the potential to improve the quality of patient health care by reducing errors in testing and consequently decreasing inappropriate treatment [26]. Nevertheless, as shown in the present work, there are lots of gaps to fill before starting with accreditation procedures. Only when the issues discussed herein have been solved can African health laboratories begin to seek accreditation.

The authors hope this work will mark the first step in this direction, allowing at least basic healthcare to be offered in the African region, with no wastage of resources and all the advantages technological progress has to offer.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.
Financial Support: None declared.
Employment or leadership: None declared.
Honorarium: None declared.
Competing interests: The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

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