The Path to Implementation of A Clinical Laboratory System in A Developing Country

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Title: The path to implementation of a clinical laboratory system in a developing country

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Abstract

Background

An effective laboratory system is an essential component of a public health system caring for patients with communicable and non-communicable diseases. Unfortunately, in developing countries this system is often sub-optimal, which negatively impacts health care. This paper describes the current situation of the clinical laboratory sector in Haiti and highlights challenges that exist in Haiti and other developing countries as they try to establish a clinical laboratory system.

Method

A cross-sectional survey was conducted in 30 laboratories across Haiti from January 19 to February 4, 2016. The laboratories surveyed were public or mixed public-private sector facilities belonging to different levels of the healthcare hierarchy. Labs were visited and directors of the health care institutions, lab managers, and members of their teams were interviewed and National Public Health Laboratory documents and information about the legal framework of the laboratory system was reviewed.

Results

The National Laboratory of Public Health is the reference lab for the national lab network and plays a key role in epidemiologic surveillance. Investigators felt that the general conditions in the nation's labs (83%) are good, but numerous deficiencies are identified. Electricity is often limited and 86% of facilities have mixed energy system. Bacterial cultures and susceptibilities are not performed. Most of the lab technologists (88.2%) have received only 2 two-year training certificates, while only the remainder (11.8%) had completed three-year programs training. Few continuing education opportunities are available. Equipment repair is

available in more facilities (83%) than routine maintenance (63%) and is complicated by the diversity of brands employed. A total of 93% of the labs participate in the quality control program run by the National Lab.

Conclusion

The establishment of an effective national laboratory system requires coordination and input from many areas, including regulation of the sector, training of the technicians, sound infrastructure (including a stable supply of electricity) and dependable communications. Achieving this in developing countries will only be possible if different actors, national and international, coordinate their efforts.

Keywords: developing countries, clinical laboratory, network

Introduction

Developing countries have a heavy burden of both communicable and non-communicable diseases requiring concerted actions to try and limit their spread (1). One of the major hindrances in fighting infectious diseases in developing countries is their limited laboratory capacity, an element critical for the appropriate diagnosis and treatment of patients (2). In the 2008 Declaration of Maputo, the governments of 33 countries and many international health agencies recognized the important role of clinical laboratories in health care and recommended that governments develop national laboratory policies and strategic plans for their implementation (3)(4).

In Haiti, two years after the Declaration of Maputo, the National Laboratory of Public Health (LNSP: *Laboratoire National de Santé Publique*-) in collaboration with its associated partners, developed a National Strategic Plan 2010-2015. This was followed in 2015 by a National Laboratory Policy. Through a partnership between the public LNSP and GHESKIO which is a private institution (GHESKIO: Groupe Haitien d'Etudes du Sarcome de Kaposi), as well as between institutions northern (Fondation Mérieux, European Commission) and southern hemispheres (Institut Africain de Santé Publique), a new project emerged: SP-Haiti Lab. The focus of this new project was the improvement of clinical laboratories across Haiti. Hence, one of the first objectives of the SP-Haiti Lab is to contribute to elaboration of a new Health Laboratory Policy and the new National Strategic Plan.

As a prelude to preparing long term strategies and policies, the Maputo group advised that situational analyses of the laboratory sectors in each country be undertaken to best adapt strategies to the realities and needs on the ground. In addition, these situational analyses would serve as baselines from which to monitor future progress in the laboratory sector. The aims of

this article are to identify gaps to implementation of a health laboratory system in this developing country and to discuss measures that can address them. In this paper, we perform and describe the situational analysis of laboratories carried out in Haiti: the legal framework in which they are working and the current state of their human resources, infrastructures, and equipment.

Methods

Study Setting

The study was performed in Haiti in 30 laboratories from the public and mixed (private/public) sector (Table 1). All of the laboratories chosen are located within Haitian health care institutions throughout the country. A cross-sectional national survey was conducted from January 19 to February 4, 2016.

Table 1: Distributions of laboratory visited by type and level in the health hierarchy

Healthcare Institutions	Level of Institution					Public/Mixed	
	HU	HD	HCR	CAL	CSL	Public	Mixed
OUEST							
Hôpital Universitaire de la Paix	X					X	
CMS Petite Place Cazeau				X			X
Hôpital Fermathe				X			X
SUD EST							
Hôpital Saint Michel		X				X	
HCR Cayes Jacmel			X			X	
Hôpital St Joseph La Vallée Jacmel				X			X

SUD							
Hôpital IC des Cayes		X				X	
Hôpital Ste Anne de Camp Perrin				X		X	
Dispensaire Sacré Cœur de Charpentier					X		X
NIPPES							
Hôpital Ste Thérèse de Miragoane		X				X	
HCR de l'Asile			X			X	
Clinique Bethel de Fonds- des-Nègres				X			X
GRANDE ANSE							
Hôpital St Antoine Jérémie		X				X	
Hôpital Ste Agnès de Beaumont				X		X	
Sant Lespwa/HHF				X			X
CENTRE							
Hôpital Ste Thérèse de Hinche		X				X	
Centre de Santé de Maissade				X		X	
Clinique St Joseph				X			X

Thomassique							
NORD							
Hôpital Universitaire Justinien	X					X	
Hôpital de Milot				X			X
Hôpital Saint Jean Limbé				X			X
NORD EST							
Hôpital Fort Liberté		X				X	
CS Sainte Suzanne					X	X	
CMS Ouanaminthe				X		X	
NORD OUEST							
Hôpital IC (Port de Paix)		X				X	
Hôpital Notre Dame de la Paix			X			X	
Centre Médical Beraca				X			X
ARTIBONITE							
Hôpital de la Providence des Gonaïves		X				X	
CS St. Pierre Desdunes				X		X	
Rhéma Bocozele				X			X
TOTAL	2	8	3	15	2	19	11

105 HU university hospital; HD: district hospital; HCR referral hospital; CAL
106 clinics with inpatient beds; CSL clinics without inpatient beds

107

108 ***Study population and sampling of the laboratories surveyed***

109 The study population consisted of laboratories from different levels of health care hierarchy:
110 public hospitals (university, provincial hospitals and referral community hospitals), laboratories
111 in public and mixed health centers with and without beds (CALs – clinics with inpatient beds,
112 and CSLs – clinics without inpatient beds, respectively). Sampling was done from a list of
113 known laboratories, with three laboratories selected per department. Therefore, for the 10
114 provinces of Haiti, a total of 30 laboratories were recruited. Out of the 30 laboratories visited, 19
115 (63%) were from the public sector and 11 (37%) were public/private (mixed). These facilities
116 were further distinguished based on the institutions with which they were associated: 2 were
117 teaching hospitals (HU), 8 were departmental hospitals (HD), 3 were community hospitals
118 (HCR), 15 CALs and 2 CSLs.

119

120 Explanations for the study were provided to the interviewees. The personnel interviewed
121 included:

- 122 - The provincial directors of health, hospital directors or the chief physicians and the facility
123 managers in the case of health centers.
- 124 - Laboratory managers and their teams who facilitated the collection of laboratory information.
- 125 -LNSP management, who provided the information and documentation needed to describe the
126 institutional and regulatory organization of laboratories in Haiti.

127 ***Data collection***

128 Data collection was performed principally by using a survey. This survey was pre-validated in
129 three laboratories at the West Province of Haiti. This survey included both closed and open-

ended questions. For other questions (e.g., observations), direct observations were performed by investigators. The investigating team was made of national technicians working at the National Laboratory of Public Health and also international technicians from the Mérieux Foundation and the Institut Africain de Santé Publique. The observations of investigators regarding the general conditions were based on the appearance of laboratory roofing, floors, doors, windows, walls, furniture and brightness.

Data analysis

Quantitative data were analyzed using SPSS. Qualitative data were analyzed manually.

Results

Regulatory texts and strategic documents

Investigations described the hierarchical organization of the health sector. At the bottom, are the CALs and the CSLs. On the second level are the community hospitals and on the third level, the provincial hospitals. The Ministry of Health (MOH) 2004 National Strategic Plan for Health Sector Reform highlights the importance of strengthening public health facilities including their laboratories. A five-year strategic plan of the National Network of Laboratories 2010-2015 has been developed. A draft of the National Medical Laboratory Policy of the Republic of Haiti was drafted in March 2015, but has yet to be adopted by the government. Hence a new draft was elaborated and adopted recently in 2018 by the MOH.

Structures working in the field of laboratories

The National Public Health Laboratory (LNSP) is the laboratory of reference for the national network with a triple mission of: training, diagnosis and research in the field of public health;

epidemiological surveillance, and; early warning. The LNSP has a close relationship with the Laboratory and Research Epidemiology Department (DELR). The DELR, in turn, is responsible for planning, regulating and coordinating all data received on priority communicable and non-communicable diseases. This data allows the DELR to maintain an early warning system and to promote the integration of prevention and protection activities against these diseases. Besides the LNSP and DELR, others structures in the Ministry of Health (MOH) are also involved in the laboratory sector (*e.g.*, the pharmacy department and professional training departments).

Laboratory services

Laboratory services routinely performed throughout Haiti include creatinine (70%), transaminases (50%), CBC count (77%), sickling test (70%), Widal test (87%), VDRL/RPR (70%), and malaria test (80%). None of the labs in our study were able to perform CPK, Hemoglobin electrophoresis, coagulation tests (PT, PTT), detection of *Cryptococcus* antigen, routine bacterial culture and antimicrobial susceptibility testing (Table 2).

Table 2: Lists of tests by Laboratories

Tests	Numbers of laboratories doing tests					
	HU	HD	HCR	CAL	CSL	Total
Biochemistry						
Urea	2/2	7/8	1/3	9/15	1/2	20/30
Glucose	2/2	8/8	2/3	13/15	2/2	27/30
Creatinine	2/2	7/8	1/3	10/15	1/2	21/30
Uric acid	2/2	6/8	0/3	5/15	0/2	13/30

Clinical laboratory system in Haiti

Calcium	1/2	4/8	0/3	3/15	0/2	8/30
Sodium/Potassium	2/2	5/8	0/3	5/15	0/2	12/30
Transaminases (AST, ALT)	2/2	6/8	0/3	8/15	1/2	15/30
Bilirubin total/Conjugated	2/2	4/8	0/3	6/15	0/2	12/30
Amylase	0/2	1/8	0/3	2/15	0/2	3/30
PAL ???	1/2	1/8	0/3	2/15	0/2	4/30
CPK	0/2	0/8	0/3	0/15	0/2	0/30
Total Cholestrol	2/2	7/8	0/3	8/15	1/2	18/30
HDL/LDL	2/2	7/8	0/3	7/15	0/2	16/30
Triglycerides	2/2	7/8	0/3	9/15	1/2	19/30
Abluminuria and Glucosuria (urine dip sticks)	2/2	6/8	2/3	12/15	2/2	24/30
Total Protein	2/2	4/8	0/3	5/15	0/2	11/30
CRP	2/2	5/8	1/3	5/15	0/2	13/30
PSA	0/2	2/8	0/3	1/15	0/2	3/30
Hematology						
White and Red Blood cell count	0/2	1/8	0/3	2/15	1/2	4/30
Hematocrit	0/2	3/8	1/3	6/15	1/2	11/30
Hemoglobin	0/2	3/8	1/3	6/15	1/2	11/30
CBC	2/2	7/8	2/3	11/15	1/2	23/30
CD4 count	2/2	6/8	1/3	6/15	0/2	15/30
VS	2/2	6/8	2/3	5/15	0/2	15/30
Bleeding time/ coagulation time	2/2	6/8	3/3	8/15	0/2	19/30
Blood Type	2/2	6/8	2/3	11/15	1/2	22/30

Clinical laboratory system in Haiti

Emmel Test (Sickling test)	2/2	6/8	2/3	9/15	2/2	21/30
Hbg Electrophoresis	0/2	0/8	0/3	0/15	0/2	0/30
Coagulation (PT, PTT)	0/2	0/8	0/3	0/15	0/2	0/30
Immuno/serology Tests						
Widal test	2/2	7/8	1/3	14/15	2/2	26/30
VDRL/RPR	2/2	5/8	2/3	14/15	0/2	21/30
ASO	2/2	5/8	0/3	6/15	0/2	13/30
HIV	2/2	4/8	2/3	12/15	0/2	20/30
Antigen Hbs	0/2	2/8	0/3	1/15	0/2	3/30
Pregnancy tests	1/2	6/8	1/3	11/15	2/2	21/30
PPD	1/2	5/8	1/3	5/15	0/2	12/30
H pylori serology	1/2	7/8	2/3	8/15	1/2	19/30
Rheumatoid factor	0/2	1/8	0/3	1/15	0/2	2/30
Dengue serology	0/2	1/8	0/3	0/15	0/2	1/30
Parasitology						
Stool KOP	2/2	7/8	3/3	11/15	1/2	24/30
Malaria tests(Smears and RDT)	1/2	7/8	3/3	11/15	2/2	24/30
Blood Microfilaires	0/2	1/8	0/3	2/15	0/2	3/30
Cryptococcus antigen	0/2	0/8	0/3	0/15	0/2	0/30
Bacteriology						
Urinary sediment	0/2	5/8	1/3	6/15	1/2	13/30
Vaginal smears	2/2	3/8	2/3	11/15	1/2	19/30
CSF cell count and biochemistry	0/2	1/8	0/3	0/15	0/2	1/15

AFB smears	1/2	2/8	2/3	7/15	0/2	12/30
Uroculture + AST	0/2	0/8	0/3	0/15	0/2	0/30
Coproculture +AST	0/2	0/8	0/3	0/15	0/2	0/30
Hemoculture + AST	0/2	0/8	0/3	0/15	0/2	0/30
CSF (Culture + AST)	0/2	0/8	0/3	0/15	0/2	0/30
Expectorated sputum culture	0/2	0/8	0/3	0/15	0/2	0/30
Gene Xpert TB	1/2	2/8	0/3	0/15	0/2	3/30
Papanicolaou (PAP test)	0/2	0/8	0/3	1/15	0/2	1/30

167

168

169 ***Laboratory Facilities***

170 The general conditions of the majority (83%) of the premises housing laboratories are deemed

171 satisfactory by investigators, although a variety of deficiencies are described (Table 3).

172 Inconstant supply of electricity (Table 4) does not allow for the lighting and consistently cool

173 temperature necessary for good laboratory practices. To compensate for the irregular supply of

174 electricity by the public network, 86% (26/30) of the laboratories have a mixed energy input

175 consisting of generators, solar energy and accumulators (Inverters). Eight laboratories (26%) do

176 not have running water and use cisterns.

177

178 Table 3: Overview of the premises

179

Items	Evaluation		
	Not present or	Satisfactory	Very satisfactory

	insufficient		
Roofing	5/30 (16%)	25/30 (84%)	0/30
Floor covering	5/30 (16%)	25/30 (84%)	0/30
Wall cladding	8/30 (26%)	22/30 (74%)	0/30
Doors and windows	6/30 (20%)	23/30 (76%)	1/30 (3%)
Furniture	6/30 (20%)	20/30 (66%)	4/30 (13%)
Benches	6/30 (20%)	19/30	5/30 (16%)
Lighting	14/30(46%)	12/30 (40%)	4/30 (13%)
Air conditioning	14/30 (46%)	13/30 (43%)	3/30 (10%)
Cleanliness of rooms	5/30 (16%)	23/30(76%)	2/30 (6%)

180

181

182

183 Tableau 4: Availability of electricity, water, gas and proper sewerage

Items	Available	Not available
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Electricity	26/30	4/30
Electric support (UPS, stabilizers)	19/30	11/30
Water	22/30	8/30
Gas	4/30	26/30
Sewers/septic tanks	26/30	4/30

184

185 ***Laboratory staff***

186 *Profile of the laboratory staff*

187 Of the technical staff in the laboratories visited, 26 of the technologists (11.8 %) have three years
 188 of training, 195 (88.2%) have two-year certificates and there are 16 laboratory assistants
 189 (bacilloscopists). There were no doctors or pharmacobiologists working in any of the
 190 laboratories visited, even at the university hospital level. There is continuing education available
 191 at 3 labs (10%), advanced training or periodic staff evaluation in 3 (10%) laboratories.

192 ***Staff supervision***

193 During the previous 12 months, 29 laboratories (96%) were supervised by different structures
 194 such as: LNSP and others NGO working in the health sector (e.g. PEPFAR /CDC); Groupe
 195 Haitien d Etude du Sarcome de Kaposi, and Partners in Health. The main problems raised by
 196 representatives of these supervisory systems, which are chronic in nature, are: the insufficient
 197 numbers of trained personnel; the lack of equipment, reagents and consumable materials; the

unsuitability of certain infrastructures; the unavailability of electricity, and; the lack of monitoring and training in the use of fire extinguishers.

Equipment

Only 63% of laboratory facilities conduct routine maintenance on their equipment while 83% perform repair work. Equipment maintenance is provided by the LNSP (Biomedical Unit), laboratory staff, and equipment suppliers. The maintenance and upkeep of equipment is complicated by the diversity of brands employed (Table 5). Out of the 54 centrifuges encountered in the labs, there are 21 different brands.

Table 5: Frequency of the brands of basic equipment listed

Equipment	Total number	Number of different brands
Microscope	95	15
Centrifuge	54	21
Spectrophotometer	19	6
CBC count machine	19	3
CD4 count machine	15	2

Procurement, storage and management of reagents and consumables materials

Public and mixed laboratories receive reagent allocations from the MOH through programs and partners. The sources of supplies are local private providers and the regional depots where reagents and consumables materials are stored. Eighteen laboratories (60%) purchase a part of their reagents from their own budget. The storage of reagents is dependent on the supply of

electricity to the laboratories. In 9 laboratories (30%), the storage of the reagents does not meet the conditions recommended by the manufacturer either due to lack of electricity or inadequate refrigerator temperature monitoring. Stock monitoring occurs regularly in 21 laboratories (70%), which is reflected in the updated inventory tracking sheets. The method of stock management applied is First Expire First Out (FEFO) in most laboratories. However, 70% of laboratories reported stock shortages for reagents and consumable materials for periods ranging from 3 days to one year, and the presence of out of date materials was reported in 73% of laboratories.

Quality assurance management system

There is a national quality assurance program run by the LNSP. In our laboratories sample, internal quality control is implemented in 70% of the laboratories and 93% participate in the national quality control program organized by the LNSP. The LNSP procedures manual is available in only 27% of laboratories visited. Also, only 56% of the laboratories have a sampling procedure, 30% a sample receiving procedure, and 40%, cleaning and waste management procedures.

Hygiene, biosafety and laboratory safety

Personal protective equipment is available in most laboratories. To protect the staff and users of the laboratory, a number of instructional documents are displayed, usually pictograms or signs of prohibited practices, procedural requirements or limitations. There is no national program for the protection of health personnel by broad vaccinations. A hepatitis B vaccination initiatives exist in only six laboratories (20%).

Communication

Not all laboratories have the necessary communication capabilities: only six laboratories (20%) have a service phone; 19 (63%) have at least one computer, and 15 (50%) have internet connection, even if it is irregular. For data management, 18 laboratories (60%) have a computerized laboratory management systems (LMIS) which is only used for people living with HIV. The LMIS systems in use are OpenElis and ISanté. Only one laboratory uses the LMIS to record and edit all hospitalized patient results.

Role of Laboratory Personnel in the Health System

Personnel from only 11 laboratories participate in patient care meetings. Laboratory staff are included in 8 out of 10 hospital infection control committees. In the case of diagnosis of a microorganism with epidemic potential, 21 (70%) laboratories communicate the information to the national health system. The majority (90%) of laboratories refer to the LNSP for specific pathogens. The routine transfer of aggregated epidemiological data is not systematic, with only 13 laboratories (43%) sharing data.

Discussion

Effective clinical laboratories play an essential role in the health care system by providing the data that guide treatment of infectious and non-infectious illness. Unfortunately, the lab sector in developing countries is often neglected (5). Regardless of the levels of interest, creating and supporting a laboratory system in resource limited settings presents many challenges. Developing national laboratory policies and strategies has been recommended to help streamline processes (4). These elements form the keystone supporting the establishment of a laboratory system that can help a country handle health threats (5). As a first step, it is important

to conduct situational analyses of the laboratory sector to assure that planning reflects the realities and needs on the ground. We have conducted such an analysis through surveys and investigations and identified the structure and state of clinical laboratory medicine in Haiti, its strengths and the many challenges it confronts.

Regulation of the laboratory sector

The main objective of the SP-Haiti Lab is to help the MOH and its international partners produce a new National Health Laboratory Policy, to be followed-up by the National Strategic Plan and, finally, the Operational Plan. At the end of these activities, new tools will be available to define both the general approach and specific conduct of the laboratory sector in Haiti. The different actors working in the field of public health have the responsibility of delivering the highest quality service possible for the population, and to use resources rationally. Accordingly, good governance is a key component of achieving an effective service (6) and strengthening the health care system as a whole (7). Once established, it will be important to make certain that the regulations are implemented. Effective implementation will depend on the support of national leadership and partners from international institutions. This task may not be easy as it known that collaborative governance is sometimes difficult to establish in developing countries due to weak central authority, limited institutional infrastructures and insufficient resources(8).

Structures in the field of clinical laboratories

One of the most significant achievements in Haitian laboratory medicine was the 2006 creation of the LNSP. The lack of an enforceable national laboratory policy, however, continues to undermine the development of a LNSP-led national network in Haiti. Without such a framework,

it is difficult to determine which problems to prioritize while apportioning limited resources and how to assure that policies are observed (9). These issues get more complex when you consider funding and governance. For example, to encourage a more centralized approach, the LNSP has developed a strategy urging regional technicians to conform more to national standards. Yet these technicians are often paid by international partners, making it hard to enforce compliance with national guidelines in any predictable or long-term manner. This begs the larger question of the paradox of international aid. Since, public health sector funding in developing countries is often insufficient, aid from the international community are important (10) and contributes to increase life expectancy (11). However, this can undermine the central authority. Also, foreign assistance can have a negative impact upon national government expenditures on the health sector. For example, for every \$1 USD, governments in developing countries may decrease contributions between \$0.43 and 1.14 (12) (10)

Services, infrastructure and laboratory housing

It remains a major weakness that routine culture and antimicrobial susceptibility testing is not performed in Haitian labs. Although reliance on clinical assessment for diagnosis and management remains a mainstay of medical practice, particularly in developing countries (e.g. cholera in Haiti)(13), purely clinical algorithms can be flawed and lead to inappropriate and excessive treatment. These issues are illustrated by a study from Ghana in which 251 children were admitted to the hospital with a clinical diagnosis of malaria (based upon WHO criteria). Nevertheless, 69/251 children (27%) had negative malaria smears but 40% of the children had bacteremia confirmed by blood cultures. Moreover, 13% of 182 children with positive malaria smears had concurrent bacterial sepsis while mortality was highest in patients with clinically diagnoses malaria, a negative malaria smear and bacterial sepsis (14). This underscores the

importance of routine bacterial culture and susceptibility testing to support clinical diagnoses and inform antimicrobial coverage.

Although investigators felt the majority of the structures housing laboratories are satisfactory, they have also listed numerous significant deficiencies. There is, however, no standardized lab design and an absence of certain spaces that are essential for good practices, such as sampling rooms (absent in 30% of laboratories), laundries (absent in 77% of laboratories) and, toilets for staff (absent in 57% of laboratories). Nevertheless, studies conducted in eight countries have shown that infrastructures (amenities, equipment, and available medications) are not necessarily related to quality of care: health care services with the same level of infrastructure can deliver a range of different quality care (15) .

Laboratory staff

Only the LNSP is run by a clinical pathologist. All of the others laboratories, including those in teaching hospitals, are run by laboratory technologists most of whom have completed only 2 year training programs. Regardless of whether this level of training is sufficient, this reality can lead clinicians to question the credibility of laboratory results. (16). Moreover, state accreditation for technicians is difficult because of the lack of standardized curricula or oversight from qualified professors in diverse programs. Since 2011, the LNSP, in collaboration with the Mérieux Foundation has offered a bachelor's degree in medical sciences, but this program only accepts around 18 students per year due to funding issues. The expansion of this training could assure sustainable, comprehensive and standardized training on a national level. Robust continuing education, so important in developed countries, has yet to develop in Haiti but is another important long-term goal (17) .

326 ***Equipment***

327 The great diversity of laboratory equipment brands creates barriers for proper maintenance. In
328 fact, most of the equipment in labs has been provided by Haiti's partners in an uncoordinated
329 manner, with no maintenance plans in place. To address this problem, donation charters should
330 be developed that take into account the country's willingness to master the diversity of brands,
331 with assistance, and hence properly maintain important laboratory equipment. This chart could
332 follow the WHO recommendations for donations (18). The MOH, however, must then be
333 prepared to fill in gaps that can occur when the rejection of donation creates shortages that could
334 jeopardize public health. The presence of so many different brands also highlights the
335 importance of instituting a process to harmonize the country's clinical laboratory reporting. This
336 would make it possible to compare results from different procedures, facilitating patient
337 management and the application of guidelines (19).

338 Finally, better servicing of equipment might prevent breakdown. The maintenance system,
339 currently provided by the LNSP (Biomedical Unit), laboratory staff (routine maintenance) and
340 equipment suppliers, is a key element in healthcare. It has been shown that 40-70% of medical
341 devices and equipment in developing countries have issues related to function: broken, unused or
342 unfit for purpose (20). It is also important to keep in mind that approximately 66% of equipment
343 out-of-service could be put back into service with a basic knowledge. Hence, giving technicians
344 basic knowledge and training can make a difference (21) .

345 ***Procurement, storage and management of reagents and consumable materials***

346 Besides the modest amounts of reagents some laboratories are able to purchase, most public and
347 mixed laboratories receive reagents from partners. This underlines the strong dependence of
348 Haitian labs on outside support. Although many developing countries are dependent on

international health care aid, much of the actual funding comes through vertical programs and does not contribute to a global upgrade of the health care system (22). In fact, the laboratory system in Haiti is quite resilient as evidenced by the few shortages in essential reagents observed in laboratories. In order to establish a sustainable and efficient long-term supply system, it would be helpful to adopt a specific budget line for laboratory funding within the state healthcare budget. In addition, the inconsistent supply of electricity, also threatens the availability of these essential chemicals. Other forms of modern energy, like solar power could be developed as an option (23).

It is important for stakeholders to understand that the laboratory sector is a national health necessity that must be run by the government and cannot be at the mercy of benevolent strangers (19). To realize this sustainability, the MOH should assume its leadership role in trying to solve problems of supply chain management in Haiti, by targeting the specific weaknesses identified by the situational analysis (24).

Laboratory analysis activities

Quality assurance system

The national laboratory quality assurance program run by the LNSP should be strengthened in order to better coordinate and guide lab function. Strengthening the laboratory evaluation process using the evaluation grid published in 2014 would enable the establishment of a National Laboratory Quality Label System that could be modeled on the WHO Afro SLIPTA process (25). Mentorship of laboratory personnel through short class sessions linked to site supervisions as well as coaching for specific problems could result in improved lab capacity and performance and guide the various labs toward national accreditation (26). Improvements in information

technology (e.g. computers or internet access) would be a major step in promoting effective quality assurance systems. The absence of such technological improvements means that labs must continue to rely on traditional mentoring approaches which require funding for travel, etc. and may, ultimately, be more costly and less effective. A more specific quality assurance question is the decision of whether to buy or prepare chemical and microbiologic panels: the former approach presenting financial challenges and the latter, technical ones.

Hygiene, biosafety and safety at the lab

Most labs have personal protection equipment, but we must work to target 100% availability. A key element to improving hygiene, biosafety, and safety in labs is the designation of a champion who should address staff education and proficiency monitoring (27). It is also important that technicians be trained in the risks of infectious diseases transmission, and how to handle infectious and biohazard products (28) because in some developing countries, up to 95% of laboratory technicians may have poor knowledge of biosafety (27). A further goal should be to upgrade labs to the level required by international health regulations, which could also provide an opportunity to promote hygiene, biosafety and overall lab safety (29). There is also no national program for the protection of health care personnel by vaccination. Few hepatitis B vaccination initiatives exist in Haitian laboratories even though HBV infection is well-known risk to laboratory personnel. A routine personnel vaccination program against this virus should be put in place (30).

Communication

Communication between the laboratory technicians and clinicians is important to patient care as 60-70% of health care decisions are based on laboratory results. In the case of critical ill patients,

it is essential that this communication be swift as well (31). A valuable first step in this process would be to provide lab personnel and clinicians with the means to communicate more efficiently through phone calls, internet or others modalities. As discussed earlier, even when contact is made, however, the difference in levels of education between clinicians and laboratory technicians may lead the former to question the credibility of the results, which could undermine patient care (16). This further supports the need for accreditation and continuing education for laboratory personnel. Yet it is also important to understand the communications barriers between clinician and laboratory team by conducting studies and workshops that could help appreciate the other's concerns and perspectives. These challenges can have benefits not only for individual patient care, but also for the implementation of public health programs, like the antimicrobial stewardship program (27).

The Role of the Laboratory in the Health System

At an individual healthcare facility level, the laboratory has an important role for diagnosis and treatment. As we have discussed, reliance on clinical assessment alone has pitfalls. It has been shown, in fact, that basic laboratory tests in rural centers in developing countries yield a change of diagnosis and treatment in 45% of patients (32). In developed countries, it is assumed that the contribution of the laboratory is generally higher, around the "70% claim" rule (33). This contribution is particularly true when infectious diseases are involved, and in the face of nosocomial infection outbreaks (33).

The lab also plays a central role in national epidemiologic surveillance. It was, in fact, through the efforts of the LNSP that in 2010, two days after the MOH was notified of the first cases of diarrhea, a confirmation of *V. cholerae* serogroup O1, biotype Ogawa was established (34).

Further study revealed the Nepalese origins of this strain (35). The lab also plays follows the ongoing progress in the elimination of malaria in Haiti (36).

One of the major, long-term health sector challenges is the integration of all public and private clinical, food safety and environmental laboratories into a cohesive, collaborative system working together to improve public health and quality of care. Information sharing between different layers and actors in the system which will positively impact healthcare (37). It is also important to recognize that the introduction of new laboratory technologies in the public sector does not always lead to better patient outcomes. Rather, the integration of new technologies and protocols should be supported by the best available evidence (38)(27). Finally, it is important reflect on what type of lab services and policies are most suitable for Haiti and other developing countries: point of care testing for remote areas or centralized laboratories with a network system of reference; technicians broadly trained or with narrow specialization; laboratories with more autonomy and flexibility or traditional dependence; laboratories that are more open to participation in international research with developed countries (with opportunities for funding and acquisition of expertise), or laboratories that close the door to this option because of their inherent vulnerabilities and the inapplicability of the results for their population. (39).

Strengths and limitations

This is, to the best of our knowledge, the first study to give an overview of the clinical lab sector in Haiti. The study did not include private labs (of which there are possibly 256) which represent 44% of the laboratory sector, so it is unknown how these labs function, what they perform and how they contribute to this sector. Also, no interviews were conducted with patients or physicians whose opinions could give us another perspective on the lab sector in Haiti. Nonetheless, we feel this study can help us understand the general laboratory landscape and

define and prioritize problems that should be addressed through a national laboratory policy and the national strategic plan.

Conclusion

The development of a clinical laboratory system in a resource limited country is a complex but essential element to improving health care and reducing mortality. Multiple challenges must be overcome to enhance the clinical laboratory sector in Haiti: economic, political, and those of governance. Since the National Laboratory in 2010, many new promising initiatives have taken place: definition of a national network of laboratories; drafting of regulations, and implementation of a quality assurance system. However, many practical and chronic problems remain, including: proper training, equipment shortages, supply chain management, energy and electricity deficiencies, etc. Nevertheless, there is continued support from the Haitian Government and national and international partners. There is also greater integration of other stakeholders, such as universities, professional associations, and distributors of reagents all of whom wish to be a part of the process of building a national laboratory system and improving clinical laboratory medicine in Haiti.

List of abbreviations

CAL: clinics with inpatient beds

CSL: clinics without inpatient beds

DELR: Laboratory and Research Epidemiology Department

FEFO: First Expire First Out

GHESKIO: Groupe Haitien d'Etudes du Sarcome de Kaposi

HCR: Referral hospital

462 HD: District hospital

463 HU: University hospital

464 LNSP: Laboratoire National de Santé Publique

465 MOH: Ministry of Health

466

467 **Declarations**

468

469 **Ethics approval and consent to participate**

470 This study was considered as a Non-Human Subject Research and hence approval for this
471 study by an Institutional Review Board was not required by Haitian law (Executive order
472 published at the Haitian official journal “Le Moniteur” on December 23, 1999). The Haiti Ethical
473 Review Committee also considered this activity to be non-research. It was included as part of
474 routine laboratory supervision activities performed by the National Laboratory of Public Health.
475 Furthermore, this work was approved by the Ministry of Health of Haiti and investigators
476 followed the ethical principles for non-human subject research projects (e.g., Informed consent,
477 Privacy and confidentiality protections). Verbal informed consent was obtained for all
478 participants, because with this research there was no more than minimal risk of harm to subjects
479 during the meeting/survey. All methods were carried out in accordance with relevant guidelines
480 and regulations.

481

482 **Consent for Publication**

483 Not applicable

484

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

There's no competing interests involved in this study for any of the authors of this article.

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Author contributions

M.L., J.S., C.M., G.A.J., P.A., S.K., E.L., J.B., J.B, P.D., M.S. were in charge of the conceptualization and methodology of the study. J.S, C.M., M.C and E.L participated in the field survey; M.L. and J.S were involved in data curation and formal analysis; M.L, J.S, S.K., M.F.C, D.M.P, G.M., L.M.K., M.J.Z., P.E.K wrote the main manuscript text. All authors reviewed the manuscript.

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