Strengthening Laboratory Systems in Sudan 2017

Strategic Directions & Gaps

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SECTION 1: Situation analysis

1.1 Wider health system context

The health system in Sudan has witnessed several changes that aimed to include some initiatives toward achieving the objectives of health sector reforms initiated since 1992 up to most recent changes in 2015. The period following the civil war was characterized by continuous improvement in the performance of key health outcome indicators especially those related to preventable diseases and health problems. Sudan remains in a state of epidemiological transition in which infectious and communicable diseases are still endemic with an increase in the prevalence of non-communicable and degenerative diseases. There are remarkable improvement in major health outcomes in the country. While the overall health expenditure out of the public expenditure was 11.6% in 2014, still the overall expenditure on health is inadequate in Sudan, and the balance of spending across segments of the health system may be ameliorated to deliver the expected outcomes.

The Ministry of Health remains the insurer of last resort for 70% of the population, which reflects the government efforts to address the inequities in access to health care. The current public financing for health services tends to focus more on curative care and gives relatively less focus to areas such as disease prevention and public health management in primary care. The network of primary health centres ranges from simple dispensing centres that operate sometimes only once every month, to well-developed comprehensive primary health care centres, most of it are operated by the Ministry of Health. The PHC Expansion Project has been one of the major transformational projects of health system recently. According to 2015 statistics, there are many hospitals in Sudan, with a rate of 6.7 bed per 10,000 population. The utilization of the private hospital sector has increased tremendously in recent years. Sudan has a low number of specialist physicians, pharmacists and a low number of nurses per capita; at 4.1, 4.5 and 8.3 respectively. The issue of balanced skills mix is high on the agenda, especially with limited number of nursing and midwifery personnel registered in the country.

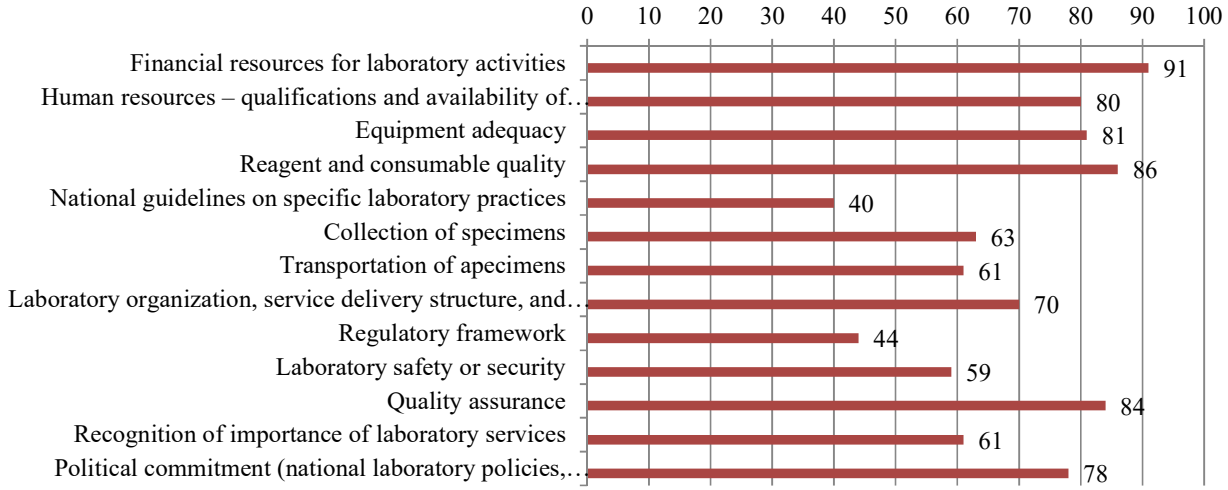
Significant efforts were made to improve on the health information system over the past few years. However, information about morbidity and mortality at national level remain suboptimal, and most of the data in Sudan are usually obtained from studies done through certain projects. There are efforts towards developing a national health information system at the Ministry of Health. The epidemiological surveillance internet-based DHIS2 system generates substantial information regarding communicable diseases as well as other health conditions.

Many donors and partners has expressed interest to support the Sudanese public institutions to support Health Systems. The technical and financial assistance provided to the healthcare system has been channeled focusing on: (1) Strengthening healthcare institutions and enabling them to face the increased demand on services and the scarcity of resources; (2) Ensuring wider access to a primary health care package of basic services; and (3) Improving access to hospitals and specialized referral care. While this investment was essential to address the current gaps in the health system, the remaining gaps and required funding is still huge.

1.2 Current internal situation

Health laboratories continued to play central role in health response in Sudan to protect lives and prevent diseases. The Department of National Lab, supported by other Laboratories across the country, is striving to full fill its mission to provide high quality services at all levels. Since its establishment, the National Labs and other affiliated Labs have witnessed continuous development in its capacities and services. By applying thoroughly systematic assessments and carefully designed plans, the qualifications and services of these Labs were continuously improved. The development of National Laboratory Strategic Plan 2016 – 2020 represents an important opportunity to further strengthen the capacity of health system in Sudan to deliver its mission for the next critical period. In 2016 a comprehensive National Public Health Laboratory Assessment has been conducted in different areas related to capacity of Laboratories system at different sectors. The figure below (figure 1) summarizes the main findings of this assessment.

Fig 1: Laboratory system gabs (%) in sudan



On other hand, this analysis will focus on current challenges and gaps that are targeted under this funding proposal. Four areas have been identified, as aggregated priorities, for this situational analysis. These include: (1) Management capacity and systems, (2) Quality and safety, (3) Equipment and supplies, (4) Information systems.

First: Management capacity and systems

1. Laws, regulations and standards:

Currently there are some national health laws that address laboratory services which are in place, with some state standards regulate laboratory services according to international guidelines. However, national health laws do not comprehensively address all laboratory services issues. The laws are not regularly updated according to laboratory service's needs. The laws are not communicated and shared with staff which leads to lack of awareness of it and adherence to it. In addition, there are no unified written, updated and communicated technical standards for services provision, incl. quality, safety, human resources. High staff turnover, similar to other health services, leads to incomplete process of laws, regulation and standards development, execution and monitoring. According to recent assessments, only % of laboratories in compliance with the national quality standards.

2. Management system:

Essential infrastructure to deliver laboratory services at national level are present to some extent. In addition, we know that the critical mass of human resources are sufficient in quantities at national and state levels. Expansion of lab services (service coverage), in remote areas is ongoing especially under PHC expansion plan. Despite this, there is lack of structured, updated and harmonized lab management system at national, state and facility levels, where clear roles, responsibilities, accountabilities at each level need to be defined.

From recent assessments were know that there is insufficient management capacity at the national and state laboratories to play the role as reference laboratories. Inadequate training on management and leadership (operational and staff management) is one of the main gaps in this area. Lack of regular monitoring and evaluation activities, including the supportive supervision and regular monitoring and review meetings. All of these gaps were attributed to insufficient financial support for laboratory management at service level. In total, the recent assessments indicated that about 25% of laboratories with functioning laboratory management system. Majority of states (14 states) have no strategic plan aiming at strengthening laboratory services or other strategic plan(s) with a laboratory component. And more than half of all states (11 states) have no specific budget assigned for public health laboratory activities.

3. Human resources:

With shortage in financing, we know that human resources management and development activities are partly supported and implemented. Human resources capacity development is sometimes donor dependent causing problems of sustainability and are not always according to priorities. The previous period has witnessed some initiatives in different areas, however the staff turnover and brain-drain have both resulted in gaps of available competencies and expertise. This has also resulted into clear gaps in some areas and scarcity of some specialties; e.g. laboratory management experts. On the education side, an assessment in 2015 highlighted that the current curriculum of academic and vocational education is not harmonized with needs of laboratories (including safety and quality). In

addition, we know that training is not based on needs assessment and not standardized and coordinated. Retention is limited due to poor salaries, resources and facilities, including at the management level. Different assessments shown that only 20 %of health laboratories that have skilled personnel with recent training received in priority areas. The national policy highlighted the needs for more coordination with relevant stakeholders in this area to achieve better outcomes.

Second: Quality and safety

1. Premises and safety:

With different initiatives been implemented, the current Lab infrastructure conforms to minimum lab requirement, still there is some gaps and room for further development. Despite that; there is a lack of standards of premises design according to level and function, including safety, especially at subnational levels. A recent assessment concluded that the current premises are not safe for both workers and customers. This was attributed mainly to limited availability of financial resources allocated for premises and their maintenance.

There are good opportunities towards achieving better standards especially with the current governmental commitment to establish comprehensive safety policy and other governance tools. Still there is lack of comprehensive national regulations and rules on biosafety and chemical safety, and gaps in the implementation of existing safety regulations. Recent assessments highlighted the needs to develop more standards, guidelines and SOPs on laboratory biosafety, chemical safety and infection control at institutional level, including infrastructure. The assessments have highlighted also the gaps in training activities related to biosafety. Integral to current gaps, there is also a lack of biosafety and waste management equipment at institutional level in different sectors. A critical area that needs further improvement is the current capacity for appropriate analysis of relevant chemicals in human and environmental media. Some small projects have been initiated in this aspect, but the current challenges require stronger approach to build these capacities. Currently there are only 6% of laboratories that have functioning Bio-Risk Management units. Compared to other areas of safety, assessments shown that there are better capacities in handling and management of radioactive materials (including waste management). Governance tools and control measures are in place and

implemented. Still continuous capacity building is needed in this area to ensure quality of different related operations. Recent assessments has highlighted some gaps that needs to be supported in this area.

In general, only few of the laboratories have risk assessment document (report) available, and no information is available on how many of these laboratories have plans for risk mitigation. But when compared to health facilities, one will find that none of HF laboratories have risk assessment document (report) available. In addition, only 8 states have dedicated and trained team in biosafety/ biosecurity.

2. Quality management system:

During the last two decades there are some ongoing quality activities and projects in place, and some resources have been allocated to support quality improvement initiatives. Still there is a lack of quality management system structure at national, state and institutional levels with clear organizational arrangements. These gaps include also the inadequately trained staff on quality management and limited regular training programs on quality. As highlighted before, the leadership of the Laboratory systems are committed towards quality, however there is clear need for more unified standards in this area to be adopted at all levels. While partners has been supportive on issues related to quality, still quality assurance programs are limited and needs to be strengthened both internally and externally as well. In the Laboratory System Assessment, the laboratory quality assurance gaps was found to be at (84%) in Sudan. Assessments highlighted the fact that 25% of Public Health Laboratories prepared (implement) for national quality standards.

Third: Equipment and supplies:

In Sudan, there is a national regularity body for laboratory technology that is functioning. In collaboration with different stakeholders, there a system in place for purchasing and inventory control of required equipment and supplies, but there is a need to develop the guiding policy in this area, and more work is needed to match the procurement process to current needs and demand. This requires achieving unified and regulated system to support the flow of commodities through the health system to lower levels, which is based on robust needs assessment. The most recent assessment relevant to this area has shown

that the equipment adequacy gaps was found to be at (81%) and also the consumables quality of reagent gaps was at (86%). In the Laboratory Facilities Assessment, the equipment adequacy gaps was found to be at (78%) and also the consumables quality of reagent gaps was at (49%). It was also noticed that 19% of laboratories that have functioning systems for equipment standardization, calibration and decommissioning. In addition, there is insufficient capacity at laboratory technology management department in terms of staffing and available competencies. Assessments have also highlighted the current gaps related to network system for storage and distribution. Advancing the information technology in managing the available resources is needed and some initiatives were supported, but not materialized in this area.

Fourth: Information systems:

1. Laboratory information management system (LIMS):

Information management at FMOH has been critical component to strengthen the capacity of different departments and functions within the ministry, Laboratories was not an exception. Despite the gains and success in this area, still the information management systems at different levels are fragmented and far from being integrated. This has resulted to clear challenges related to LIMS; as only 26% of laboratories (at regional and states) having LIMS, and only few of these have their LMIS connected to national public health laboratory network. This was also further weakened by the poor capacity (including infrastructure) for data management and reporting quality, as no standardized reporting system is in place. Human resources capacity is central for this challenge with lack of skilled staff for data collection and reporting.

2. Laboratory network:

In Sudan the networking among national programs is partially in place which is the basis for comprehensive services, still there is a room for more integrated and more efficient utilization of available resources. State level referral labs are in place in some states, with some gaps in the current capacities that need to be further strengthened. However, there is limited lab referral system; with limited guidelines, formats and trained personnel. There is a working stream currently focusing on developing working document that

specifying structure of laboratories networks. There is current needs to develop a well-defined package of services for each laboratory level with linkage between levels is in place; integration is critical in this area. With weak coordination between health laboratories and other sectors, this also leave the room for better coverage and complementarity of the services. This has also resulted into weak information sharing among laboratories in different sectors. In addition to creation and activation of wider networking approach, there is a need to train and certify staff working in members' laboratories on packing and shipping of biological samples.

SECTION 2: Strategic plan and funding gaps

2.1 Strategic plan

The National Laboratory Strategic Plan 2016 – 2020, (NLSP), has been developed in 2015 in consultative process with full engagement of different stakeholders at national and subnational levels. As highlight by HE The Minister of Health in his forwarding message; this strategic plan "*… provides direction to laboratory strengthening efforts and ensures efficient use of government funds and donor investments as well as the development of a sustainable system of laboratory services…, ….the national laboratory strategic plan document reflects the strong commitment of the FMOH for improvement of the laboratory sector in the country. The national laboratory strategic plan is out in an integrated manner in-line with the country's managerial and financial resources*."

The plan has defined 11 strategic objectives in different aspects related to laboratory services in Sudan. Below is a short account of these objectives.

Strategic objective 1: Laws, regulations and standards

Laboratory services abide by the nationally-recognized and enforced quality and ethical standards and guided by relevant and updated laws, regulations and guidelines.

Strategic objective 2: Laboratory Management System (LMS)

Laboratory management system in Sudan is in place and implemented, with clear structure, roles and responsibilities, job descriptions, and accountability mechanisms defined, harmonized and updated for all levels of laboratory system.

Strategic objective 3: Monitoring and evaluation

Establish a system to monitor and evaluate performance of laboratory Strategic objectives and services and provide means for continual quality improvement and coordination and collaboration.

Strategic objective 4: Laboratory network

Establish networking, communication and collaboration mechanism across laboratory services and with all stakeholders in different sectors to ensure rational use of equitable, accessible, affordable and quality laboratory services.

Strategic objective 5: Laboratory services financing

Establish effective, evidence-based and sustainable financing mechanisms to ensure uninterrupted provision of adequate resources for health laboratory services at all levels.

Strategic objective 6: Laboratory premises and safety

Laboratories handle biological, chemical and radiological materials with adequate level of protection for patients, personnel, community and the environment, in accordance with national and international biosafety and biosecurity guidelines and regulations.

Strategic objective 7: Human resources

Provide and retain adequate numbers of appropriately qualified and motivated personnel, with a skill-mix appropriate to each facility needs.

Strategic objective 8: Equipment and supplies

Provide all laboratories with appropriate, certified, functional, well maintained equipment and adequate amount of nationally regulated, good quality reagents and consumables to support uninterrupted provision of services according to mandated scope of work.

Strategic objective 9: Laboratory information management system

Establish a laboratory information management system to provide relevant and timely data for patient care, laboratory management, disease surveillance, evidence-based planning, policy formulation, and research.

Strategic objective 10: Research

Support high quality research based on national public health laboratories' priorities to inform evidence-based policy and planning for improving clinical and public health outcomes.

Strategic objective 11: Quality management system and accreditation

Ensure provision of accurate and reliable tests' results in timely and cost-efficient manner to population of Sudan.

2.1 Funding, full budget and funding gaps

Based on a recent costing of the national strategic plan, the total amount of funding required to implement the activities of the plan is estimated at USD 8,157,830 for 5 years. From this budget, most of the resources (69%) required for the first year to establish different critical work streams.

The following is summary and overview of the budget analysis and required resources under each strategic objective of the national strategic plan. In addition, the table shows the major gaps in terms of urgency and importance highlighted for the purpose of the funding proposal.

Strategic objectives	Total required funding
SO1: Laws, regulations and standards	197,587
SO 2: Laboratory Management System (LMS)	670,704
SO 3: Monitoring and evaluation	372,144
SO 4: Laboratory network	10,656
SO 5: Laboratory services financing	0
SO 6: Laboratory premises and safety	4,527,456
SO 7: Human resources	241,200
SO 8: Equipment and supplies	1,773,787
SO 9: Laboratory information management system	193,464
SO 10: Research	158,304
SO 11: Quality management system and accreditation	12,528