ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

FIND
Diagnosis for all

Defining tier-specific laboratory testing in African countries

STUDY REPORT
OCTOBER 2022

LESSONS FOR THE DEVELOPMENT OF NATIONAL ESSENTIAL DIAGNOSTICS LISTS

CONTENTS

ACKNOWLEDGEMENTS

We thank the 43 key respondents from Burkina Faso, Cameroon, Ethiopia, Kenya, Nigeria, Uganda and Zimbabwe for agreeing to participate in individual or group interviews despite their busy schedules. They shared their knowledge, views of and rich experiences with their national laboratory systems and essential diagnostics. This enabled us to extract lessons for eventual development of national essential diagnostics lists. Please be assured of our appreciation and deep admiration for the work you have been doing and are planning for the outreach of laboratories and make essential diagnostics accessible to the population.

We also thank FIND, the principal funder of this study, and Mikashmi Kohli and Ezekiel Borro, who gave useful suggestions for the study proposal and the qualitative interview guide. We also acknowledge Jenny Grunwald, Delores Mack and Priya Yerra from University of Washington for their contributions. Please be assured of our highest esteem.

The study team:

> **Winny Koster** *(author)*

> **Elishebah Mutegi**

> **Francis Ocen**

> **Michael Maina**

> **Collins Otieno**

> **Albert Gautier Ndione**

> **Kekeletso Kao**

> **Lucy Perrone**

> **Pascale Ondoa** *(principal investigator)*

ABBREVIATIONS AND ACRONYMS

AFCAD	African Collaborative Initiative for Advancing Diagnostics
AMR	Antimicrobial Resistance
AMREF	African Medical and Research Foundation
ASLM	African Society for Laboratory Medicine
BF	Burkina Faso
BRTI	Biomedical Research and Training Institution (Zimbabwe)
CAM	Cameroon
CDC	Centres for Disease Control (and Prevention)
CHAI	Clinton health access initiative / CHAI Clinton HIV/AIDS Initiative
CHN/CHU	Centre Hospitalier National/Centre Hospitalier Universitaire
CHR	Centre Hospitalier Régional (Burkina Faso)
CM/CMA	Centres Médicaux/Centres Médicaux Avancés (Burkina Faso)
COVID-19	Coronavirus Disease 2019
CSPS	Centre de Soin et de Promotion Sociale (Burkina Faso)
DLS	Directorate of Laboratory Services (Zimbabwe)
DOC	Document
EDL	Essential Diagnostics List
EID	Early Infant Diagnosis
EML	Essential Medicine List
EPHI	Ethiopian Public Health Institute
EPSA	Ethiopian Pharmaceutical Supply Agency
ETH	Ethiopia
FHI	Family Health International
FIND	Foundation for Innovative New Diagnostics
FMOH	Federal Ministry of Health (Nigeria)
HIV	Human Immunodeficiency Virus
IVD	In Vitro Diagnostics
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority

KEN	Kenya
KMTC	Kenya Medical Training College
KNCV	Royal Netherlands Tuberculosis Foundation
KNH	Kenyatta National Hospital
KU	Kenyatta University
LabCoP	Laboratory Systems Strengthening Community of Practice
LMICs	Low- and middle-income countries
MACEPA	Malaria Control and Elimination Partnership in Africa
MLSD	Medical Laboratory Service Division (Nigeria)
MNCH	Maternal, New-born and Child Health
MoH	Ministry of Health
MSH	Management Sciences for Health (Nigeria)
MTRH	Moi Teaching and Referral Hospital (Kenya)
NASCOP	National AIDS & STIs Control Program (Kenya)
NCCP	National Cancer Control Strategy (Kenya)
NCD	Non-communicable Disease
NEDL	National Essential Diagnostics List (for invitro diagnostics)
NEML	National Essential Medicines List
NGO	Non-Governmental Organization
NHLDS	Department of National Health Laboratory and Diagnostic Services (Uganda)
NIG	Nigeria
NLTWG	National Laboratory Technical Working Group (Nigeria)
PEPFAR	President's Emergency Plan for AIDS Relief
PHCU	Primary Health Care Unit (Ethiopia)
PSI	Population Services International (Ethiopia)
RDT	Rapid Diagnostic Test
RESAOLAB	Réseau d'Afrique de l'Ouest des Laboratoires de Biologie Médicale
TB	Tuberculosis
UG	Uganda
UHC	Universal Health Coverage
UNICEF	United Nations Children's Emergency Funds
UON	University of Nairobi
USAID	United States Agency for International Development
VL	Viral Load
WHO	World Health Organization
ZIM	Zimbabwe

EXECUTIVE SUMMARY

Introduction

This report presents the findings of a study conducted by the African Society for Laboratory Medicine (ASLM). The main study objective was to collect information from African countries on existing national guidance documents and on decision making when selecting tier-specific in-vitro diagnostics (IVD) that could be the basis for recommendations to supporting countries in developing a National Essential Diagnostics List (NEDL) or a similar guidance document. The study findings inform recommendation for eventual development of national guidelines for essential IVDs and how to support countries in the endeavour. The study had a mixed-method design. The quantitative arm implemented a search for relevant documents in the 55 African countries (362 were found) and a content analysis of 292 documents from 44 countries. The qualitative arm conducted in-depth semi-structured (group) interviews with 43 respondents from seven countries who were (potentially) involved in developing and implementing national essential IVD guidelines. Interviews were conducted by Zoom video conferencing for five countries: Nigeria, Burkina Faso, Cameroon, Ethiopia and Zimbabwe; face-to-face interviews were conducted in Uganda and Kenya.

Findings

Documents

Twenty-seven countries had at least one document addressing tier-specific laboratory testing. One country (Nigeria) had developed an NEDL, while 10 had a national document aimed at standardising/harmonising testing across the laboratory network (Botswana, Burkina Faso, Cameroon, Ethiopia, Gabon, Kenya, Malawi, Uganda, Tanzania, Zimbabwe). The other 16 countries had one or more documents that defined testing by tier, often for vertical disease programmes. The documents for vertical disease programmes were more recent than the standardising/harmonising testing documents (range 2009-2021; median 2014) and not all of the latter had been implemented at the time the data were collected. The harmonisation documents were more extensive than a standard NEDL, because they not only list essential IVDs as an NEDL does, but also include equipment, consumables, and sometimes laboratory personnel and infrastructure requirements for the IVDs by laboratory/health care tier. The Nigerian NEDL (2021) is a stand-alone document and also a Chapter in the Nigerian Laboratory Policy. The NEDL will be a budgeted theme in Nigeria's National Laboratory Strategic Plan, which awaits finalisation.

The national harmonisation documents did not identify tests for the level of community and health facilities without an on-site laboratory, as the World Health Organization (WHO) recommends doing for an NEDL. The Nigerian NEDL followed those WHO guidelines by distinguishing two tiers: i) community level and health care facilities without a laboratory and ii) health care facilities with a laboratory on-site and reference laboratories. The document review found that 55% of malaria documents addressing IVDs (N=31), 32% of such HIV documents (N=28) and 18% of such tuberculosis documents (N=28) identified IVDs for the community level. In fact, in all countries of the qualitative study, community health workers and/or staff in health posts and health centres without a laboratory did rapid diagnostic tests (RDTs), usually for malaria, HIV, pregnancy, and albumin and protein (with urine dipsticks); some of these tests were specified in vertical disease programme documents.

State of national laboratory system

In the seven countries of the qualitative study, respondents and information from documents indicated that laboratories remain weak links in the health care system. Generally, except for the laboratories supported by disease and laboratory strengthening programmes, laboratories face problems related to insufficient and unqualified human resources, poor maintenance and unavailability of equipment, unavailability of sufficient and appropriate consumables and tests, inadequate national funding and dependence on donors, and inefficient organisation and coordination. Partly, these

problems are related to the low status of laboratories and laboratory professionals in the health care domain and the low position of Laboratory Services in the Ministry of Health (MoH) hierarchy.

Stakeholders in the laboratory domain and development of documents

The top three stakeholder categories mentioned as being involved in 292 documents' development are the MoH (mentioned in 100% of documents), funding agencies (56%) and implementing partners (47%). When focusing on stakeholder involvement in the development of the 11 national standardisation documents (including the Nigerian NEDL), we found that in addition to the top three above, the public sector laboratory services (managers, directors, and in-charges) were mentioned in nine of the 11 documents. In the development of the Nigerian NEDL, all stakeholder categories were involved, as WHO advises. Within the MoH, obviously, the Laboratory Services section would be most involved in selecting priority IVDs. Its position within the MoH – being a department with a budget, or a sub-section without budget – would influence how much decision-making power the section has. However, not only its position within the MoH, but also its connection with and support by the Minister and international fundings and technical partners was found to play a role in the Laboratory Services decision-making power. In Nigeria, the strong connection and keen interest of these stakeholders in developing the laboratory system facilitated developing the NEDL that was guided and written by a team of national consultants in constant deliberation with the Laboratory Services and other stakeholders.

Interestingly, although the Nigerian NEDL is not anchored yet in the laboratory strategic plan, and many hurdles have yet to be overcome before wide implementation, Nigerian study participants noted that it is already used by the groups of stakeholders in its development, including the Medical Laboratory Science Council of Nigeria's Public Health IVD Control laboratory, which prioritises testing and validating IVDs on the NEDL. The Nigerian experience proves that in NEDL development it is key to involve all stakeholders in (future) NEDL implementation, including regulators and government procurement offices.

IVD selection criteria

Only 28% (n=48) of the 169 documents that addressed IVDs (out of 292) mentioned the criteria for selection of IVDs (by tier). Even in the 11 standardisation documents, these criteria were not always specified, and 45% did not mention the considerations used. For the 48 documents that contained information on test selection criteria, the test performance (for instance, specificity/sensitivity/accuracy) was the main consideration at 67%, followed by disease prevalence consideration at 38%. Considerations pertaining to lists of diseases prioritised for surveillance were indicated in eight of the 48 documents and lists of essential medicines were indicated in six of the 48 documents. It should be noted that the qualitative study participants identified additional main criteria for selecting IVDs by tier when they developed the harmonisation documents other than the criteria categories employed by the document review. Their top three criteria were: the types and capacities of available laboratory personnel, the available clinical personnel and level of care provided, and the available equipment. In addition, countries mentioned cost considerations when prioritising tests. Interestingly, for the harmonisation documents in three countries, stakeholders decided to make three priority categories of IVDs: Vital, Essential, and Necessary, with an eye on procurement agents and funders, reasoning that funding always is a problem. Participants also mentioned considerations related to disease burden and alignment to the National Essential Medicines List (NEML), which were categories in the document review.

Gender considerations

Participants mentioned that gender was not a criterion for selecting essential IVDs, although some study participants noted that some tests for priority health care needs are gender specific, e.g., pregnancy, and cervical and breast cancer tests for women. We did not probe whether there were also tests specific for men. The qualitative study found there was no strategy for equal gender representation in workshops for document development, laboratory committees or consultant teams, because normally in workshops, committees and teams, organisations and departments are invited which are then represented by an individual with required qualifications, and the gender of this individual was reported as not being an issue in their selection.

Plans to develop and implement an NEDL

Because an NEDL intends to contribute to stronger laboratory services and thus to improved national health care delivery, stakeholders were in favour of developing an NEDL or updating the national harmonisation/standardisation document. Vertical disease programmes increasingly realise that, for their programme to be successful, they need to

support general laboratory services and not only strengthen selected laboratories for their own programme. Not all countries in the qualitative study intended to develop a stand-alone NEDL. They considered their (old) harmonisation document more comprehensive, because those documents included reagents, consumables, equipment and sometimes also personnel needed for the essential IVDs. An NEDL would only be a part of this harmonisation document that they hoped to update. The study participants noted that an NEDL can only be implemented when there is a plan for dissemination, implementation, and monitoring and evaluation. For implementation, the required equipment, supplies, consumables and laboratory personnel should be specified, and the legislation, regulations and procurement should be arranged and coordinated. All these plans require funding.

Lessons and recommendations

Lessons from the study inform recommendations for development and implementation of an NEDL or similar guidelines for tier-specific essential IVDs. Recommendations address countries and partners, such as ASLM, FIND and WHO, intending to support the NEDL development.

- Have the Minister of Health initiate/endorse the process of development. The Minister is the final decision maker and can ask for the funding, technical and implementing partners to support the process. ASLM and other supporting partners should advocate with the Ministers of Health for their commitment.
- Involve all categories of stakeholders in the NEDL development process. When all are involved in decision-making discussions, they feel committed and take ownership and may start implementing even before the NEDL is officially launched. Include regulatory bodies and procurement agencies.
- Recruit well respected, local laboratory scientists who are experts on IVDs to be consultants for the development of the NEDL. They must lead the process, with full involvement of all laboratory domain stakeholders.
- Secure budgets for laboratory landscape analysis, stakeholder workshops, national consultants, dissemination and implementation of the NEDL.
- Identify a wide range of RDTs for the community level and health facilities without a laboratory on-site to expand access to testing. In the analysis of the laboratory landscape, study which tests are already performed and review the latest vertical disease programme documents for community-level tests.
- Let countries decide whether they want to develop an NEDL or revise their harmonisation document and have an NEDL (following the WHO Essential Diagnostics List [EDL] format) as part of the harmonisation document. Before starting, complete a cost analysis of the process and secure funding (get information from the Federal Ministry of Health [FMOH], WHO and Management Services for Health in Nigeria).
- In developing and implementing an NEDL, countries could learn from the general adoption and use of the WHO Essential Medicines List; it was beyond the scope of the present study to analyse the literature on this topic.

1 INTRODUCTION

1.1 The aim of the study

This report presents the findings of a mixed-methods study conducted by the African Society for Laboratory Medicine (ASLM) on existing national guidelines for laboratory-tier-specific diagnostic testing in African countries. The tier structure of the laboratory network, from basic to sophisticated, is intended to promote access to testing services for most of the population in a cost-effective way and in the context of limited resources.

In May 2018, the WHO released the first edition of the EDL as a generic guide that countries can use to select the diagnostic tests that satisfy the priority health care needs of the population based on the local burden of diseases, public health relevance, evidence of efficacy and accuracy and comparative cost-effectiveness. The second edition of the EDL (EDL 2) was released in 2019, and the third, EDL 3, in 2020. The EDL lists generic categories of IVDs, rather than brands. Given the overall low availability and access to essential diagnostic in many low- and middle-income countries (LMICs) (The Lancet Global Health, 2021), WHO encourages countries to take up, contextualize and operationalize an EDL into national health and laboratory policies and plans. WHO guidance is essentially a 'how-to' for MoH to develop or update an NEDL to further improve access to IVD testing in support of Universal Health Coverage (UHC) programmes and national emergency preparedness and response efforts.

The aim of this study was to generate information that can guide the WHO Regional Office for Africa strategy in supporting countries to develop and implement NEDLs, which can then be plugged into national diagnostic operationalization plans.

1.2 Literature review

1.2.1 Status of laboratory services and IVD availability in Africa

Within national MoHs in African countries, laboratory services are often not prioritised, and their management may be divided among several departments, resulting in a lack of budgeting, planning and diagnostic accountability (Greenslade & Ginsburg, 2019). Laboratory services suffer from lack of (sufficiently) qualified human resources at various levels, poor supply chains for diagnostics and erratic supply and maintenance of laboratory equipment (Schroeder, 2021; Yadav, 2021). Ondoa et al. (2017) report that countries behind in strategic planning for national laboratories at the end of 2013 were more likely to be francophone countries located in West and Central Africa that have historically low HIV prevalence.

The literature reports disparities in diagnostic availability in LMICs, particularly in primary care settings. Diagnostic availability normally increases in higher level health care facilities (Yadav, 2021; Yadav et al, 2021; Ondoa et al., 2017). Even for priority public health diseases, the availability and quality of tests is low (Yadav et al., 2021). Ondoa et al. (2017), analysing national laboratory policies and plans in sub-Saharan African countries, found that the these problems are associated with several factors, including the lack of attention paid to the budget available or needed for the provision of laboratory services or for the implementation of laboratory improvement strategies. There is also a lack of a practical framework for monitoring and evaluating laboratory services and the implementation of national laboratory policies, which do not allow for indicators to measure the performance of laboratory services, including the availability of diagnostics (Ondoa et al., 2017).

1.2.2 Stakeholders in the laboratory domain and in prioritising IVDs

International agencies have been prioritising supporting laboratories, including funding IVDs for specific disease programmes such as HIV/AIDS, tuberculosis, and malaria. This has made diagnostics for these diseases more readily available, including at the primary health care level, and has led to significant improvements in diagnosis in LMICs (Yadav, 2021). In addition, more recently the coronavirus disease 2019 (COVID-19) pandemic has caused international organisations and donors to realise the urgency of availability and access to high-quality diagnostics (The Lancet Global Health, 2021). On 16 November 2017, the Africa Centres for Disease Control and Prevention launched the Africa Collaborative Initiative to Advance Diagnostics (AFCAD) to promote the diagnostic agenda in the African region through better coordinated and synergized efforts that align with the priorities of MoHs. The AFCAD partnership includes, among others, ASLM, the Institute for Health Research, Epidemiological Surveillance and Training, WHO Regional Office for Africa, the Clinton Health Access Initiative (CHAI), the African Field Epidemiology Network and UNITAID (Greenslade, 2019).

1.2.3 Information basis for developing an NEDL

Prior to the launch of the WHO EDL in 2018, countries have rationalized the use of diagnostics at different tiers of the health care and laboratory network through a variety of operational and normative guidance documents recommending minimal testing packages based on the availability of infrastructure, workforce, skills and equipment. That guidance can be found under various document names, including: 'Standardisation of diagnostics', 'Harmonisation policies for laboratories', 'National test menu' or 'National norms for laboratory services'. Often these national guidelines do not include the community tier as recommended by the WHO EDL. In contrast, the national IVD guidelines for vertical disease programmes (HIV, tuberculosis, and malaria) often do include this community tier.

The selection of essential IVDs for a national list could be based on the country's disease burden, the national priority diseases list, or the NEML. However, in many African countries, data on national disease burden are not available or are unreliable and therefore not a good basis for an NEDL (Ondoa et al. 2021; Oskam, 2021). Because national priority diseases lists are difficult to establish, countries could draw on various global lists to establish their national lists. These include UHC, in which little attention is given to priority infectious diseases except for tuberculosis and HIV. There is also the International Health Regulations surveillance list, which has 10 basic priority tests to diagnose diseases, but not all tests are relevant to all countries and others, such as antimicrobial resistance tests, are missing. The WHO list of 10 priority diseases for research does not correspond to the priority diseases in each country, especially in the LMICs where non-communicable diseases are increasing and infectious diseases other than HIV and tuberculosis are present. It is therefore important that the specific realities of each country be considered to set up national lists of priority diseases that will allow the rational development of an NEDL. Furthermore, for successful NEDL implementation, all elements of the laboratory system must be in place and functional and thus considered when creating the list (Oskam, 2021).

A reliable information basis for selecting IVDs for an NEDL would be the NEML. Most countries have an updated NEML with the medicines needed to address the national priority health problems. An NEDL based on the NEML would ensure availability of medicines to cure or prevent diagnosed diseases and conditions (Schroeder, 2021). Ideally, disease management and diagnostic services should be aligned by tier of health care facility. Lack of (sufficiently) qualified human resources at various levels, poor supply chains for diagnostics and erratic supply and maintenance of laboratory equipment mean that this alignment is not always easy to attain (Schroeder, 2021; Yadav, 2021).

1.3 Study objectives:

In the eventual development of an NEDL, countries should build on their experience with development of existing national 'test menus' across the laboratory domain and for vertical disease programmes. This would include the stakeholders that were involved, the criteria used in test selection for specific laboratory tiers, and considerations regarding operational conditions, constraints and opportunities.

Therefore, the main study objective was to collect information from African countries on existing national guidance documents and on decision making when selecting tier-specific diagnostics that could be the basis for recommendations to support countries in developing an NEDL or a similar guidance document.

The main study objective was broken up in the following specific objectives:

1. To assess the availability and format of national guidance documents that define diagnostic services at different tiers of the health care or laboratory system for each of the 55 African Union Member States; within the documents to explore (quantitatively):
    1.1. The type of documents defining testing by tier;
    1.2. The basis for determining diagnostics at each tier;
    1.3. The scope of testing;
    1.4. The stakeholders involved in the development of the documents.
2. To explore the in-country decision-making processes for prioritising IVDs in the tiered health care and laboratory network in a selected number of countries, including:
    2.1. The role of different stakeholders in prioritising IVDs in the tiered network;
    2.2. The bases for prioritising IVDs in the tiered network;
    2.3. The main drivers of (or barriers to) the availability of diagnostics within the different tiers of the laboratory system and community-level system.
3. To give recommendations for the development and implementation of an NEDL.

1.4 Report content

The structure of this report is as follows: Chapter 2 describes the methodology of the two study components, which implied the desk review arriving at quantitative data and the in-depth qualitative interviews. The chapter includes the study questions for the two components. Chapters 3 to 8 present the study findings: Chapter 3, the national laboratory systems; Chapter 4, national and programme documents addressing laboratories; Chapter 5, stakeholder involvement in and processes of document development; Chapter 6, steps in document development, including criteria for selecting priority IVDs; Chapter 7, country plans to develop and implement an NEDL or similar document; Chapter 8, recommendations by participants of the qualitative study. In Chapters 4, 6 and 7 we devote sub-sections to Nigeria, being the only country with an NEDL. In Chapter 9 we discuss the findings and give our recommendations for support to countries in development and implementation of an NEDL or similar documents.

2 METHODOLOGIES

2.1 Study design

The study used a mixed-method design, triangulating quantitative and qualitative data. A study team from ASLM started with a desk review, the 'quantitative arm', that used an analysis frame for review of 362 documents from 55 countries. After the preliminary quantitative analysis, two external qualitative researchers experienced in studies of the laboratory domain were responsible for the 'qualitative arm'. They collected data through in-depth, semi-structured interviews with key informants who were (potentially) involved in developing and implementing national essential IVD guidelines in seven countries. In addition, the consultants searched relevant documents from the document review for qualitative details and context about the national laboratory systems and services for these seven countries.

2.2 Methodology of the desk review

2.2.1 Study questions

To attain the quantitative study objectives, we formulated the following study questions:

1. What are the proportions of countries with developed/revised national policies and strategic plans guiding the implementation of diagnostics at various tiers of the networks across the 55 Member States?
2. What are the categories of documents defining tier-specific diagnostic test menus and which document categories do not define diagnostics or tier-specific diagnostics?
3. What are the bases of test selection?
4. Who are the stakeholders involved in the development of documents?
5. To what extent is the countries' tier-defined testing for selected diseases aligned with the WHO EDL recommendations?

2.2.2 Country and document selection

All 55 African Union Member States were eligible for inclusion in this analysis. For each of the Member States, we conducted an online search for key documents covering general health, laboratory and disease-specific documents. Based on the ASLM researchers' experience, the categories of documents most likely to contain information on diagnostics by tier were:

1. National health policy and/or strategic plan
2. National laboratory policy and/or strategic plan
3. National health laboratory procurement plan
4. National tests menus/norms/standardisation of diagnostic
5. National HIV strategy (or plan)
6. National tuberculosis strategy (or plan)
7. National malaria strategy (or plan)
8. Maternal, new-born and child health strategy (or plan)
9. Non-communicable diseases strategy (or plan) (for example, diabetes)

Any other documents that had reference to diagnostic tests, for instance national documents that were not listed above but gave guidance on other infectious diseases (e.g., cholera, cancer, Ebola, etc.), including pandemic preparedness plans were categorized as 'others'.

Search strategy

An online search for the proposed categories of documents by country was performed using the document and country names in web search engines. The following sources were used: Google search engine, country's MoH and laboratory services websites, other grey literature located on government websites, and PubMed/journals. For documents not in English, Google translate was used for the initial search and scanning of documents. ASLM contact persons in four countries (Nigeria, Burkina Faso, Tanzania and Cameroon) were engaged to support retrieval of relevant documents known to exist but not found from the online search.

Documents were scrutinized for validity using their development, start and end dates. Documents' effective date provided information on whether they predated the 2018 first edition of the WHO EDL, in which case their development would not have been influenced by the WHO model list.

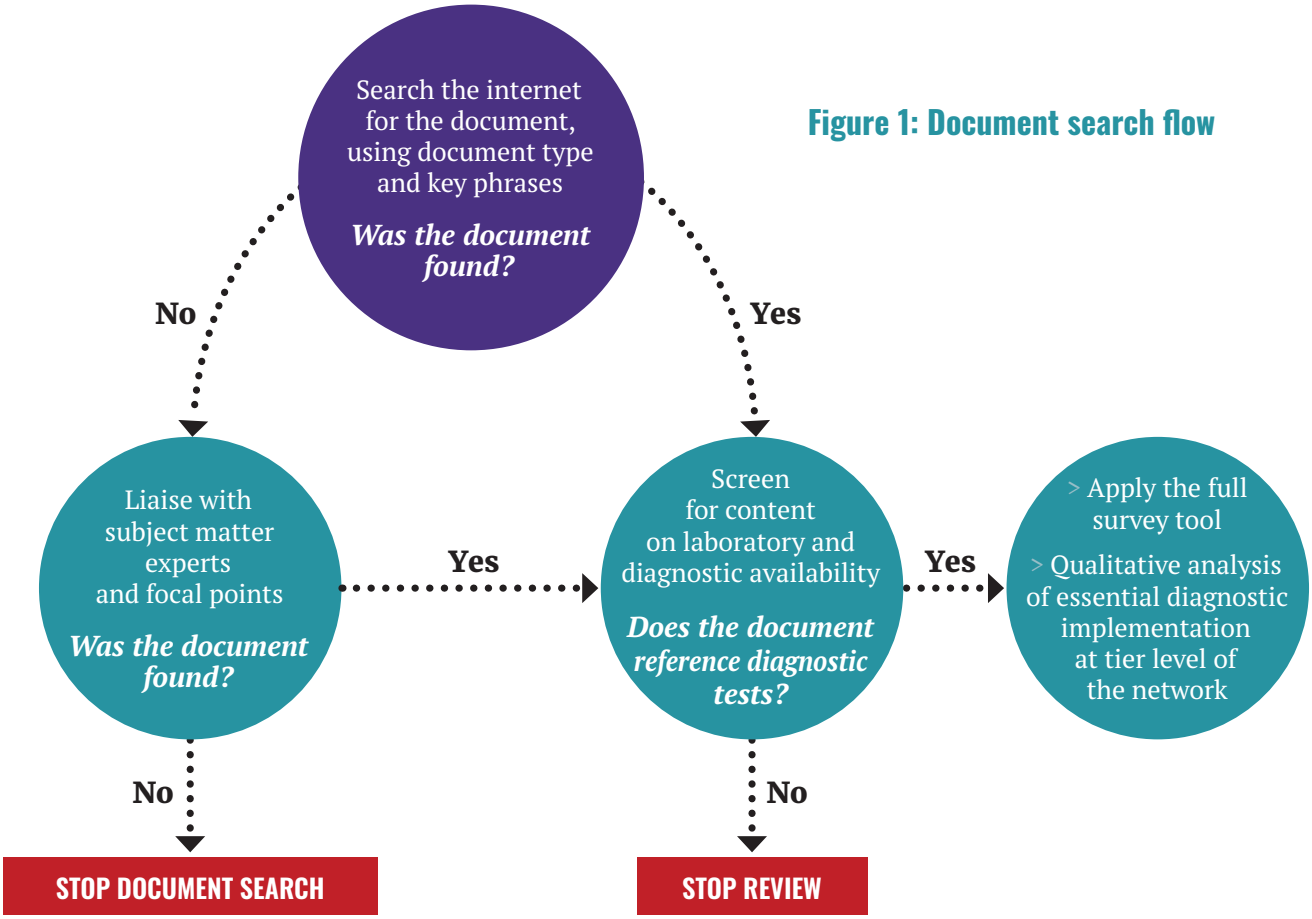


Figure 1: Document search flow

2.2.3 Document analysis

All documents in English, French and Portuguese were searched and reviewed. Two teams were created to manage the search process for English and French/other language speaking countries to allow for an exhaustive process. The teams included two members from ASLM, one representative from FIND, three graduate-level Master of Science Students in Laboratory Medicine and Pathology from the University of Washington. All identified documents were saved in an online shared folder to facilitate remote access by all study teams.

Analysis template

An analysis template was created in line with the study questions. It served the document search and review. The document search outputs displayed the category of documents identified by country, while the document review outputs highlighted the content of the documents that were eligible for analysis. Documents were reviewed for content on laboratory-based diagnostics and only those with that information were subjected to the survey tool for further analysis (see Figure 1). Thus, review outputs summarized whether laboratory-based diagnostics by tier were encompassed in the documents, stakeholder involvement in development of the document was mentioned, and criteria for test selection, recommended test packages and actual testing available on the ground were mentioned.

Review process

Eligible documents were assigned to the reviewers and subjected to a manual review through a stepwise scanning of documents through searching for key words in response to a set of questions. The data were then captured in an online database (Google Forms) and the data were then stored in a Google Sheets database in preparation for analysis. The set of questions covered the document name, type, test by level specification and stakeholders involved in the development of the documents. Test menus and country documents that addressed laboratory testing by tier of laboratory network were further subjected to a review to ascertain alignment to the WHO EDL second edition (EDL 2) guidance (WHO, 2019). All responses from the Google Form were auto linked to and aggregated in a recipient Google Sheets database.

Data management

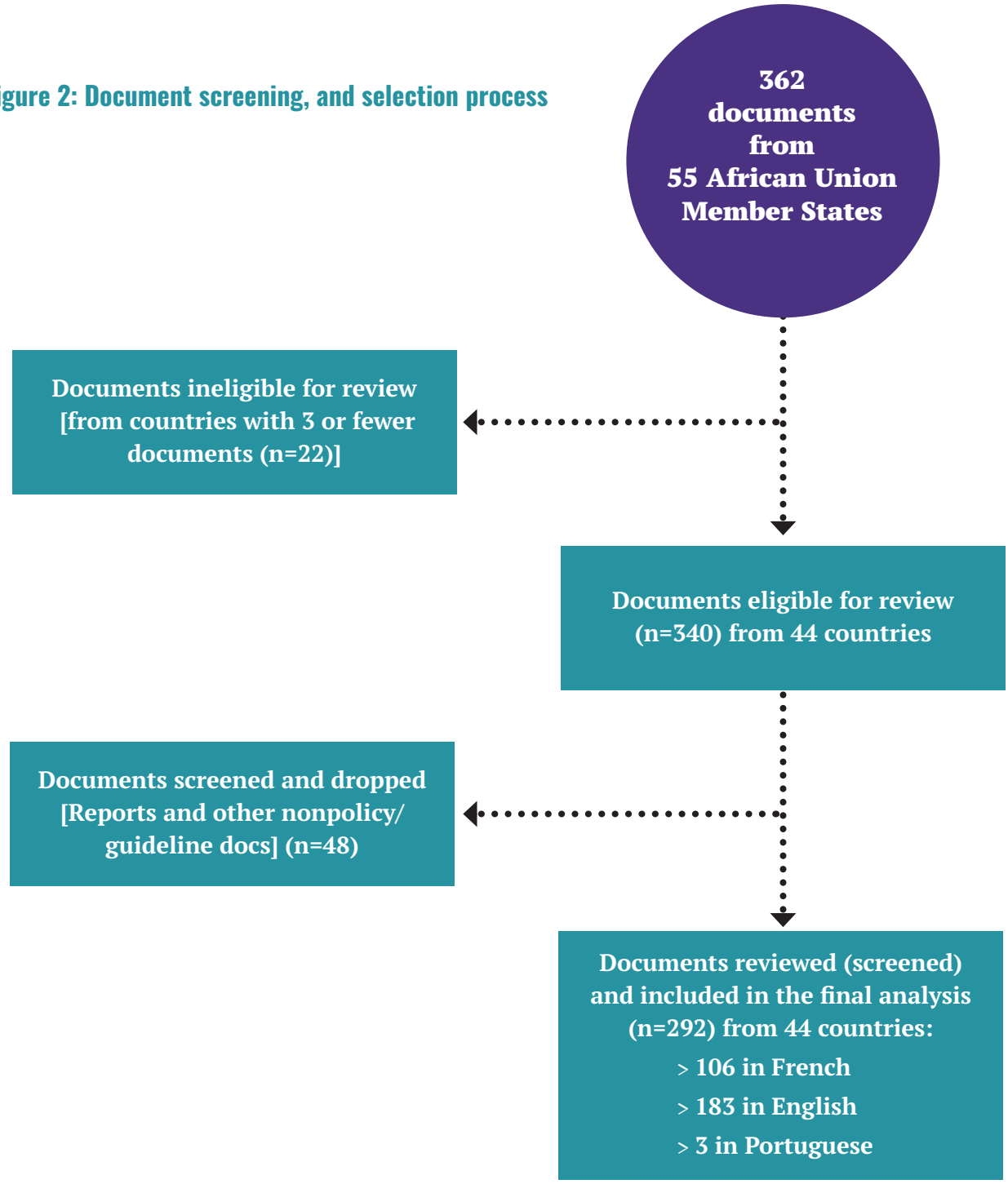
Data for the study were collected through a structured review of national policy and guidance documents that were most likely to contain information on diagnostic availability by tier level gathered through online and physical searches. Documents that did not meet our inclusion criteria (e.g., workshop reports, non-national documents, research articles, etc.) were not included in the analysis. The review of the documents was guided by a predesigned analysis guide and the information were collated to provide an appreciation of the extent of diagnostic services prescription by level/tier, and stakeholders that provided support during the development of these documents. All country documents and analyses outputs were stored in an online ASLM shared folder for future reference.

Findings from the search were summarized and presented to provide an illustration of what was available for guidance of diagnostic services by level, ownership and stakeholder involvement in the development of guidance documents across Member States whose documents were reviewed. The data were summarized and maintained within an MS Excel database and then analysed using Tableau® and SPSS®.

Data analysis

Descriptive statistical analysis was performed to summarize data and obtain proportions of document category available by country, percentage of documents addressing laboratory testing and those addressing laboratory testing by tier of the laboratory network. Associations between stakeholder involvement in the development of documents and the extent to which the document addresses laboratory testing were assessed using the Chi-square test. The level of significance was set at $p=0.05$. Additionally, in the identified national test menus and documents that had tests by tier, recommended tests for HIV, malaria, tuberculosis and maternal, newborn and child health (MNCH) were compared with those listed in the WHO EDL 2 to determine adherence to the WHO EDL 2 guidance.

Figure 2: Document screening, and selection process



Sample: Documents selected

A total of 362 documents were identified from 55 African Union Member States. Due to the project time constraints, we prioritised countries with at least three documents; thus, 340 documents from 44 countries were eligible for review. Of these 340, 49 were dropped for full content review, because they appeared to be reports or other non-policy or non-guideline documents **(Figure 2)**. Of the 292 reviewed documents, 11 were test menu/NEDL or standardisation documents, 16 were national laboratory policy/guidelines documents, three were national health laboratory procurement plans, 65 were national health policy/guidelines documents and 161 were disease-specific programme policies and guidelines [HIV/AIDS (43), malaria (40), tuberculosis (31), MNCH (22), non-communicable diseases (25)]. Twelve documents fell under the 'other' category.[1] **(Table 1)**

[1] Other documents included: National Drug (Medicine) Policy/Treatment Guideline; WHO Co-Operation Documents; National Strategic Plan Adolescent Health and Young People; Neglected Tropical Diseases Plan; National Community Health Strategy; National Response and Contingency Plan for Covid-19 Documents; National Documents on Prevention and Control of Plague; National Preparedness Plan on Ebola Virus Disease; National Guidelines for Setting Up A Medical Laboratory in Nigeria; MoH Clinical Practice Guidelines; *Plan de Développement de Ressources Humaines du Système de Santé du Cameroun* 2013-2017; National Multisectoral Strategic Plan.

Table 1: Documents reviewed by category (N=292)

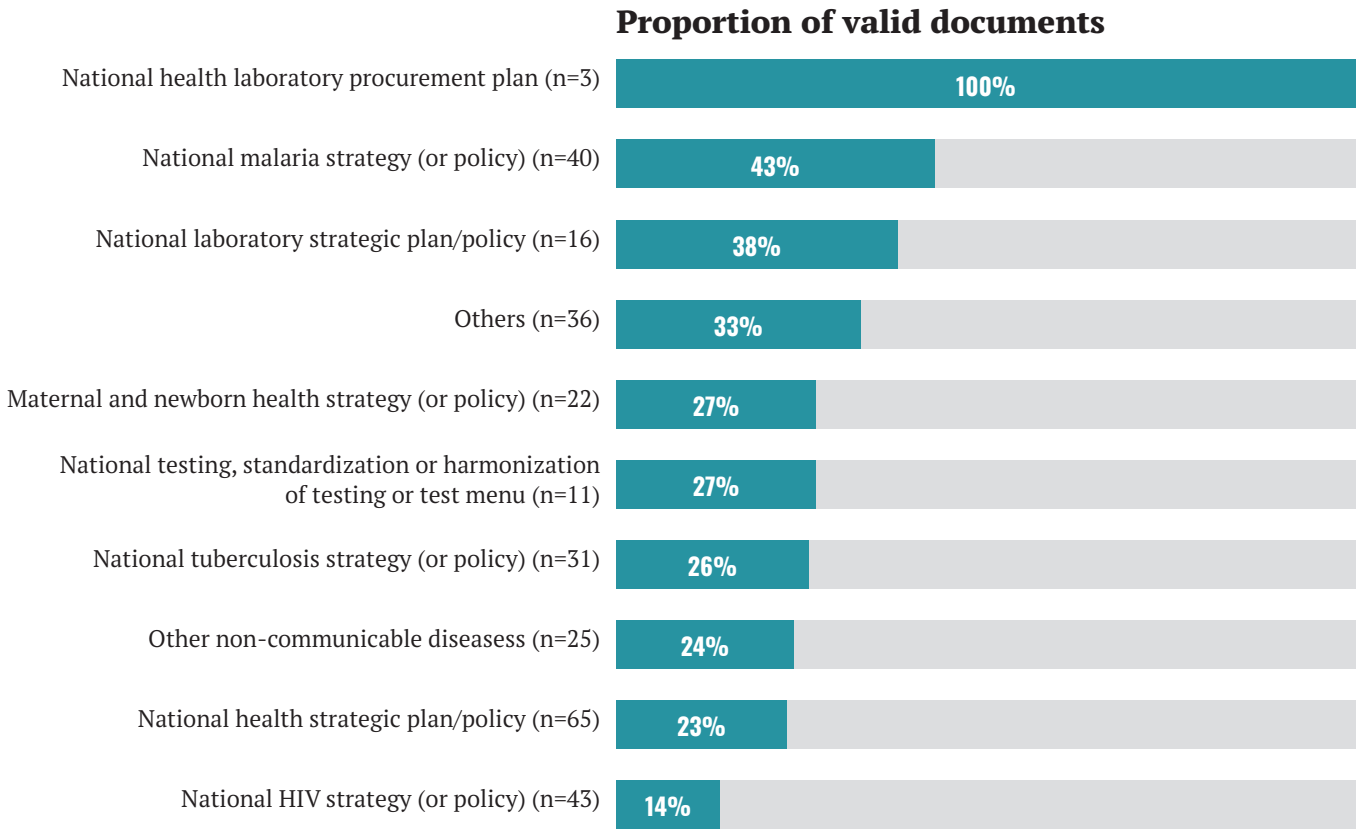
Category	Number	% (N=292)
National health policy and/or strategic plan	65	22%
National laboratory policy and/or strategic plan	16	5%
National health laboratory procurement plan	3	1%
National tests menus/norms/standardisation of diagnostic/NEDL	11	4%
National HIV strategy (or plan)	43	15%
National tuberculosis strategy (or plan)	31	11%
National malaria strategy (or plan)	40	14%
Maternal, new born and child health strategy (or plan)	22	8%
Non-communicable diseases strategy (or plan)	25	9%
Others	36	12%

Validity of reviewed documents by category

From the distribution, the documents were produced on average between 2012 and 2015 and valid until 2018. National health policies / strategic plans, national HIV policies / strategic plans and national malaria policies / strategic plans had a more widespread distribution for when the documents were produced. National laboratory policy / strategic plan documents and national testing and standardisation or harmonisation strategies had a relatively compact distribution of validity end, though most are currently valid and a majority end after 2022.

Using the WHO EDL development year (i.e., first edition of 2018) as the benchmark for validity, laboratory procurement plans, laboratory policies or plans, vertical disease programmes for malaria and tuberculosis documents and national health policies or plans were more recent than harmonisation documents. More recent documents could have used the WHO EDL guidelines. Figure 3 below illustrates the proportion of documents that were deemed valid given they were produced after 2018.

Figure 3: Percentage of documents by category that were produced in or after 2018



2.3 Methodology of the qualitative study arm

2.3.1 Qualitative study questions

The main question of the qualitative study, addressing the general objective, was: By what processes did countries arrive at national reference documents for prioritised IVDs by tier of the health/laboratory system and what are the lessons for development of national essential diagnostics lists.

This main study question is divided in the following study sub-questions:

1. Through which documents are countries defining essential IVDs at various tiers of the laboratory system?
2. What are the considerations to assign (or to not assign) essential IVDs to various tiers of the health care/ laboratory system, including the community tier; what role does gender play?
3. Which national committees or working groups exist or are planned to be constituted that were/are responsible for development of documents on guidance for tier-specific prioritisation of IVDs and which stakeholder categories are represented and missing in these committees; how are genders represented?
4. What are the present and foreseen facilitating and hindering factors at different laboratory system tiers in the availability and implementation of priority IVDs?
5. In what ways do/would prioritising IVD in national guidelines (such as NEDL) mitigate some of the bottlenecks to availability of essential IVDs?
6. What is the in-country knowledge of the WHO EDL and guidelines to develop an NEDL and in what ways do countries perceive the WHO EDL and guidelines to be useful in prioritising IVDs in tiers of the health care/ laboratory system and solve problems in availability of IVDs?
7. What are recommendations to MoH and other stakeholders for (guidance in) developing and implementing an NEDL?

2.3.2 Study participants and sampling

Study participants were decision-makers and other stakeholders (potentially) involved in the selection of IVDs for national guidance documents, including an NEDL. Sampling of countries and respondents for the qualitative study was purposeful and was informed by provisional findings from the desk review and in consultations between the ASLM desk review team and the consultants.

Sampling of countries

The qualitative study sampled seven of the 28 countries (out of a total of 44 countries that had at least one document addressing IVDs in tiers of the laboratory system), because these countries could share their experiences about how decisions were made to assign IVDs to tiers. These seven countries were known to have or to have started the process of developing national guidance for essential IVD and included: Burkina Faso, Cameroon, Ethiopia, Kenya, Nigeria, Uganda, and Zimbabwe.

Sampling of respondents

Firstly, the study's principal investigator from ASLM sent a letter to the seven ASLM LabCop[2] country representatives introducing the overall study, the qualitative study and the two consultants. Secondly, the consultants requested these representatives to populate a table with names and background of potential key informants for their country. After receiving the populated table, the consultants had a 30-minutes to 1-hour Zoom meeting with the representative in which s/he could give more information on these individuals' role in the national laboratory system and IVD prioritisation and add persons to the table, in case the consultants considered a potential key informant group was missing. In this Zoom meeting, the consultants and the LabCoP representative made a plan for the sequence of interviews and which persons to include in group interviews.

[2] The Laboratory Systems Strengthening Community of Practice (LabCoP) is led by ASLM, with funding from the Bill & Melinda Gates Foundation. LabCoP is made up of a diverse group of stakeholders and country teams (currently 16) comprised of laboratorians, laboratory managers, clinicians, staff of ministries of health, civil society, and others. (https://aslm.org/what-we-do/labcop/)

2.3.3 Data collection tools

Data collection was conducted through interviews using a semi-structured interview guide tailored to the country and the key informant. Themes in the guide followed the study questions and included: laboratory system; stakeholders in the laboratory system; national committee/working groups on IVDs; national laboratory documents; documents with guidelines on IVDs; stakeholders, processes, and criteria for prioritising IVDs; and intentions and plans to develop and implement an NEDL.

The generic interview guide is provided in Annex 1. The country-specific interview guide was made after scanning the relevant documents in the document-review database for details and in most cases was refined after responses from first interviews for the same country. In the document database, the consultants studied country-specific details among others on: organization of the health care and laboratory system; names of tiers; challenges in the health care and laboratory system; content of and years covered by the documents; guidelines for IVDs at tier level, including community level; bases for IVD selection; and stakeholders involved in development of the document.

The two consultants pretested the draft generic tool with ASLM LabCoP representatives in Uganda, Kenya, and Burkina Faso between 17 February 2022 and 01 March 2022.

2.3.4 Data collection

In total, 28 (group) interviews were conducted, involving 43 participants, 19 women and 24 men (Table 2 and Annex 2). Data collection began 7 June 2022 and ended 25 July 2022. After the introductory interview by Zoom with the country's ASLM LabCoP focal point or other keyperson from the MoH laboratory section, in five countries consecutive interviews were held by one or both consultants using Zoom; the first being a group interview with key persons from the MoH Laboratory Section. After first analysis of this interview, in most countries, additional (group) interviews were held with representatives from technical and implementing partners, MoH laboratory section directors who had not participated in group interviews, and/or regulatory bodies. The consultants visited Uganda and Kenya together with the ASLM NEDL team where they conducted face-to-face interviews. In fact, in these two countries data collection started with a 3–5-hour participatory session with keypersons from the MoH laboratory section and reference laboratories.

Table 2: Number of respondents in interviews, by gender and country

Country	Total respondents	Female	Male	Total (group) interviews
Burkina Faso	3	1	2	3
Cameroon	7	4	3	4
Ethiopia	4	1	3	3
Kenya	10	4	6	6
Nigeria	9	3	6	6
Uganda	7	3	4	4
Zimbabwe	3	3	0	2
TOTAL	43	19	24	28

2.3.5 Data handling, analysis, and reporting

Two research assistants transcribed the interviews' audio-recordings in Microsoft Word documents. Data analysis was conducted in three steps. The consultants: i) entered the answers of multiple interviews and document analysis into one country-specific question guide; ii) summarized the country findings in a topic-matrix by country – analysing differences and similarities from different data sources; iii) compared similarities and differences in findings by theme across countries and explained differences from country contexts. We present the country details by theme in text boxes. In the report, we refer to documents analysed in the qualitative study by abbreviation of the country and document number in Annex 3 (for example BF DOC2).

2.4 Ethical considerations

Solutions IRB gave ethical clearance for the qualitative and quantitative study, Protocol #2022/03/6.

Since we considered the topic of this study not sensitive and in the interest of the respondents, we did not expect that participating in this study would cause any harm. Potential respondents have received information on the study and the question guide in advance by email and were requested to participate and indicate their availability. Before the interview, they were asked their consent for audio-recording. Only two respondents did not agree to audio-recording and two respondents asked to pause recording when they mentioned potentially sensitive issues (related to critiquing others). One potential key informant was approached several times, but for reasons unknown to the consultants, did not appear in the (two) scheduled Zoom meetings.

All interview participants received the final draft qualitative report and were able to check the information for their country; participants from five countries sent their comments which were incorporated in the final qualitative report. We did not receive input from the Cameroon and Uganda respondents.

The consultants informed the research assistants that information from the interviews was confidential and not to be shared with others. They research assistants removed the files from their laptops after they submitted the transcriptions approved by the consultants.

2.5 Study limitations

Development of guidance documents on IVDs is ongoing, and we might have missed some more recent documents; we stopped searching in November 2021. We have not been able to study documents in Arabic-speaking countries, e.g., Algeria, Libya, Morocco, West Sahara, nor were we able to review two documents from Ethiopia that were available only in the Amharic language.

One limitation was the phased nature of the document and qualitative study. The quantitative categories were already identified before the qualitative data were collected; therefore, some qualitative findings could not be compared with quantitative findings. For example, we could not confirm whether important stakeholders, such as regulatory bodies and procurement offices, mentioned in the qualitative study had been involved in development of documents. Additionally, the 'silo' category of MoH was too broad; it would be interesting to determine which MoH departments were involved and played a leading role.

Documentation of IVDs development is ongoing, and some more recent documents may have been missed; searching stopped in November 2021. Additionally, since our method was mostly limited to online search of the internet, we might have missed hard copies of available documents not posted online. Documents posted in Arabic from countries like Algeria, Libya, Morocco, and West Sahara have not been studied, nor have we been able to review two documents from Ethiopia that were written in Amharic.

3 NATIONAL LABORATORY SYSTEMS

3.1 Laboratory Services in the Ministry of Health

The laboratory services section of the MoH obviously plays a pivotal role in the development of documents related to IVDs. Its position within the MoH and allocated budget indicate the section's power to develop and implement documents. The qualitative study found that, apart from Uganda, the laboratory services are sub-divisions of other MoH departments, or a laboratory wing of an autonomous institute (e.g., the Ethiopian Public Health Institute [EPHI]). In Uganda, the Department of National Health Laboratory and Diagnostic Services (NHLDS) is one of the departments of the MoH as the technical arm on laboratory aspects. In this report, we use the term 'Laboratory Services' when we refer to the section of the MoH and the laboratory wing of the autonomous institute in Ethiopia that deals with national laboratory services. Within each country, the Laboratory Services section has various names, including national laboratory services, division, directorate, department **(Table 3)**.

Table 3: Names and position of laboratory services and units in Ministries of Health, by country

Country	Name of Laboratory Services in Ministry of Health
Burkina Faso	*Direction des Laboratoires de Biologie Médicale* is one of the 4 technical directorates of the *Direction Générale de l'Accès aux Produits de Santé*
Cameroon	*National Directorate of Laboratories* is within the General Inspectorate of Pharmaceutical Services and Laboratories
Ethiopia	*Laboratory Services* is one of the three focus areas of the EPHI – an autonomous public health institute
Kenya	*Department of Laboratory Services* is under the Directorate of Public Health
Nigeria	*Medical Laboratory Service Division* (MLSD) is under the Department of Hospital Services
Uganda	*Department of National Health Laboratory and Diagnostic Services* (NHLDS)
Zimbabwe	*Directorate of Laboratory Services* (DLS) is in the Department of Curative Services.

3.2 Defining tiers in the laboratory system

The qualitative study explored how tiers of the laboratory system link to the health care pyramid, because an NEDL is intended to address laboratory-tier-specific testing. Across the seven countries, obviously, more sophisticated laboratories are at higher level health care facilities. At the community level and in health facilities without a proper laboratory, community health workers and (outreach) non-laboratory health staff perform RDTs. In Burkina Faso, Nigeria, Uganda and Zimbabwe, the laboratory tiers coincide with the health facility tiers, whereas in Ethiopia, Cameroon and Kenya, even though the laboratory system is modelled on the health care pyramid, their levels are different **(Text Box 1)**.

Text Box 1:
Laboratory tiers in relation to health care pyramid

- **In Burkina Faso**, the laboratory tiers follow the 4-tiered health care pyramid: i) Health and Social Promotion Centre (CSPS); ii) Medical Centre/Medical Centre with Surgical Branch (CM/CMA); iii) Regional Hospital Centre (CHR); iv) National or University Hospital Centre (CHN/CHU). There are about 155 public laboratories and about 50 private laboratories in Burkina Faso. At the community level, RDTs for HIV, malaria, COVID-19, albumin/protein, and pregnancy are performed.

- **In Nigeria**, at the primary level, the ward health care system consists of health posts, primary health clinics and primary health care centres. The latter are supposed to have a basic laboratory. At the secondary level, general hospitals are required to have a laboratory with three sections: clinical chemistry and microbiology; parasitology; haematology and blood bank. In addition, some general hospitals have a histopathology laboratory. At the tertiary level are medical colleges, federal medical centres, specialist hospitals and teaching hospitals with specialized services, including laboratories. At the community level and in primary level facilities without laboratories, community health workers and non-laboratory staff perform RDTs for malaria.

- **In Uganda** laboratories are present in health care facilities at all five levels of the health care pyramid: Health Centre III, Health Centre IV, general hospitals, regional referral hospitals, National Specialist Hospitals. Hubs covering 30 to 40 laboratories within a 40 km radius have been created to strengthen laboratory capacity.

- **In Zimbabwe**, laboratories are organized along the health services referral chain. However, some rural and urban clinics do not have on-site laboratories. At the community level and at health facilities without a laboratory, testing for HIV, malaria, and COVID-19 is performed by community health workers, nurses, and primary counsellors.

- **In Ethiopia**, laboratories are found at three tiers of the health care pyramid: i) Health centres of the Primary Health Care Unit (PHCU); ii) general hospitals; and iii) specialized hospitals. The laboratories are divided in four tiers: i) national reference laboratories at EPHI; ii) regional reference laboratories (1 and 2 include the uniformed forces laboratories and central blood bank laboratories); iii) hospital laboratories, including regional, zonal and district hospital laboratories; iv) health centre laboratories including health post laboratories (which are often minimal). At the community level, health extension workers and staff of health posts without laboratories perform malaria RDTs and pregnancy tests. These community workers are trained, and their tests' quality is monitored by laboratory professionals at health centres with a laboratory.

- **In Cameroon** there are four tiers in the laboratory system, whereas the health care pyramid has three levels (central, intermediate, and peripheral). The distribution of laboratories in Cameroon follows the hospital organization composed of general and central hospitals (level IV), regional hospitals (level III), district hospitals (level II), district medical centres and integrated health centres (level I). There are about 80% public laboratories, 20% private for-profit (faith-based or secular) laboratories and about 5% private non-profit (faith-based) laboratories. At the community level, community health workers carry out RDTs for HIV, malaria, and COVID-19 and pregnancy tests (free of charge) for persons living with HIV.

- **In Kenya**, the health care pyramid has six levels including i) community (household units); ii) dispensaries; iii) health centres; iv) sub-county hospitals; v) county hospitals; vi) the Moi Teaching and Referral Hospital (MTRH), Kenyatta University (KU), Kenyatta National Hospital (KNH) and referral hospitals. The laboratory system has only 4 tiers: i) community (household units); ii) dispensaries and health centres; iii) county hospitals and sub-county hospitals; iv) MTRH, KU, KNH and referral laboratories. At the community level, mobile teams of community health workers visit households to perform RDTs for malaria, blood sugar, and HIV.

3.3 Challenges in the laboratory system

NEDLs intend to alleviate some of the problems in availability of and access to diagnostics and general challenges in the national laboratory system. The respondents in the qualitative study note that laboratories remain weak links in the health care system. Challenges relate to poor infrastructure; insufficient and unqualified human resources; problems related to equipment, consumables and tests; inadequate funding; and inefficient organisation and coordination **(Text Box 2; refer to the Abbreviations list for full country names)**.

Text Box2: Challenges in the national laboratory systems

Poor infrastructure

Infrastructure problems mentioned were insufficient and cramped laboratory space (ETH, UG) and lack of standardisation of laboratory infrastructure (NIG). Generally, the laboratories supported by disease programmes (HIV, tuberculosis, and malaria) and laboratory strengthening programmes are of higher quality than unsupported laboratories. In Nigeria, for example, PEPFAR-supported laboratories are fully equipped with machines, functional, air-conditioned, and renovated, unlike the other laboratories that are dilapidated and where many tests are done manually.

Insufficient and unqualified human resources

Human resources are a major challenge across countries, because they are either insufficient or poorly distributed between the city and the periphery (ETH, BF), or poorly qualified (ZIM, KEN), or because qualified human resources are available but not absorbed into the public system (NIG). In Cameroon, a specific problem mentioned concerns the non-harmonisation of profiles of the different professionals working in the laboratories.

Problems related to equipment

Challenges related to equipment maintenance are reported across countries. In Ethiopia, maintenance is not centralized but divided over various sections which results in a limited rapid response system. Responsible for maintenance are the Pharmaceutical and Medical Equipment Directorate at the federal MoH, equipment maintenance teams under EPHI, and teams at the regional health offices. Other reported equipment problems are the wide variety of equipment in peripheral laboratories (ETH); difficulty in controlling the cold chain (CAM) resulting in the inability to perform tests requiring water or electricity. In Zimbabwe, the lack of awareness among laboratory stakeholders about harmonisation and standardisation guidelines is described as the main cause of poor equipment maintenance and utilization.

Problems related to consumables and tests

Stockout of consumables and tests are described as challenges in all countries, despite prior quantification of needs (BF). Respondents in some countries noted that scarcity of tests are mainly concerns for common diseases and conditions, while there are no test and consumable shortages for diseases of vertical programmes. The excessive cost of tests (KEN, NIG) and the non-adoption and non-dissemination of the essential laboratory commodity list (KEN, DOC1) are cited as obstacles to be managed. The supply of reagents and tests into countries remains a major challenge. Thus, the problem of quality control of reagents entering Cameroon, irregularity of supply and stock-outs, regulation of the arrival of tests in Uganda and difficulties in procurement were identified as obstacles. In Ethiopia, procurement and supply of laboratory consumables is irregular and stocks are surplus or insufficient. In Zimbabwe, there is no national procurement coordination (hospitals procure for themselves); however, the recently established DLS logistics unit is expected to improve national procurement, supply, and monitoring.

Inadequate funding

Inadequate funding for laboratories and dependence on donors who only fund laboratory services specific to their interventions were mentioned as challenges across countries. In Burkina Faso, despite the development of a laboratory strategic plan, lack of funding has delayed its implementation. Inadequate funding has also resulted in a lack of autonomy for the laboratories (CAM, BF, KEN)

Inefficient organisation and coordination

In Ethiopia, the lack of an enforceable technical regulatory mandate from EPHI over regional or peripheral laboratories and the lack of coordination between EPHI and vertical disease programmes is seen as a source of inefficiency. Lack of laboratory autonomy is reflected in the weak laboratory information and data management system (ETH). In Zimbabwe, health facility laboratories report to the Department of Clinical Services and to the Provincial Medical Director. This has led to reporting complications, which have significantly compromised the ability of DLS to manage and coordinate services in the country.

3.4 Stakeholders in the laboratory domain

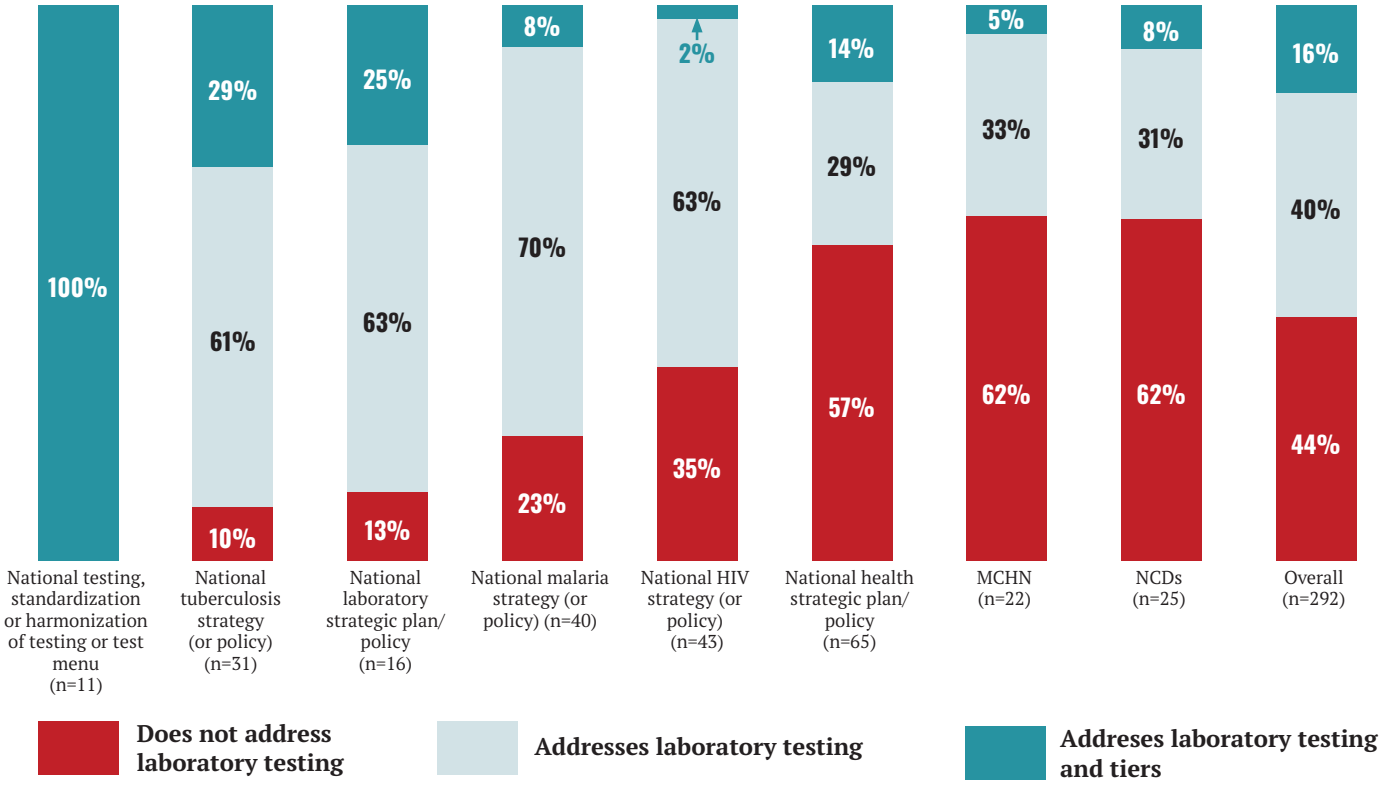
In all seven countries of the qualitative study, the same international stakeholders are involved for technical, financial and implementation support of national laboratory services. The documents and respondents cited WHO, United States Agency for International Development (USAID), United States CDC, and ASLM as technical support partners. For implementation CHAI, ASLM, Africa CDC, United States President's Emergency Plan for AIDS Relief (PEPFAR), USAID, and United States CDC are identified as the main partners. The usual stakeholders for funding are The Global Fund to Fight AIDS, Tuberculosis and Malaria, World Bank (WB), FIND, CHAI, USAID, United Kingdom Aid Direct, and United Nations Children's Emergency Funds (UNICEF). In addition to these cross-cutting international partners, other mentioned stakeholders are country-specific: *le Réseau d'Afrique de l'Ouest des Laboratoires* (RESAOLAB), SYSMEX Burkina, Davycas, *Institut de Recherche en Santé, de Surveillance Épidémiologique et de Formations-Dakar* in Burkina Faso; Africasud, Métabiota, Infectious Disease Detection and Surveillance, Georgetown University in Cameroon; National Aids & STIs Control Program, tuberculosis program, National Cancer Control Strategy, Malaria Program, Disease Surveillance and Response, Influenza Program, Kenya Medical Supplies Authority, Mission for Essential Drugs and Supplies, Kenya Medical Laboratory Technicians and Technologists Board, Pharmacy and Poisons Board in Kenya; Management Services for Health (MSH), Federal Ministry of Health (FMOH), states, Primary Health Care in Nigeria; Department of Defence, Walter Reed Project, Training and Advisory Services, MoH departments, civil society, national associations of laboratory workers, medical bureaus in Uganda; and the Medical Laboratory and Clinical Scientists Council of Zimbabwe in Zimbabwe.

4 DOCUMENTS DEFINING TIER-SPECIFIC DIAGNOSTIC TEST MENUS

4.1 Document review for tier-specific test menus

Out of the 292 documents reviewed, 196 (58%) addressed laboratory testing; 46 of these (16% of all) addressed laboratory testing as per a laboratory network tier. All 11 national test menus/NEDL addressed testing by tier of the laboratory network. Tuberculosis, national laboratory policies/plans, malaria and HIV programme-specific documents were most likely to address laboratory testing but did not necessarily address testing by tier (90%, 88%, 78% and 65% respectively) **(Figure 4)**.

Figure 4: Proportion (%) of document categories addressing laboratory testing and per laboratory network tier



The 292 documents reviewed were from 44 countries. Twenty-seven countries had at least one document that addressed tier-specific testing within the laboratory network. Among those 27 countries, one country had developed their NEDL, while 10 had a national document aimed at standardising/harmonising testing across the laboratory network, which is similar to an NEDL. The other 16 had one or more documents that defined testing by tier, often for vertical disease programmes.

Among the 17 remaining countries, 14 had one or more documents that defined testing, but not by tier, whereas three countries had documents that did not address testing. Table 4 shows countries' progress in developing guidelines for essential IVDs by tier, whereas Annex 4 lists the relevant documents (whereby it should be noted that the documents closest to an NEDL are listed and not all country's documents in the review).

Table 4: Countries' progress in defining test by tier of the diagnostic network

Has NEDL	Has a national document that standardises/ harmonises testing by laboratory tier	Has document(s) that defines testing per the tiered network	Has document(s) that defines testing not per the tiered network	Countries with only documents not defining testing
Nigeria	Botswana	Angola	Cabo Verde	Congo
	Burkina Faso	Benin	Chad	Comoros
	Cameroon	Burundi	Djibouti	Niger
	Ethiopia	CAR	Equatorial Guinea	
	Gabon	Côte d'Ivoire	Guinea	
	Kenya	DRC	Guinea Bissau	
	Malawi	eSwatini	Madagascar	
	Uganda	Ghana	Mozambique	
	Tanzania	Lesotho	Rwanda	
	Zimbabwe	Liberia	São Tomé and Príncipe	
		Mauritania	Seychelles	
		Mauritius	Sierra Leone	
		Namibia	South Sudan	
		Somalia	Sudan	
		South Africa		
		Zambia		

4.2 Zooming in on harmonisation documents

Analysis of the test harmonisation and standardisation documents of the seven qualitative study countries showed that these documents were more elaborate than a standard NEDL with priority tests by tier, because many also included equipment, consumables, and sometimes laboratory personnel. Except for the Nigerian NEDL, they did not include the community tier as part of the laboratory system. In five countries, the guidelines were rather old, with publication dates ranging from 2009 to 2015, and they did not indicate the period that the document covers (see Annex 3). Only two countries had more recent documents: the Nigerian NEDL (2021) and the Uganda third edition of the standard test menu (2017-2020) **(See Text Box 3)**.

Text Box 3:
Details of harmonisation documents

- **In Burkina Faso**, the *'Normes en Matière de Laboratoires d'Analyses de Biologie Médicale: Infrastructures, Equipements Et Analyses Essentielles Par Niveau des Formations Sanitaire Publiques (2009)'* [Standards for Infrastructure, Equipment and Essential Medical Biology Tests for Public Health Facilities] defines the equipment, consumables and construction standards of the laboratories by tier but does not specify the required personnel at each level (BF DOC1). Although the overall document is not revised, respondents noted that regular revision sheets reflect changes in consumables and tests reflecting the rapidly changing epidemiological situation. Thus, in Burkina Faso, updated infrastructure and equipment standards have been defined. In addition, respondents pointed out that the list of essential diagnoses has now been defined by level of care and personnel.

- **The 'Kenya Essential Medical Laboratory Commodity List'** published by the MoH in February 2014 gives guidelines for IVDs by tier (KEN DOC1). In addition, the document gives information on equipment, consumables but not by laboratory level. It does not define the appropriate personnel. Respondents noted that this document has not been disseminated to implementers and was not anchored well in MoH national or county-level leadership organizations and has not been revised. The document was made before devolution when plans and policies were valid from national to lower levels; nowadays, county governments are the second level of government, with their own rules and roles (KEN INT).

- **In Zimbabwe,** the document 'Laboratory Harmonisation and Standardisation in Zimbabwe, 2015' is akin to an NEDL, because it guides the selection, procurement and deployment of equipment, consumables and personnel by laboratory level (ZIM DOC1). It was developed by Laboratory Services with support from USAID and is to be updated and revised every two years.

- **In Uganda,** the 'Standard Test Menu Techniques and List of Supplies for Health Laboratory Services in Uganda, (3rd edition, 2017-2020)' defines testing, techniques and supply requirements by laboratory tier but excludes the community level (UG DOC1). There is no information on the personnel required at each level. The document defines IVDs based on the VEN criterion to distinguish between Vital, Essential, and Necessary tests.

- **Ethiopia** had the document 'Master Plan for The Public Health Laboratory System In Ethiopia' (Second Edition, 2009 – 2013). Appendix 1 of this document defines the minimum laboratory testing services across laboratory tiers. It also presents tables for the analyses by tier with examples of equipment and supplies for each test. In Appendix 2, the document defines the minimum requirements for laboratory equipment by level with the tests the equipment performs and the presentation of three models (ETH DOC4).

- **In Cameroon,** the document entitled 'Organization of Laboratories According to the Health Pyramid in Cameroon, 2011' defines the minimum service package including tests, equipment, and staff by laboratory tier (CAM DOC2). According to the respondents, this document has not been validated or adopted, but still it is used when granting an administrative license or an authorization to open and operate a laboratory. The respondent from Cameroon CDC regretted that this solid document is not being implemented.

4.2.1 Case: The NEDL of Nigeria

The Nigeria National Essential Diagnostic List (2021 – NIG DOC1) consist of two parts: i) the lists with IVDs and ii) the findings from the laboratory landscape study that informed the list of IVDs. The NEDL gives guidelines on essential IVDs for two tiers: i) Community and health care facilities without laboratory; ii) Health care facilities with a laboratory (from primary to tertiary level). Nigeria has used the WHO EDL 2 (2019) format of two levels (with and without laboratories on-site) and adapted the WHO survey tool to map the national laboratory landscape.

The Nigerian NEDL enlists 145 IVDs for clinical settings covering primary, secondary, tertiary, and national reference laboratories, including 65 general IVDs for detection and aid to the diagnosis of a range of disease conditions, 73 disease-specific IVDs, and seven IVDs for screening of blood donations. At the tier of community and health care facilities without laboratories the NEDL includes 12 general IVDs and 15 disease-specific IVDs. Diseases include cholera, hepatitis B and C, HIV, malaria, syphilis, tuberculosis, and peptic ulcer. For IVDs related to specific diseases (not the general IVDs), the NEDL tables specify in columns by disease: i) type of diagnostic test(s), ii) test purpose, iii) assay, iv) specimen type, v) information on WHO/national regulatory prequalified, and vi) supporting guidance and guideline documents. The NEDL does not specify brands of IVDs and does not categorise by laboratory tier. The consultants involved in the Nigerian NEDL explained that laboratories and medical professionals, managers and policy makers at different tiers are to select IVDs from the NEDL that they deem necessary to tackle the disease burden in their area and in the selection consider the local context related to what tests and human resources are available in the facility, the infrastructure, power and water supply.

The Nigerian NEDL is flagged off as a stand-alone document and is also a chapter in the national laboratory policy 2021-2025 (NIG DOC4). It will be a budgeted theme in the National Laboratory Strategic Plan 2022-2026 (at the time this study was conducted, the draft awaited finalisation and validation).

4.3 Documents on vertical disease programmes

Desk review findings showed that more than half of the countries had documents on vertical disease programmes (HIV, malaria and tuberculosis), and just less than half had documents on MNCH. Most countries had HIV, malaria and tuberculosis documents that addressed IVDs, but not many had documents that addressed IVDs by laboratory or health facility tier. However, more than half of the countries had malaria documents that addressed IVDs for the community tier **(Table 5)**.

Table 5: Countries with documents on vertical disease programmes and MNCH addressing IVD by tier

Disease / Programme	No. of countries with document (% of all countries, N=44)	No. of countries with document addressing IVDs (% of countries with document)	No. of countries with document addressing IVDs by tier (%)	No. of countries with documents addressing IVDs at community tier (%)
HIV/AIDS	33 (75%)	25 (76%)	1 (3%)	9 (27%)
Malaria	32 (73%)	26 (81%)	3 (9%)	17 (53%)
Tuberculosis	26 (59%)	25 (96%)	9 (35%)	5 (19%)
MNCH	18 (41%)	6 (33%)	1 (6%)	1 (6%)

A similar pattern was observed for programme documents, rather than countries: malaria programme documents addressed relatively more of the community tier **(Table 6)**.

Table 6: Documents on vertical disease programmes and MNCH addressing IVD by tier, including community tier

Disease / Programme	No. of Documents	No. of documents addressing IVDs (% of total documents)	No. of documents addressing IVDs by laboratory tier (% of documents with IVDs)	No. of documents addressing IVDs at community tier (% of documents with IVDs)
HIV/AIDS	43	28 (67%)	1 (4%)	9 (32%)
Malaria	40	31 (79%)	3 (10%)	17 (55%)
Tuberculosis	31	28 (90%)	9 (32%)	5 (18%)
MNCH	22	7 (33%)	1 (14%)	1 (14%)

A more detailed analysis of the vertical disease programme guideline documents for malaria, HIV and tuberculosis (tuberculosis/leprosy in Ethiopia) in four countries of the qualitative study showed that they are more recent than most of the harmonisation documents. They also included IVDs at the community level **(Text Box 4)**.

Text Box 4:
Details on vertical disease programme guidelines in four countries

- **In Ethiopia,** the 'National Strategic Plan Tuberculosis and Leprosy Control – 2013-2022' document gives guidelines on the IVDs by tier, including the community level. Other information includes regarding budget, identification of problems in the laboratories, stages, and stakeholders in implementation. The 'HIV/AIDS Strategic Plan 2015-2020' also reports tests by tier. The 'National Strategic Plan for Malaria Prevention, Control and Elimination in Ethiopia 2011-15' defines tests by tier, including community level, and gives a budget and stakeholders for implementation. Health professionals have been trained on the use and interpretation of results of multi-species RDTs. Ethiopia recently introduced laboratory-based quality control testing for malaria RDTs that will ensure the procurement and use of quality assured RDTs (ETH DOC1).
- **In the Nigerian 'Malaria Strategic Plan 2014-2020',** goal 2 is laboratory-based and states that all persons seeking care and suspected of having malaria should be tested by RDT or microscopy by 2020. It also states that there must be universal access to parasitological confirmation of malaria at all levels, which is possible with RDTs as from the PHC level (NIG DOC2).
- **In Burkina Faso,** the 'Malaria Operational Plan 2019' promotes parasitological diagnosis of malaria at public and private health facilities, community levels, and through quality control/quality assurance of laboratories (BF DOC3).
- **In Cameroon,** the 'National Malaria Control Strategic Plan' projects that by 2023, at least 80% of suspected malaria cases seen in health facilities and in the community are confirmed by tests. A quality assurance manual has been developed to define the type of diagnostic test to be performed (CAM DOC 3).

4.4 Tier-defined testing alignment with WHO recommendations

The WHO EDL recommends IVDs for two tiers: i) community settings/health facilities without laboratories and ii) clinical laboratories/facilities with conventional laboratory infrastructure. The WHO brochure on EDL and NEDL development (WHO, 2021) states that countries can decide which IVDs to select from the WHO EDL and which to drop or add and at which laboratory tier to use them, depending on their epidemiology, human resources and infrastructure.

This study reviewed the 11 country national documents aimed at standardising/harmonising testing across the laboratory network for their alignment to WHO EDL 2 guidance for HIV infection, tuberculosis, malaria, and MNCH programmes for the two tiers. (Annex 5 shows the recommended tests by tier.)

Apart from Nigeria's NEDL, all other national documents standardising tests by tier across diseases and conditions were silent on community-level testing. The Nigerian NEDL lists the same tests for HIV infection, tuberculosis, malaria, and MNCH as the WHO EDL 2, and has added RDTs for syphilis, cholera, hepatitis B and C and peptic ulcer. It should be noted that guidelines for vertical disease programmes more often specify tests for the community level (Tables 4 and 5). These vertical disease programme guidelines could then be used when countries want to develop their NEDL, including all priority diseases and conditions, as the Ethiopian team developing the NEDL is already doing.

For the tier of clinical laboratories/facilities with conventional laboratory infrastructure, the reviewed documents contained most of the tests recommended by WHO. Table 7 shows that Tanzania's harmonisation document contained most of the WHO's recommended tests for HIV, tuberculosis, malaria and MNCH programmes, followed by Nigeria's NEDL. Gabon's, Burkina Faso's and Cameroon's documents that aimed at standardising/harmonising testing across the laboratory network were the least compliant.

Table 7: Harmonisation documents' compliance to the WHO EDL 2 tests recommendations for laboratories

Programs/ Diseases	Tests	BOT 2019	BF 2009	CAM 2011	ETH 2013	GAB 2012	KEN 2014	MAL 2009	NIG 2021	TAN 2018	UG 2017	ZIM 2015
HIV	HIV 1/2 antibody (RDT/Immunoassay)											
	Combined HIV antibody/p24 antigen (RDT/ELISA)											
	Immunoglobulin plasma levels (IgG, IgA, IgM)- (RID/ELISA)											
	Qualitative HIV virological nucleic acid test (EID NAAT)											
	Quantitative HIV virological nucleic acid test-(VL NAAT)											
	Lymphocyte subtype enumeration: CD4, CD8, CD20 and CD15/26 cells (Flow Cytometry)											
	Cryptococcal antigen-CrAg (RDT/ELISA)											
TOTAL HIV COMPLY (N=7)		6	5	4	6	7	7	5	6	7	5	5
TB	TB Culture/DST											
	TB (Microscopy)											
	TB Nucleic Acid Test (Genexpert)											
	Count of TB Nucleic Acid Test (TB LAMP)											
	M. tuberculosis DNA mutations associated with resistance (Molecular Line Probe Assay -LPA)											
	Lipoarabinomannan (LAM) antigen (RDT)											
TOTAL TB COMPLY (N=6)		2	0	0	2	0	3	2	5	4	3	3
Malaria	RDT											
	Light Microscopy											
	Glucose-6- phosphate dehydrogenase (G6PD) activity –(Semiquantitative fluorescent spot test)											
TOTAL MALARIA COMPLY (N=3)		2	1	0	2	2	3	2	3	3	3	2
MNCH	Syphilis (RDT/ELISA)											
	Antibodies to T. pallidum and to HIV-1/2 (RDT)											
	Non-treponemal rapid plasma reagin (RPR) test (Particle/ charcoal agglutination assay)											
	Non-treponemal venereal disease research laboratory (VDRL) test (Flocculation test)											
	T. pallidum hemagglutination (TPHA) test											
TOTAL MNCH COMPLY (N=5)		3	4	0	4	1	1	2	3	4	2	2
GRAND TOTAL TESTS COMPLY (N=21)		13	10	4	14	10	14	11	17	18	13	12

COLOUR CODE KEY

The test as recommended by WHO EDL is among the listed tests in the document

The test as recommended by WHO EDL is not among the listed tests in the document

5 STAKEHOLDER INVOLVEMENT IN DOCUMENT DEVELOPMENT

Information on stakeholders in document development comes from the desk review which screened the documents for categories of stakeholders involved and tested for associations between the involvement of stakeholder categories and the extent to which the document (by category) addresses laboratory testing. The qualitative study explored the stakeholder involvement in detail for the seven countries.

5.1 Desk review findings on stakeholder involvement

A total of 291 of the 292 documents (one document that was a scan copy and could not be translated by Google Translate was dropped) were reviewed to determine the categories of stakeholders involved in their development **(see Text Box 5)**

Text Box 5:
Details on vertical disease programme guidelines in four countries

- Government: Ministries of Health
- Public sector laboratory services (managers, directors, in-charges of public sector laboratories)
- Private non-profit sector laboratory services (e.g., NGOs, faith-based)
- Private for-profit sector laboratory services
- Professional health associations for microbiologists / medical doctors / laboratory staff
- Research groups
- Academic institutions
- Implementing partners
- Funding agencies
- Others

As expected, the MoHs participated in the development of all 291 documents. Second in involvement were the funding agencies, third were the implementing partners and fourth were professionals. Least involved were research groups **(Table 8)**.

Table 8: Stakeholders involved in development of documents (multiple responses)

Stakeholder	Number of documents that mention the stakeholders' involvement	% of documents that mention the stakeholders (N=291)
Ministries of Health	291	100
Funding agencies	164	56
Implementing partners	137	47
Professionals	78	27
Academic institutions	58	18
Public-sector laboratory services	44	15
Private non-profit sector laboratory services	31	11
Others*	31	11
Research groups	18	6

**Other government departments (other than MoH, e.g., Gender, Children, and Social Protection, Ministry of Youth and Sports); traditional medicine representatives; civil society; public; faith-based organizations; political leaders.*

Associations between the involvement of the above-listed stakeholders in development of national guidance documents and the extent to which the documents addressed laboratory testing were evaluated. The documents were categorized into three groups: 1) those that did not address testing, 2) those that addressed testing but not at tier level and 3) those that addressed testing in a tiered network.

There were significant associations between involvement of certain groups in development of documents and the extent to which the document addressed laboratory testing. Statistically significant associations were observed for the involvement of public sector laboratory services (P-value <0.001), private non-profit sector laboratory services (P-value <0.001), funding agencies (P-value 0.0084), implementing partners (P-value 0.0013), professional associations (P-value =0.0159) and stakeholder classified under 'others' (P-value =0.0067) **(Table 9)**.

Table 9: Associations between stakeholder involvement document development and extent documents addressed laboratory testing

Stakeholder	Involved	Does not address testing (n=123)	Addresses testing but not at tier level (n=123)	Addresses testing in tiered network (n-46)	Total N=292	Chi-square	P-value
Ministry of Health	Yes	123 (100%)	123 (100%)	46 (100%)	292 (100%)	–	–
	No	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
Research groups	Yes	3 (2%)	11 (9%)	4 (9%)	18 (6%)	3.15	0.0760
	No	120 (98%)	112 (91%)	42 (91%)	274 (94%)		
Academic institutions	Yes	24 (20%)	17 (14%)	12 (26%)	53 (18%)	2.15	0.1429
	No	99 (80%)	106 (86%)	34 (74%)	239 (82%)		
Public sector laboratory services	Yes	4 (3%)	21 (17%)	20 (43%)	45 (15%)	35.54	<0.001
	No	119 (97%)	102 (83%)	26 (57%)	247 (85%)		
Private non-profit sector laboratory services	Yes	0 (0%)	22 (18%)	9 (20%)	31 (11%)	21.93	<0.001
	No	123 (100%)	101 (82%)	37 (80%)	261 (89%)		
Funding Agencies	Yes	81 (66%)	57 (46%)	27 (59%)	165 (57%)	6.95	0.0084
	No	42 (34%)	66 (54%)	19 (41%)	127 (43%)		
Implementing partners	Yes	73 (59%)	45 (37%)	20 (43%)	138 (47%)	10.35	0.0013
	No	50 (41%)	78 (63%)	26 (57%)	154 (53%)		
Professionals	Yes	43 (35%)	23 (19%)	13 (28%)	79 (27%)	5.82	0.0159
	No	80 (65%)	100 (81%)	33 (72%)	213 (73%)		
Other stakeholders	Yes	5 (4%)	20 (16%)	6 (13%)	31 (11%)	7.35	0.0067
	No	118 (96%)	103 (84%)	40 (87%)	261 (89%)		

We reviewed stakeholder involvement in the development of national documents aimed at standardising/ harmonising testing across the country, including NEDLs. Although the involvement of these stakeholders varied from country to country, besides the MoH, public sector laboratory services (managers, directors, in-charges of laboratories), funding agencies and Implementing partners were the main stakeholders that played a leading role **(Table 10)**.

Table 10: Stakeholder involvement in the 11 countries that developed national documents defining diagnostic testing at various level of the tiered laboratory networks for priority diseases

Country	MoH	Public sector laboratory services	Funding Agencies	Imple-menting partners	Research groups	Academic institutions	Private non-prof-it sector laboratory services	Professional Health Association	Others*
Botswana	■	■	■	■	■	■	■	■	■
Burkina Faso	■	■	■	■	■	■	■	■	■
Cameroon	■	■	■	■	■	■	■	■	■
Ethiopia	■	■	■	■	■	■	■	■	■
Gabon	■	■	■	■	■	■	■	■	■
Kenya	■	■	■	■	■	■	■	■	■
Malawi	■	■	■	■	■	■	■	■	■
Nigeria	■	■	■	■	■	■	■	■	■
Tanzania	■	■	■	■	■	■	■	■	■
Uganda	■	■	■	■	■	■	■	■	■
Zimbabwe	■	■	■	■	■	■	■	■	■

COLOUR CODE KEY

■ The stakeholder is named to have been involved in document development process

■ The stakeholder is not named to have been involved in document development process

5.2 Details on stakeholders in document development

Laboratory technical working groups with a wide range of national and international stakeholder members exist in Burkina Faso, Uganda, and Nigeria. These working groups have been or will be involved in developing documents with IVD guidelines. Nigeria is the only country with an established National Laboratory Technical Working group (NLTWG), inaugurated by the Minister of Health on 27 January 2017 **(Text Box 6)**. In the four other countries, no formalised technical committees on laboratories exist. However, in Ethiopia, Kenya and Zimbabwe, ad-hoc teams or working groups consisting of staff from the laboratory services, some with technical assistance from partners, develop(ed) laboratory harmonisation guidelines, policies and other documents **(Text Box 7)**.

Text Box 6: Laboratory technical working groups

- **The Nigerian National Laboratory Technical Working group (NLTWG)** has many sub-committees, including one on IVDs. The NLTWG is an advisory body, meeting every three months, whose mission is to *'provide technical guidance for coordination of medical laboratory systems, services and oversight function on the implementation of laboratory policies by the tiers of government and other stakeholders in Nigeria.'* (NIG DOC4). This federal technical working group encourages states to establish their own laboratory technical working groups, and it already supported six states in developing their own. The 53 NLTWG committee members represent MoH departments, associations and organisations, including amongst others the National Blood Transfusion Service, National Agency for the Control of AIDS, national tuberculosis program, Medical Laboratory Science Council of Nigeria, Medical and Dental Council of Nigeria, Nigeria Institute of Medical Research, professional associations of medical scientists and pathologists, Nigerian Centre for Disease Control, WHO, USAID and all United States Government partners. The percentage of women in the committee varies, because membership is at the department and organisation level; membership is not based on personal qualifications. The MoH decides on the member departments, organisations, and associations and these groups select and send their representatives. One respondent felt that some implementing partners of (smaller) donor agencies that are not passing through the FMOH Laboratory Services should also be members, so to align them with official national laboratory policies and guidelines.

- **In Burkina Faso** two complementary technical committees exist. The first is a committee of experts on standards, techniques, methods, protocols and algorithms for biological diagnosis. Members include around 30 specialists from different sections of laboratory medicine and management, public health and infectious disease, including four medical biologists from private laboratories. The second is a committee of experts on infrastructure, biosafety, equipment, personnel, reagents and laboratory consumables consisting around 20 members from different departments of MoH, parastatals and external experts (BF DOC 1).

- **Uganda** has a 'laboratory supply chain technical committee', which includes coverage of IVDs, that meets every month. Furthermore, there is an 'MoH quantification procurement unit', which is not specific to laboratories but for all MoH departments. Members of these committees are from the top management of the MoH, the laboratory team, the clinicians, and the suppliers (to demonstrate performance of equipment). Respondents from the laboratory department noted that it is key to involve clinicians, because they request the tests.

Text Box 7:
Stakeholders for development of IVD guidelines in countries without official technical committees

- **In Ethiopia,** the director of the National Laboratories Capacity Building Directorate of EPHI assigned a team of four staff members to a working group to draft an NEDL – two women and two men. For the other documents that were analysed for this study, international stakeholders funded the process of document development and gave technical assistance. Funding often came through The Global Fund. Partners include Carter Centre, WB, USAID, WHO, UNICEF, UNITAID, MACEPA, PSI, and CHAI (ETH DOC 1,2,3,4,5)

- **In Kenya** an ad-hoc committee was once created from the Laboratory Diagnostic Services Unit and the National Public Health Laboratory Services (NPHLS) to develop the Essential Medical Laboratory Commodity List, 2014 (KEN DOC1). Technical and financial assistance came from various partners and institutions, including KEMRI, KNH, UON, MSH, AMREF, KMTC and USAID; the committee was dissolved after the document was finalised.

- **In Zimbabwe,** the (previous) director assigned a small committee from the Laboratory Services to work on revision of the 2015 laboratory standardisation and harmonisation document (ZIM DOC1). For development of the latter document many stakeholders were involved including national disease programmes, departments of the MoH, reference laboratories, Central, Provincial and District Hospital Laboratories, provincial scientists, scientific councils, and the financial, technical, and implementing partners (including WHO, PEPFAR, BRTI, IDBS, CHAI, and USAID (ZIM DOC1).

- **In Cameroon** DPLM as a structure develops guidelines and policies in collaboration with some technical branches of the department including *Laboratoire National de Contrôle de Qualité des Médicaments et d'Expertise, Inspection Générale des Services Pharmaceutiques, Service de l'homologation et de la Pharmacovigilance, Ordre National des Pharmaciens du Cameroun, Syndicat National des Pharmaciens du Cameroun*. Respondents in Cameroon believed that once the national laboratory policy is written, they will be able to set up different laboratory technical working groups. However, lack of funding from the MoH to set up and have such groups functional is a barrier as is getting the working groups to be included as part of the organisational chart: regulatory, litigation, and disease programmes should be part of such technical committees.

6 DEVELOPMENT OF GUIDANCE DOCUMENTS ON IVDS

This chapter presents quantitative and qualitative findings on the criteria that countries used for selecting IVDs for their national lists (section 6.1). Section 6.2 gives qualitative information on the different approaches and steps in the development of documents with IVD guidelines and the discussions between stakeholders.

6.1 Considerations that inform the selection of priority tests

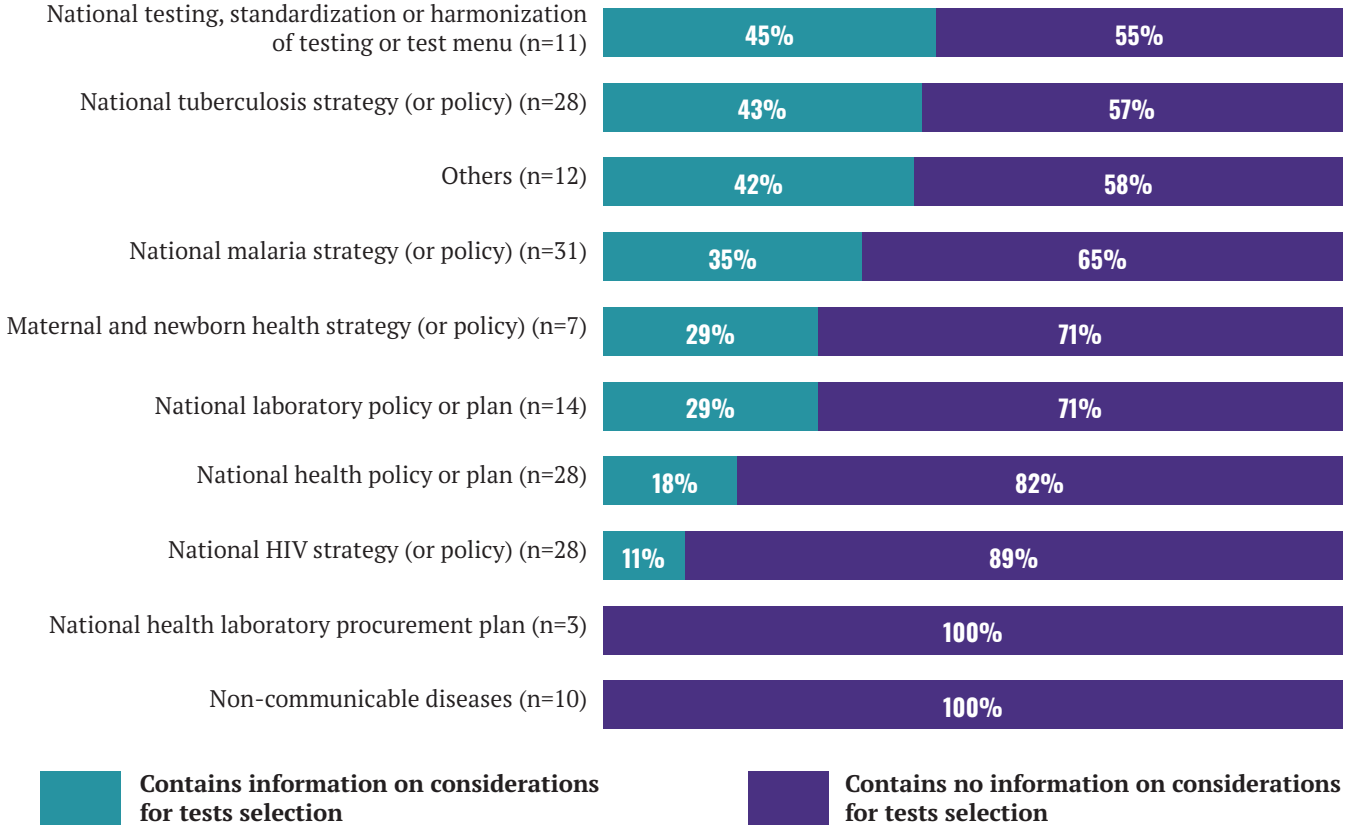
For development of documents, stakeholders must make decisions on which IVDs to include in the national IVD guidelines, in which they consider several selection criteria. The document review scanned documents for mentions of selection criteria in the categories: prevalence of disease, test performance, essential medicines list, disease prioritised for surveillance, and others. The qualitative study explored details for these selection criteria and the discussions between stakeholders.

6.1.1 Test selection criteria from the document review

Seventy-two percent (121) of the 169 documents addressing laboratory testing did not have information on what informed tests selection.

Concerning categories of documents, test selection considerations were most mentioned in standardisation or harmonisation of testing documents, including NEDL (45%). Forty-three percent of tuberculosis strategies and 35% and of malaria strategies had information on why specific tests were selected. Only 11% of HIV / AIDS documents contained information on the bases for test selection, and none of the documents in the non-communicable diseases category mentioned this **(Figure 5)**.

Figure 5: Percent of documents by category that contained information on test selection criteria



For the 48 documents that contained information on criteria for test selections, test performance was the main consideration for 67% of documents, followed by consideration of prevalence of disease (38%). Only eight of 48 documents indicated considerations related to lists of diseases prioritised for surveillance, and six of 48 indicated considerations related to lists of essential medicines **(Table 11)**.

Table 11: Selection criteria mentioned in documents that contain information on test selection (multiple response)

Test Selection criterion	No. of documents with mention	Percentage of documents with mention of test selection criteria (N=48)	Percentage of all documents with mention of addressing testing (N=169)
Test performance	32	67%	19%
Disease prevalence	18	38%	11%
List of disease prioritised for surveillance	8	17%	5%
List of essential medicines	6	13%	4%
Others	6	13%	4%

6.1.2 Details on selection criteria for essential IVDs

The respondents in the qualitative study, who had all been all involved in development of documents identifying essential IVDs, mentioned eight considerations in the selection of tests by tier of health care facility/laboratory:

1. The types and capacities of laboratory personnel present (BF, CAM, ETH, KEN, NIG, ZIM).
2. The types and capacities of clinical personnel present and levels of care provided (BF, CAM, KEN, NIG, UG).
   > Kenyan respondents noted that at the higher tiers of health care, the IVDs for lower levels should be included, considering that in the outpatient departments of higher tiers, RDTs are done. Respondents in Cameroon and Uganda mentioned that their country uses 'minimum health care packages' by health facility tier that the IVDs should be aligned to.
3. Types of equipment, instruments and technology present required for the IVD (CAM, ETH, KEN, NIG, ZIM).
4. Align IVDs with the national 'essential medicine list', updated annually (KEN, NIG)
5. Disease burden (BF, ETH, ZIM) and priority health care needs of the population (KEN, NIG)
6. Vertical disease programmes (ETH, ZIM)
7. Accessibility of health care facilities and laboratories; the ease of regularly transporting inputs for IVDs should be considered, with some areas being not accessible (BF)
8. Cost of tests (KEN, NIG, UG, ZIM).
   > For the standardisation and harmonisation documents of Kenya, Uganda, and Zimbabwe the laboratory specialists and clinicians decided to make three priority categories of IVDs: Vital, Essential, and Necessary, with an eye on procurement agents and funders, reasoning that funding always is a problem. A respondent in Uganda explained: *'If national stores get money, they will focus on Vital. If they have more money, they can go to Essential. If they have even more money, they must go to Necessary'.*

It should be noted that the three first selection criteria should be aligned, to not cause problems, as identified by a respondent in Cameroon: *'So when you look at our structure you can see the different tiers, they come with the human resources capacity and the structural capacity. But some laboratories now are expanding their human resources, so they have a medical biologist, or they have a technician, technologist in those facilities and so they just maybe put some equipment there, but the structure does not meet even the equipment that is needed* [for certain IVDs] so that's the challenge.' Respondents from Uganda and Cameroon pointed out that the laboratory tiers and the health care facility tiers do not always correspond **(see Text Box 8)**.

We explored whether gender was one of the criteria for selecting IVDs. Most respondents answered something like: *'not really, because generally diseases are not gender specific'*. However, all countries consider pregnancy-related tests (gender specific) essential. The Kenya and Ethiopia teams specified that a few other gender-specific tests were on their priority IVD list, namely cervical and breast cancer tests. The Ethiopia team expressed that they would consider gender as a criterion for prioritisation in the NEDL they are developing. It should be noted that when we say 'gender', we mean 'women'. Gaps in access to health care can be very serious for men as well, but we have not explored this.

We could not compare qualitative and quantitative findings, because most of the test's selection criteria reported by respondents were not among the selection categories in the document review. Only disease prevalence and alignment to essential medicines lists were included in the document review.

Text Box 8 zooms in on the test selection in Kenya, Cameroon and Uganda. The Kenyan document specifies brands of IVDs and equipment. In Cameroon and Uganda, respondents noted challenges regarding selection of tests by health care tier.

Text Box8: Selection of tests in Kenya, Cameroon, and Uganda

Case of Kenya – Selecting brands of IVDs and equipment

The Kenya document specifies the criteria used for selecting specific brands of tests and commodities on their lists (KEN DOC1), which is ahead of the selection of general essential IVDs:

1. ***Safety:*** Scientifically proven and acceptable in its expected way of use for health care workers and patients.
2. ***Quality:*** The products should comply with internationally acceptable quality standards, as recognized by the Kenya Medical Laboratory Technicians and Technologists Board or other duly recognized regulatory body. The standards should include stability under expected conditions of storage and use.
3. ***Performance:*** Sensitivity and specificity should meet the WHO requirements for each product indicating the percentage for each commodity/supply.
4. ***Comparative cost-benefit:*** A favourable cost-benefit ratio (in terms of use) compared with alternative products should be applied.
5. ***Local suitability/appropriateness:*** Preference should be given to tests or supplies with which laboratory staff is well familiar and that are suitable and reliably available in the local setting.
6. ***Local manufacture:*** To improve availability and reduce costs, the test or commodity should have the possibility of being manufactured locally.

Case of Cameroon and Uganda – problem of selecting essential IVDs by health care tier

Cameroonian and Ugandan respondents saw some difficulties in identifying IVDs by health care facility tier, reasoning that classification based on level of health care is too rigid, because of the wide variations in laboratories and medical services across officially the same tier health care structures. They preferred a classification based on the technical level of laboratory present in a health care facility. *'The same level facility can equip its laboratory to be at higher or lower level. There are facilities that, based on their technical platform, will be classified as district hospitals and yet the laboratory already has the infrastructure of regional hospitals'*, said the respondent from Uganda Allied Health Professionals Council. The Cameroonian Laboratory Services are currently working to change the laboratory tier classification from administrative related to health care facility to technical level of the laboratory. In this way, the private sector laboratories will also be able to define their tier.

6.2 Steps in document development

The qualitative study found that the series of drafts and final documents on essential IVDs were either written by a consultant recruited and paid for by an international partner, or by a small committee from the Laboratory Services.

Drafts were presented in a series of workshops: Usually the first workshop was with laboratory specialists, after which the authors made a revision to their first draft. This first revision was subsequently presented to a wider group of stakeholders from different MoH departments, health care facilities, regulatory bodies, professional associations, implementing partners, civil society, and international funding and technical partners. For some documents there was a third workshop for validation of the final draft document with all stakeholders. Finalised documents must be sent to the Minister of Health for endorsement and adoption. Some documents must go to the Prime Minister's office, to the National Assembly, or, if a document has legal implications to a Directorate of Legal Affairs and Litigation (to be checked against the texts and laws of the country). Not all finalised documents have been endorsed and implemented, for example, the Kenyan 'Essential Medical Laboratory Commodities List' of 2014 (DOC KEN1), as respondents noted.

Text Box 9 zooms in on the development of the Ugandan and Zimbabwean documents addressing IVDs. The details of the development of the Nigerian NEDL are in section 6.2.1.

Text Box 9: Development of documents addressing IVDs in Uganda and Zimbabwe

- **In Uganda,** respondents from Laboratory Services explained that before they wrote their 'Standard Test Menu, Techniques and List of Supplies' (UG DOC1), together with the MoH management and the national stores the Laboratory Services did a nation-wide assessment of the available and in-use types of laboratory equipment and supplies. After this inventory, the Laboratory Services convinced the MoH management that the country had to go through harmonisation and standardisation to reduce the large number of different products in the supply chain. During a series of workshops, clinicians from different tiers of the health care pyramid identified tests they needed for their clinical practice. The laboratory technical specialists then decided on the priority tests for different tiers, based on the national minimum health care package to include in the document.

- To develop the 'Laboratory Harmonisation and Standardisation in Zimbabwe' document (ZIM DOC1), two meetings were held. In the first three-day meeting, clinicians and laboratory professionals at different levels of the health care pyramid, from MoH and technical and implementing partners, reviewed the current tests offered in laboratories, evaluated testing gaps, decided on long term treatment shifts, established the tiered laboratory network, and identified opportunities and challenges for implementation. The 40 meeting participants agreed on five-tiered testing levels (rural, district, provincial, central and reference), considering human resources, testing technique complexity and the availability of specialist medical practitioners. The outcome of this meeting was a list of recommended tests stratified by laboratory tier and categorized by priorities ('must have', 'should have', 'may have' tests). The second five-day technical evaluation meeting aimed at reviewing the recommended test menus, standardising test menus, developing methods and techniques for each test, and outlining instrument specifications, as well as human resource requirements. The 27 participants were laboratory scientists and experts in different areas of diagnostics services, including vertical disease programmes. The final document contains a standard list of instruments (with brands) required for the proposed IVDs by tier (Table 7), required human resources by tier **(Table 8)**, and an implementation plan.

6.2.1 Case: Steps in development of the Nigerian NEDL

Preamble, getting stakeholders motivated

1. Nigeria was one of the three countries selected as WHO pilot countries to develop an NEDL – the others were Bangladesh and Kenya.[3] Nigerian professor Emeribe who is member of the WHO strategic advisory group of experts on IVD 'sold' the idea to the Nigerian Minister of Health.
2. WHO Nigeria, a member of the NLTWG, sensitized the group on the desirability of a Nigerian NEDL during a meeting in 2019, and the NLTWG agreed on the importance of developing one.
3. The MoH officially requested WHO for technical and financial support for the development.
4. WHO assigned two consultants to lead the process, one of them was Prof Emeribe. In the meantime, independent from WHO, MSH had also appointed a consultant to support development of an NEDL. MSH had funding from The Global Fund in the Health System Strengthening Programme to support the Laboratory Services in revising key documents, including the laboratory policy and strategic plan. An NEDL would be part of these documents. The three consultants (two men, one woman) worked together as a team, with Prof Emeribe as lead.

Survey to understand laboratory landscape

5. The first step in the development of the NEDL was a national laboratory landscape survey *'to let us understand the landscape of what is there at primary level, secondary level, tertiary level, and public health level. We wanted to know what is there and to know what is needed'* as Prof Emeribe noted. The consultants presented a draft survey tool, based on the WHO EDL 2nd edition, to the NLTWG. Questions in the tool related to IVDs presently used, priority diseases, human resources, equipment, infrastructure and barriers to access IVDs. The NLTWG made inputs to the tool, which involved dropping and adding some diseases to the priority diseases list.
6. After pretesting of the tool, the survey took place in February 2020 at 62 institutions in six States, in primary, secondary and tertiary public and private laboratories. WHO paid for the survey. Data collection was on paper and in electronic formats, the latter used for data analysis. MSH appointed and paid for a data analysis consultant who was already on MSH staff.
7. Surprising findings from the survey were: i) the IVDs present in facilities that the consultants and Laboratory Services had expected not in use anymore; ii) large variations in findings across States and health care facilities.

Drafting the NEDL

8. Consultants made a draft NEDL based on the IVDs they found in the survey and those IVDs that were unavailable, but they considered essential. Criteria they used for including IVDs in the draft NEDL were:
   - IVDs for conditions with high disease burden and/or high public health relevance (prone to outbreaks) where the IVDs have a clear impact on the diagnosis and management of a disease.
   - Tests encompassing care pathways of priority diseases/conditions.
   - Critical supporting tests such as complete blood count and C-reactive protein.
   - Tests that enable safe and rational use of the NEML
   - Available tests in laboratories (based on the survey)
   - Price and affordability (health financing)
   - Skills and qualifications of laboratory human resources and health practitioners to do the tests
   - Laboratory infrastructure and available amenities including electricity and reagent-grade water.

[3] Reasons why Kenya and Bangladesh have not taken up the development of an NEDL is beyond the scope of this study.

9. The consultants presented the survey findings and the draft NEDL to a large group of stakeholders in the laboratory domain. They started with a three-day workshop with laboratory experts and revised the draft NEDL. They presented the first revision of the NEDL in a three-day workshop, chaired by the chairperson of the NLTWG, with a larger stakeholder group, including pathologists, clinicians, and other bodies. Discussions were held in breakout groups (see **Text Box 10** for some of the arguments in test selection). The output of this second working meeting was the revised NEDL. A total of 96 individuals contributed to the NEDL.
10. The workshop participants had five days to read the revised final draft NEDL and send comments by email to the consultants. The consultants integrated these comments in the final NEDL.

Final NEDL

11. The consultants sent the final NEDL to the Medical Laboratory Service Directorate who then took it through the approval process of the MoH. The Minister of Health signed the document in June 2021 and he officially launched the documents on 09 May 2022.

Text Box 10: Arguments in selection of essential IVDs for the Nigerian NEDL

Respondents involved in the workshops to develop the Nigerian NEDL reported that arguments for IVD selection centred around whether some tests were appropriate for the community level; what qualification of laboratory staff could do specific IVDs; at what tier of laboratories tests could be done considering available human resources and equipment; how quality control should be organized. Pathologists and the laboratory council advocated for quality control by district laboratory scientists, but the whole group of stakeholders decided on more RDTs at the community level and in health facilities without a laboratory under the condition of quality control from a higher level (including primary health care facilities with a laboratory), reasoning that this would increase access to testing. The consultant team writing the NEDL reported in the interview: *'Labs are defending their territories but in terms of access to diagnostics it is good to upscale. For you to upscale you have to have more people doing tests that are not demanding, RDT is all about that.'* Other discussions centred around whether to keep IVDs that are commonly done in the laboratories but are no longer definitive; one example is erythrocyte sedimentation rate, which was kept on the NEDL. It was not always easy to decide on which tests to include, considering that *'Most tests are essential, but some are more essential than the others',* as one of the respondents noted. Initially, it was decided to specify tests by laboratory tier (primary, secondary, tertiary), but the final NEDL specifies tests for only two tiers: with and without a laboratory, as the WHO EDL does.

7 COUNTRY PLANS FOR NEDL

The qualitative study explored whether respondents knew about the WHO NEDL initiative, their views about it and their eventual motivations and plans for developing and implementing an NEDL. ASLM and WHO could use these findings in developing strategies to support countries willing to have an NEDL.

7.1 Plans for developing an NEDL

7.1.1 Knowledge and perceived usefulness of the WHO EDL

Respondents from Laboratory Services got to know about the WHO EDL and the advice to develop a national EDL in international workshops, but not all had seen or read the WHO EDL. 'It is on my reading table' said a respondent in Zimbabwe. Three countries (BF, KEN, UG) believed that their standardisation and harmonisation documents (from 2009, 2014, 2017, respectively) were remarkably similar, but more complete. They mentioned they will probably use the WHO EDL guidelines for revisions. The team from the EPHI (ETH) that already started developing an NEDL and the Nigerian consultants considered the WHO EDL useful (they used EDL 2).

Countries' motivation to develop an NEDL or upgrade a similar document stemmed from the need to solve or alleviate some of the present problems in the laboratory system, with over- and under-stocking and -supply of certain IVDs, erratic procurement and supply by multiple vendors, inefficient resource allocation, and problems in regulating private laboratories. Respondents in all countries saw the usefulness of having a national list with essential IVDs, either in NEDL format or in a standardisation and harmonisation document. They believed such a list would oil the IVD supply chain by guiding all those involved, including national regulatory bodies, planners, public and private procurers, funders, and public and private health facilities. Countries also saw the importance of international/regional harmonisation of essential IVDs, because this could facilitate them lobbying for resources at international level. In addition, countries having the same IVDs on their lists could motivate setting up manufacturing at a regional (African) level.

7.1.2 Plans, steps, and stakeholders to develop the NEDL

Ethiopia is in the process of developing their NEDL. The Uganda and Zimbabwe Laboratory Services plan to revise their harmonisation documents, using WHO EDL guidelines; Zimbabwe has already put this in their 2022 workplan. Kenya has plans to revise their 2014 harmonisation document, but not necessarily with the WHO EDL guidelines; their document is more extensive than an NEDL. Burkina Faso and Cameroon have no plans for a separate NEDL or using the WHO EDL for revision of documents. **Text Box 11** gives the country details.

7.1.3 (Foreseen) challenges and constraints in developing an NEDL

The main challenge in developing an NEDL or revision of harmonisation documents is funding. Countries need funding for the national laboratory landscape survey, consultants, stakeholder workshops and dissemination meetings.

Text Box 11:
Country plans, steps, and stakeholders to develop an NEDL or similar document

- **In Ethiopia,** developing an NEDL is in the 2022 Laboratory Services workplan. The former director started the initiative one year ago. He appointed a team of four (two women, two men) from the Laboratory Logistics Unit to develop a draft NEDL. The team compiled information available in other national documents, including food and drug documents; standards for laboratories and diagnostics in the Master Plan for the public health laboratory system (ETH DOC4); minimum health services package in the national health strategic plan; and Chapter 2 of the EPSA pharmaceutical procurement list 2018, which provides a list of laboratory reagents, chemicals, and supplies (not by tier of the health care/laboratory system) (ETH DOC5). The team engaged national stakeholders in two workshops. These stakeholders were experts from: national reference laboratories; disease programmes; national clinical chemistry laboratory; the MoH-linked EPSA. The team drafted the list of IVDs that were already used in the country and that they considered were needed. The following step would be a nation-wide assessment as to whether the IVDs on the draft NEDL can be performed in health facilities, considering local conditions. The already developed survey checklist includes assessment of available equipment, common diseases, infrastructure, staffing quantity and expertise, prices, and accessibility for the community. For this assessment, they needed ethical clearance from the Scientific Ethical Review office and funding. The EPHI had so far funded the process, but additional funding was now needed, which they hope to obtain from partners of disease programmes that need laboratory support, including USAID, the Royal Netherlands Tuberculosis Foundation (KNCV), CHAI, FHI. Funds are also needed for a consultant to do the final writing and for a dissemination workshop to raise awareness among stakeholders working in regional health bureaus who are going to implement the NEDL. When the final document is ready it will be sent to the MoH for review and approval. After MoH's approval, they will send the document to the Ethiopian Standard Agency for publication and distribution. Because they need technical and financial assistance, also for implementation, they will try to accommodate all international and local stakeholders' interests and incorporate funders and regulatory bodies.

- **The Laboratory Services in Uganda and Zimbabwe** intend to revise and update their harmonisation documents (UG DOC1; ZIM DOC1), using the WHO EDL guidelines. In Zimbabwe, this revision is already in the Laboratory Services' 2022 workplan.

- **Kenya DLS** have plans to review the 'Kenya Essential Medical Laboratories Commodities List' (DOC1). They want other MoH departments to be members of a technical working group in order for the list to support the implementation of UHC.

- **The Cameroon Laboratory Services** report have no plans for development of an NEDL or using WHO guidelines in revision of their harmonisation documents.

- **In Burkina Faso,** the development of a (separate) NEDL is not on the agenda. They already have financial difficulties in revising their harmonisation document from 2009 (BF DOC1). For now, the list of essential diagnostics is part of the 2014 EML. This EML has several headings, including consumables, reagents, medicines, and diagnostics (BF DOC4). The revisions of this EML are managed by the National Agency for Pharmaceutical Regulation, which always invites the management of the Laboratory Services and other laboratory actors for the revisions according to the respondents.

7.2 Case of Nigeria: plans for implementing the NEDL

The Minister of Health officially launched the NEDL on 09 May 2022. However, respondents reported that even before that time, stakeholders who participated in its development and a wider public were already using the NEDL, because in December 2021 the FMOH Laboratory Services presented the NEDL to the National Council on Health. This council is the highest decision and policymaking body on health, in which all state ministries of health take part. FMOH and States have the right to make their own health laws but in the national council meetings, they discuss and agree on certain issues. The council agreed on the usefulness of an NEDL. In addition, procurement agencies and departments at the federal, state and facility levels already prioritise procurement of IVDs on the NEDL, and the HIV and malaria disease programmes use the list.

The Nigerian respondents envisioned that implementation of the NEDL could solve various problems in laboratories across Nigeria, including excessive costs of tests; use of different tests (that are not on the NEDL); poor availability of tests; lengthy period to get IVD-brands assessed by the Public Health IVD Control Laboratory. They mentioned that several steps should be taken before their NEDL can be fully implemented:

- ***Specify and procure equipment and supplies linked to the recommended tests.*** The Public Health Procurement agencies and manufacturers usually hand in their dossiers to the Medical Laboratory Science Council of Nigeria's Public Health IVD Control Laboratory, which assesses, validates and gives permission to supply. The IVD Control Laboratory should prioritise assessment of IVD brands, equipment and supplies that are supporting the NEDL.
- ***Recruit and train qualified personnel.*** Regulatory bodies should specify the cadre of human resources by tier and ensure that the various levels of public and private laboratories only employ qualified people and 'get rid of' the unqualified staff who are currently doing tests.
- ***Cost the NEDL*** (currently no budget is attached). Since the NEDL is part of the revised laboratory strategic plan (awaiting validation) it will be costed once the plan is finalised. To reduce the cost of IVDs, Nigeria should build in-country capacity to manufacture the IVDs on the NEDL.
- ***Anchor the NEDL in legislation.*** The National Assembly should write legislation stating that FMOH, States, disease programmes and private laboratories should use the NEDL.
- ***Procure IVDs on the NEDL in bulk.*** Organise and coordinate bulk procurement of IVDs on the NEDL for all levels of health care services.

Potential problems in the implementation of the NEDL that the respondents noted are:

- ***States not adopting the NEDL.*** The organisation and policy making for the Nigerian health care and laboratory system, with the 36 States making their own regulations, imply that States can decide to adopt the FMOH level regulations or not.
- ***Erratic procurement.*** States, public and private hospitals procure according to individual needs and available budget. Multiple suppliers are marketing different products to the autonomous health care facilities and States. Non-existence of coordination and regulation of medical products procurement may result in IVDs on the NEDL not being accessible across health care facilities.

8 STUDY PARTICIPANTS' RECOMMENDATIONS

This chapter presents recommendations by the qualitative study participants, addressed to countries that want to develop and implement an NEDL or similar guidelines for IVDs, and at ASLM, FIND and other donors who intend to support countries in these endeavours. The authors' recommendations will be given in Chapter 9, after discussion of the findings.

8.1 Recommendations for countries developing an NEDL

Steps in development of an NEDL

Respondents advised having at least two fundamental moments in the process of developing an NEDL: first, create the basic document, i.e., a first draft NEDL, and second, validate the document with a large group of stakeholders. The draft NEDL could be developed by a small technical committee from the Laboratory Services, by a workshop with all stakeholders, or by consultants; each approach has its own pros and cons. The advantage of a small technical committee first (as Kenya plans to do for revising and updating their standardisation document) is that the draft can be ready fast. The advantage of a meeting with a big group of stakeholders is avoiding some stakeholders not accepting the document because they had not been involved from the start. In bigger meetings, participants can agree on a committee to write a draft NEDL that the whole group can discuss and validate (Uganda strategy). If consultants are used, the advice was to appoint competent, respected, in-country laboratory scientists who are familiar with IVDs. The consultants should coordinate the landscape survey and write the draft and final NEDL. The advantage of consultants is that they have more time than MoH staff and must meet their contract's deadlines. The various levels of drafts should always be submitted to a larger group of stakeholders for discussion and validation in one or a series of workshops, in which technical and scope issues should be addressed. The definitive version is written by the small committee or consultants, integrating the suggestions by the workshop participants.

Study the laboratory landscape

Respondents recommended studying the country's laboratory landscape as the basis for the NEDL, including study of disease epidemiology, health facility structure, available laboratories, and any other factors deemed important. The NEDL should be aligned with the national health care delivery structure. This means considering the location of Laboratory Services within the MoH and at sub-national level and the operation of laboratories by tiers in the national health care pyramid. The laboratory landscape includes existing national tools and texts related to the prioritisation of tests, including local policies and national reference documents, such as laboratory standardisation and harmonisation guidelines. These should be reviewed and compared with WHO guidelines on NEDLs. A key point is to also map all laboratory stakeholders, so as to involve them in the process and assure their feeling of ownership of and commitment to the implementation of the NEDL.

Kenyan respondents opined that sufficient routine data on laboratories were available for the landscape analysis, whereas other countries thought they needed a laboratory landscape survey to map all information needed for an NEDL. Nigerian respondents noted that conducting a situation survey was fundamental, because even if the landscape is already known, the survey data will expose the situation, including the challenges, to the national consciousness of all stakeholders.

Involve stakeholders and resource persons

For an NEDL to be well accepted, the process should be inclusive with the participation of all tiers of the health care and laboratory system and the political decision-makers, including the senior officials of the MoH. Indeed, the Minister of Health has the capacity and responsibility to seek funding from development partners. Then, the process should move on to the medical directors of the MoH, and then to the leaders and professionals of the laboratories to make them understand how the UHC programme benefits from an NEDL. Other important country-specific stakeholders must also be identified and involved in the development process. For example, in Kenya the Council of Governors was described as an important stakeholder to involve so as to engage their counties. Beyond local stakeholders, it was recommended to involve laboratory scientists from the countries' WHO office and other partners. In Cameroon, the Ministry of Higher Education was identified as a key stakeholder.

8.2 Recommendations for countries implementing an NEDL

Countries perceived that successful implementation of an NEDL was related to how the NEDL had been developed. If the development has considered laboratory system bottlenecks, as identified by mapping the laboratory landscape, and has involved important stakeholders in development, the implementation will be smoother. Involvement of laboratory professionals and medical stakeholders is important so that they feel ownership of the NEDL and commitment to implement: *'…. because none of them (will) see the document for the first time, since they have been really involved in the development'*, as a Nigerian respondent noted. Vital stakeholders are the regulatory agencies who will ensure that only qualified personnel staff laboratories. For successful implementation of the NEDL, it is important to improve the quality management systems for equipment, human resources training, and infrastructure, and to ensure adequate procurement of IVDs on the NEDL.

8.3 Recommendations for ASLM and FIND

Study participants recommended that ASLM and FIND give them technical support in developing an NEDL or in revision of their similar documents and assist them in sourcing financial support. Financial support is needed for consultants to lead the process, for the laboratory landscape study, for workshops with stakeholders to discuss and validate drafts, for printing, and for dissemination workshops of the final NEDL. A Nigerian participant noted that: *'No African country will have enough money related to NEDL development for itself'*. Acknowledging their well-respected status, the participants recommended that ASLM and FIND advocate with the Minister of Health for development of an NEDL.

In Kenya, respondents had some specific recommendations: ASLM and FIND should provide support to the staff of the Pharmacy and Poisons Board in organizing procurement, training procurement officers, and post-market surveillance of IVDs. Concerning the study to map the laboratory landscape, the WHO respondent in Kenya thought that a separate (costly) assessment was not necessary, if sufficient information was available from routine data. He therefore recommends that ASLM support countries to find out whether their information corresponds to the WHO criteria for laboratory assessment.

9 DISCUSSION AND FINAL RECOMMENDATIONS

9.1 Discussion

The main objective of this study was to obtain information on existing national guidelines on tier-specific diagnostic testing in 55 LMICs in Africa and explore the decision-making processes leading to prioritising IVDs in the tiered health and laboratory network, in order to inform recommendations for eventual development of national guidelines for essential IVDs and an implementable NEDL. A desk review, providing quantitative data, identified 363 documents from 55 African countries and did a content analysis of 292 documents from 44 countries. A qualitative study conducted in seven countries searched for (qualitative) details in the most relevant documents (i.e., related to harmonisation and standardisation of IVDs) and conducted semi-structured interviews with 28 key respondents involved in the national laboratory system and (potentially) in selecting essential IVDs for national guidelines. The desk review and qualitative study are complementary.

Documents and tiers

The eventual development of an NEDL should build on existing documents with IVD guidelines. Of the 292 reviewed documents, 11 were national test menu/NEDL or standardisation documents, 28 were national laboratory policies or strategic plans, 65 were national health policies or strategic plans, and 161 were disease-specific programme policies and guidelines [HIV/AIDS (42), malaria (41), tuberculosis (31), MNCH (22), non-communicable diseases (24)]. Of the total 44 countries, 27 had at least one document that addresses tier-specific testing; one country (Nigeria) had developed an NEDL, and 10 had a national document aimed at standardising/harmonising testing across the laboratory network, which is similar to an NEDL. The other 16 had one or more documents that define testing by tier, often for vertical disease programmes. For vertical programmes, the documents were recent, but in most countries the general guidelines were rather old (range 2009-2021; median 2014) and not all had ever been in use.

The harmonisation documents were generally more extensive than a standard NEDL, because they also included equipment, consumables, and sometimes laboratory personnel and infrastructure requirements for the IVDs by tier. The Nigerian stand-alone NEDL is also a Chapter in the Nigerian Laboratory Policy and will be a budgeted theme in the National Laboratory Strategic Plan, which awaits finalisation. The national harmonisation documents do not identify tests at the community and health facilities without laboratory tier, as the WHO EDL recommends doing (and the Nigerian NEDL followed), but usually link the different tiers of laboratories to tiers in the health care pyramid. These documents only considered physical laboratories in the laboratory tier-structure. However, participants in the qualitative interviews acknowledged that the community and facilities without on-site laboratories should be added to laboratory tiers (and in some countries have been included already) to increase access to testing. They argued that many RDTs can be done by non-laboratory personnel, if trained laboratory staff monitor quality. In fact, in all countries included in the qualitative study, community health workers and/or staff in health posts and health centres without a laboratory already do RDTs, usually for malaria, HIV, pregnancy, and albumin and protein (with urine dipsticks); some of these tests were specified in vertical disease programme documents. The document review found that 55% of malaria documents addressed IVDs, 32% of similar HIV documents and 18% of similar tuberculosis documents identified IVDs for the community level. The developers of an NEDL could learn from the vertical disease programmes.

The Nigerian NEDL followed the WHO EDL 2 by distinguishing two tiers: i) community level and health care facilities without laboratory and ii) health care facilities with laboratory on-site and reference laboratories. During development of the Nigerian NEDL there were discussions about whether to differentiate the laboratory tiers and thus not lump all laboratories together. Stakeholders decided against differentiation, because of the difficulty of standardising laboratory tiers across the health care pyramid levels, having found great variations during the laboratory landscape survey findings that provided input for the NEDL. Study participants in other countries noted the same non-correspondence of laboratory and health care facility tiers in their country. Therefore, when assigning certain IVDs to specific tiers, one should use laboratory tiers and not health care facility tiers; national regulatory bodies that license laboratories have registers of public and private laboratories by tier.

State of national laboratory services

For the seven countries of the qualitative study, respondents and information from documents indicate that laboratories remain weak links in the health care system. Generally, except for the laboratories supported by disease and laboratory strengthening programmes, laboratories face problems related to insufficient and unqualified human resources, poor maintenance and unavailability of equipment, unavailability of sufficient and appropriate consumables and tests, inadequate national funding and dependence on donors, and inefficient organisation and coordination. Partly, these problems are related to the low status of laboratories and laboratory professionals in the health care domain and the low position of Laboratory Services in the MoH hierarchy, which results in Laboratory Services being unable to make autonomous decisions with a dedicated budget, instead relying on other departments. Other reasons for the problems are that the sub-national policy and decision-making bodies are semi-autonomous and may decide laboratories are not a priority in their jurisdiction, whereas at the national level they are. The sub-optimal state of laboratory services hinders optimal national health care delivery. Because an NEDL intends to contribute to stronger laboratory services and thus to improved national health care delivery, a cornerstone of the WHO UHC programme, there is a strong urge to develop an NEDL. Vertical disease programmes increasingly realise that for their programme to be successful, they need to support general laboratory services and not only strengthen selected laboratories for their own programme.

Stakeholders in the laboratory domain and development of documents

In the 292 documents reviewed for content, the top three stakeholder categories mentioned as being involved in the documents' development were MoH (mentioned in 100% documents), funding agencies (56%) and implementing partners (47%). Most other stakeholder categories (professionals, academic institutions, public and private non-profit sector laboratory services) were less involved (mentioned in 11% to 27% of documents), with lowest involvement by research groups (6%). When focusing on stakeholder involvement in the development of the 11 national standardisation documents, we found that in addition to the top three above, the public sector laboratory services (managers, directors, and in charges) were mentioned in nine of the 11 documents. In the development of the Nigerian NEDL, all stakeholder categories were involved, as WHO advises in their NEDL development guidelines. Categories of stakeholders that were missing in the desk review analysis but found to be important from studying details of the documents and information from the interviews were procurers and regulatory bodies.

Within the MoH, obviously, the Laboratory Services section will be most involved in selecting priority IVDs. Its position in the ministry – being a department with a budget, or a sub-section with no budget – would influence how much decision-making power the section has. Exploring this position in the qualitative study, we found that only in Uganda are Laboratory Services a separate department. In Ethiopia, Laboratory Services are a (budgeted) focus area of an autonomous public health institute, whereas in the other five countries the Laboratory Services are sub-(sub-)divisions of MoH departments. A lower position in the MoH hierarchy would negatively affect the Laboratory Services' decision-making power and access to national and international funding for development and implementation of laboratory strategic plans. However, not only its position within the MoH, but also its connection with and support by the Minister and international funding sources and technical partners play a role in the decision-making power of Laboratory Services. A strong connection and keen interest of these stakeholders in developing the laboratory system, as is the case in Nigeria and Kenya, will facilitate developing and implementing documents.

One lesson from Nigeria is that it is key to have the Minister of Health initiating/endorsing the process of developing an NEDL. In Nigeria, a facilitating factor was an active Laboratory Technical Working Group, set up by the Minister, with wide representation of stakeholders in the laboratory domain. The high status of Laboratory Services in the Nigerian MoH can be partly attributed to the close connection with the Nigerian CDC. Political commitment to the NEDL at the highest level is essential, including for resource allocation, with ministers of health being able to lobby for technical and financial assistance from international partners. Moreover, the Director General of Health Services, the Minister of Health, and the Permanent Secretary can tell other departments, counties, etc. to comply with, implement and support an NEDL.

The qualitative study found that documents are usually drafted and finalised by consultants or a small ad-hoc committee from the National Laboratory Services and presented in a series of workshops to a wide range of stakeholders in a series of workshops. The consultants or committees integrate the recommendations of these workshops in subsequent revisions.

Concerning gender representation in workshops for document development, committees and consultants, the qualitative study found there was no strategy for equal gender representation. Normally in workshops, committees and consultancy teams, organisations and departments are invited; the organisations and departments are then represented by an individual with required qualifications, and the gender of this individual was reported as not being an issue in their selection.

Criteria for selection of essential IVDs

Only 28% (n=48) of the 169 documents that addressed IVDs (out of 292) mentioned the criteria used for selection of IVDs (by tier). Even standardisation documents did not always specify these criteria; 45% did mention the considerations used for selection. For the 48 documents that contained information on criteria for test selection, test performance was the main consideration at 67%, followed by disease prevalence at 38%. Lists of diseases prioritised for surveillance in only eight and lists of essential medicines were indicated only six out of the 48 documents as considerations for test selection. It should be noted that the participants in the qualitative study identified main criteria for selecting IVDs by tier other than the criteria categories included in the document review. Their top three main criteria related to the types and capacities of available laboratory personnel, the available clinical personnel and level of care provided, and the available equipment. Many countries mentioned cost considerations when prioritising tests. Interestingly, in three countries, stakeholders decided to make three priority categories of IVDs: Vital, Essential, and Necessary, with an eye on procurement agents and funders, reasoning that funding always is a problem. Participants also mentioned considerations of disease burden and alignment to the national Essential Medicine List, which were categories in the document review. Gender was not mentioned as a criterion, although it was noted that some tests for priority health care needs are gender specific, e.g., pregnancy, and cervical and breast cancer.

Motivation and plans to develop and implement an NEDL

All qualitative study participants showed an interest in prioritising, harmonising and standardising IVDs for different tiers of the laboratory system, either by developing an NEDL or having the national standardisation and harmonisation document updated. Their interest lay in solving some of the problems in laboratory services and systems that are related to accessibility of diagnostics for the population. They foresaw that an NEDL or (revised) standardisation and harmonisation document would guide national regulatory bodies, planners, public and private procurers, funders, and public and private health facilities at all levels in prioritising the IVDs on the list. Countries also saw that international/regional harmonisation of essential IVDs could facilitate lobbying for resources at the international level. Countries having the same IVDs could motivate setting up decentralised manufacturing at regional (African) level.

Not all countries intend to develop a stand-alone NEDL. Study participants considered their (old) harmonisation documents more comprehensive, because they include reagents, consumables, equipment and sometimes also personnel needed for the essential IVDs. An NEDL would only address part of this harmonisation document they hope to update.

Concerning NEDL implementation, we can learn from the status of the Nigerian NEDL, which is a stand-alone document and also a Chapter of the updated Laboratory Policy. It will be a budgeted theme in the Laboratory Strategic Plan, because for implementation, an NEDL must include a plan for dissemination, for implementation, and for monitoring and evaluation. Before an NEDL can be implemented, equipment, supplies, consumables, and laboratory personnel should be specified for the selected IVDs. Legislation, regulations, and procurement should be arranged and coordinated. For guidelines to be used and implemented across the country, the (semi-) autonomous decision-making bodies, such as States, Departments, and health care facilities should be aligned. Interestingly, although the Nigerian NEDL is not anchored yet in the Laboratory Strategic Plan, and many hurdles must still be overcome before wide implementation, Nigerian study participants noted that the NEDL is already used by the groups of stakeholders involved in its development, including the national Public Health IVD Control Laboratory, which prioritises testing and validating IVDs on the NEDL. The Nigerian experience proves that it is key to involve all stakeholders in the (future) implementation of the NEDL, including regulators and government procurement offices, in its development.

9.2 Final recommendations

Below are the researchers' final recommendations (integrating those of the study participants) for development and implementation of an NEDL or similar guidelines for tier-specific essential IVDs, based on the lessons learnt. These recommendations are addressed to countries and partners, such as ASLM, FIND and WHO, that intend to support the development of NEDLs.

- Have the Minister of Health initiate and/or endorse the development process. The Minister is the final decision maker and can ask for the funding, and technical and implementing partners to support the process.
- Involve all stakeholders in the NEDL development process. When all participate in decision-making discussions, all feel committed and take ownership and may start implementing the NEDL even before it is officially launched. Include regulatory bodies and procurement agencies in the development of an NEDL.
- When assigning certain IVDs to specific tiers one should use laboratory tiers and not health care facility tiers. Before all laboratories are at standardised levels, the NEDL does not necessarily need to address laboratory tiers: laboratory heads, in consultation with clinicians in health care facilities, can decide what IVDs to procure, considering staffing, equipment, and amenities of the laboratory. When these stakeholders have been involved in the development of the NEDL, they will know how to proceed, what to consider and what tests to select from the list. Guidelines on how to use the NEDL should be provided in a distinct section.
- Identify a wide range of RDTs in the NEDL for the community level and health facilities without a laboratory on site to expand access to testing. Personnel of the nearest laboratory should train the community workers, monitor test quality and waste management. Laboratory Services and health care facilities could learn how to organise from vertical disease programmes.
- For developing an NEDL or revising harmonisation documents, study the essential IVDs for community and laboratory settings in vertical disease programme documents, which are generally more recent than existing general guidelines.
- ASLM and other supporting partners: Let countries decide whether they want to develop an NEDL or revise their harmonisation document.
- ASLM should start supporting the process in three or four of the countries that have indicated to WHO that they want to develop an NEDL or revise their harmonisation documents. Before starting, advocate with the Minister of Health for commitment. Cost the process (get information from FMOH, WHO and MSH Nigeria).
- In developing and implementing an NEDL, countries could learn from the general adoption and use of the WHO Essential Medicines List; it was beyond the scope of the present study to analyse the literature on this topic.

REFERENCES

Greenslade, L., Ginsburg, A.S., 2019. Boosting quality diagnostics could give Africa better health. The Lancet 393, 2492. https://doi.org/10.1016/S0140-6736(19)30718-4.

Makonim, M. 2018. Boosting quality diagnostics could give Africa better health. The Lancet 392:2426. https://doi.org/10.1016/S0140-6736(18)33116-7.

Ondoa, P., Oskam, L., Loembe, M.M., Okeke, I.N., 2021. Transforming access to diagnostics: how to turn good intentions into action? The Lancet 398, 1947–1949. https://doi.org/10.1016/S0140-6736(21)02182-6.

Ondoa, P., Van der Broek, A., Jansen, C., De Bruijn, H., Schultsz, C., 2017. National laboratory policies and plans in sub-Saharan African countries: gaps and opportunities. Afr. J. Lab. Med. 6. https://doi.org/10.4102/ajlm.v6i1.578.

Oskam, L., 2021. Challenges facing countries in disease prioritisation and national essential diagnostics lists. ASLM Special Session 2, Bringing the Diagnostics that Count into Routine Testing Services, ASLM, 10th Anniversary

Schroeder, L., 2021. An evidence-based template for developing an essential diagnostics package (from the Lancet Commission on Diagnostics). ASLM Special Session 2, Bringing the Diagnostics That Count into Routine Testing Services, ASLM, 10th Anniversary.

The Lancet Global Health, 2021. Essential diagnostics: mind the gap. The Lancet Global Health 9, e1474. https://doi.org/10.1016/S2214-109X(21)00467-8.

WHO 2019. First WHO model list of essential in vitro diagnostics. WHO Technical Report Series 1017. Geneva: World Health Organization.

WHO 2019. Benchmarks for International Health Regulations (IHR) Capacities. Geneva: World Health Organization; Licence: CC BY-NC-SA 3.0 IGO.

WHO 2020. The selection and use of essential in vitro diagnostics. WHO Technical Report Series 1022. Geneva: World Health Organization.

WHO 2021. The selection and use of essential in vitro diagnostics. WHO Technical Report Series 1031. Geneva: World Health Organization.

WHO 2021. Brochure: The WHO model list of essential in vitro diagnostics. https://www.who.int/publications/m/item/the-who-edl-brochure (31-8-2022).

Yadav, P., 2021. Supply chain issues in diagnostics. ASLM Special Session 2, Bringing the Diagnostics That Count into Routine Testing Services, ASLM, 10th Anniversary.

Yadav, H., Shah, D., Sayed, S., Horton, S., Schroeder, L.F., 2021. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. The Lancet Global Health 9, e1553–e1560. https://doi.org/10.1016/S2214-109X(21)00442-3.

ANNEX 1: (GENERIC) INTERVIEW QUESTION GUIDE

INTERVIEW GUIDE FOR KEY STAKEHOLDERS IN DEVELOPMENT OF NATIONAL GUIDANCE IN PRIORITISING IN-VITRO DIAGNOSTICS BY TIER OF THE LABORATORY SYSTEM

INTRODUCTION

This interview is part of a study conducted by the African Society for Laboratory Medicine (ASLM). The overall study objective is to explore whether and how African countries prioritise in-vitro diagnostics (IVD) for the tiered health and laboratory network. The findings of this study aim to inform recommendations for improvement of present guidelines and/or eventual development of an implementable national essential diagnostic list (NEDL).

An ASLM team completed the first part of the study, which was a document review of policy and programme documents of 55 African countries, arriving at quantitative data.

The second part is a qualitative study to explore the in-country decision making processes to arrive at prioritised in-vitro diagnostics for the tiered health and laboratory network. For the qualitative study, countries have been selected that have experience with prioritising diagnostics in the tiered laboratory network. The questions in the interview address among others, on what bases your country prioritised diagnostics, for which diseases or programmes, which stakeholders were involved, what are facilitating factors and barriers in your country to availability and access of prioritised diagnostics in tiers of the health system.

Your participation in this study is important for future steps in making essential laboratory services available and accessible to people at all levels of the health system, including community level, and so contribute to better diagnosis and surveillance of diseases and health conditions.

Two consultants are conducting this qualitative study, Dr Winny Koster (a medical anthropologist, with PhD (2003) from University of Amsterdam, the Netherlands) and Dr Albert Gautier Ndione (a socio-anthropologist, with a PhD (2017) from Cheikh Anta Diop University of Dakar, Senegal). They both have previous experience with studies in the health and laboratory domain in Africa.

We sent you this question guide in advance to be able to prepare some answers, consulting with your colleagues or other stakeholders. Dr Koster and/or Dr Ndione will conduct the interview which will last approximately 1.5 hour, by ZOOM. If you like, you can invite other stakeholders to take part in the interview.

We thank you in advance for your participation and for your precious collaboration.

TOPIC AND QUESTION GUIDE

A: BACKGROUND OF RESPONDENT:

1. Name, profession
2. Current affiliation(s), place of work, position? *Probe multiple affiliations*

B: CONTEXT OF LABORATORY SYSTEM

3. Can you explain the tiers of the laboratory system in your country, starting at the lowest level of laboratories, and how it is related to the health care pyramid?
4. Are some IVDs done at the community level, which is at health posts without a laboratory or by community health workers?

   If yes: What IVDs and who does them, and where?
5. What is your estimate of the percentage-distribution across the laboratory categories: i) public, ii) private not-for-profit and iii) private for-profit laboratories in your country?

C: EXISTING OR INTENDED NATIONAL PRIORITY IVD GUIDELINES AT TIERS OF THE HEALTH SYSTEM

6. Does MoH have national reference documents for defining essential/priority IVDs at tiers of the health and laboratory system? *NOTE: Refer to known documents*

   If no:

   6.1 What are the reasons why MoH does not define essential IVDs at tiers of the laboratory system?

   6.2 Does MoH intend to have such reference documents? If so, please specify plans (-> Q7)

   If yes:

   6.3 Can you name these documents? *Probe:* for which diseases and programmes, probe for MCH, MNCH *(NOTE: ask to send copies of those documents)*

   6.4 Do (some of) those documents also define essential IVDs for the level of the community and health posts without a laboratory?

   If no:

   6.4.1 Why is the community and health post level not included in the guidelines?

   If yes:

   6.4.2 In which documents, for which diseases and programmes are priority IVDs defined for level of health post and community? Which IVDs?

   6.5 What are MoH's considerations/criteria for assigning some essential IVDs to a specific tier (including community level)

   6.6 If applicable: Why do some documents refer to tier specific IVDs whereas others do not?

   6.7. Generally, do the considerations/criteria differ with IVDs used for clinical care or for disease surveillance? *If so,* please explain

D: COMMITTEE

7 Do you have national committee(s) or working group(s) that is/are responsible for development of documents on guidance for (tier-specific) prioritisation of IVDs?

If there are such committees:

7.1 What are the names of these committees? *Specify – when constituted with what aim?*

7.2 Who are the members of these committees (ask for each committee)? *Probe:* which group of stakeholders do they represent, what are their roles? What is the percentage of women in each committee?

7.3 Who decides on the members of these committees?

7.4 Do you think obvious stakeholders are missing from (some of) the working groups?

If so, who is missing, why are these not involved in the working group? (Note to consultant: identify the missing obvious, such as public sector laboratories, professional health associations and ask why they are not involved)

If no such working groups

7.5 Is MoH planning to assign a working group or technical committee to be responsible for development of documents on guidance for tier-specific prioritisation of IVDs?

If so: Please specify plans, who would be invited to be the members of such committees, which group of stakeholders would they represent, what diseases or programmes?

7.6 What *would be* MoH's key consideration to prioritise IVDs at various tier level (including community (mainly) based on?

E: IMPLEMENTATION OF PRIORITISED IVDS AT TIERS

8. What systems are in place for monitoring and evaluation of the actual availability of and access to (essential) diagnostics at the different tiers of the health system? (*Probe:* digital, paper-based monthly, quarterly reports etc.).

If systems in place:

8.1 To what extent is the system effective in giving insight in actual availability and access (by gender), and preventing stockout?

9. What are the problems in the availability and implementation of defined priority IVDs? *Probe for different tiers, programmes, geographic regions, specific IVDs only, Insufficient budget*
10. How are MoH, stakeholders, national guidelines trying to solve these mentioned problems?

F: WHO EDL GUIDELINES

11. Have you heard of the WHO Essential Diagnostic List (EDL) and WHO guidelines to develop national EDL? Have you read those guidelines? *Note to interviewer: if the respondent does not know, explain objectives of the EDL and NEDL*
12. In what ways do you perceive the WHO documents to be of use in prioritising IVD in tiers of your country's health and laboratory system?
13. How do you think an NEDL may solve the barriers to implementation of IVDs in tiers of the laboratory system in your country (as you identified previously)? *NOTE: refer to the barriers mentioned*
14. Does MoH intend to develop an NEDL or likewise document or have you started to develop already?

    If so: Can you, please explain the steps you took/intend to take in the process of developing an NEDL or likewise document so far?

G. RECOMMENDATIONS:

15. What are your recommendations to yourself and other countries for steps to take in eventual developing and implementation of national document with guidelines for tier specific IVDs or NEDL?
16. What recommendations (if any) do you have for prioritising tests by considering the gender of recipients?
17. What recommendations do you have for us interviewing other people who were or are to be involved in the development of guidelines for prioritising diagnostics in tiers of the health system in your country? Can you give us their contact details?

ANNEX 2: QUALITATIVE STUDY RESPONDENTS AND THEIR POSITIONS, BY COUNTRY

Country	Name	Position
Burkina Faso	MADINGAR D. Patrick	LabCop team lead, Head of the ME-QM service, *Direction Générale de l'Accès aux Produits de Santé/Direction des Laboratoires de Biologie Médicale* (DLBM/DGAP)
	KY Hervé	Head of DMI service of the *Direction Générale de l'accès aux Produits de Santé/Direction des Laboratoires de Biologie Médicale* (DLBM/DGAP)
	Dr Absetou Ba KY	Head of the laboratory of Bobodogo University Hospital Centre
Cameroon	Rina Estelle	Head of Laboratory Services, MoH
	Dr Nke Ateba	Head of department of the medical biology analysis laboratory of the Yaoundé Central Hospital
	Dr Nguwoh Philip Salomon	Executive at the National Public Health Laboratory
	Caroline Bih	ASLM staff in MoH Laboratory Services
	Dimite Laura	Laboratory officer of CDC Cameroon
	Dr Clément Ndomgmo	Biologist and epidemiologist, Associate on programs and science at the Cameroon CDC
	Dr Judith Shang	Medical microbiology, Cameroon CDC program
Ethiopia	Daniel Melese,	Acting Director, National Laboratories Capacity Building Directorate, Ethiopian Public Health Institute (EPHI):
	Daniel Demissie	Laboratory logistic team lead, at EPHI; Medical microbiologist logistic team lead
	Desalegn Addise	Laboratory logistic team member, at EPHI; Medical microbiologist, researcher, and laboratory logistics officer
	Lulit hailu	Laboratory logistic team member, at EPHI; Researcher and laboratory logistic officer
Kenya	Nancy Bowen	Division NPHLS Head NHRL (National HIV reference laboratory). Lab Cop focal person
	Mr. Peter Lokamar	D/Head DLS and Head NPHLS (National Public Health Laboratory Services) – for national reference laboratories for malaria, HIV, TB
	Lily Kirui	Head Division Diagnostic and Clinical Support (DDCS)
	Benard Sande	Former head DDCS – involved in development of essential medical diagnostics
	Stephen Bera K.	Ex NPHLS, was Global Fund laboratory team lead
	Esther Sigilai	National Oncology reference Lab
	Dr. John Kiiru	Head of Department – DLS
	Dr Sioyi –	CEO of Pharmacy and Poison Board (Regulatory Body)
	Dr. Jane Mwangi	CDC Laboratory Branch Chief
	Prof. Peter Barus	WHO Technical Advisor for laboratories

Nigeria	Adedamola Oyekunle	Laboratory Program Manager - Medical Laboratory Service Division, FMOH, ML SD-NLTWG Secretariat
	Dr Kinsley Odiabara	Director Medical Laboratory Service Division, FMOH
	Nkechi Nwoke	Retired director – DMLS
	Prof Anthony Emeribe	Lead Consultant, NEDL (WHO)
	Nonye Umahi	WHO NEDL consultant
	Dr Abiodun Olaiya Paul	Consultant, NEDL (MSH) – GF/RSSH
	Dr Donald Ofili	Deputy Registrar, Medical Laboratory Science Council of Nigeria; subcommittee lead 'Quality' of NLTWG
	Dr Nasiru Abdullahi	Consultant Pathologist (Microbiology), Jabi Abuja Federal Medical Centre Abuja
	Dr Callista Osuocha	National focal person, C19RM Project-Nigeria; (ex) Laboratory director MSH; [Now: at NACA]
Uganda	Dr. Susan Nabadda	Commissioner for the Department of National Health Laboratory and Diagnostic Services – Ministry of Health (NHLDS-MOH)
	Mr. Wilson Nyegenye	National Laboratory Equipment and Logistics Coordinator – Ministry of Health – Kampala, Uganda.
	Rita Nabukenya Eragu	Administrator at UNHLS
	Miriam Nabukenya	UNHLS Uganda
	Jonathan Ntale	CDC Uganda
	Charles Nahabwe	Uganda Allied Health Professionals Council
	William Lali Ziras	WHO Laboratory focal point
Zimbabwe	Norah Sukutayi Vere	National laboratory coordinator, HIV Program; Also in DLS, LabCop representative. Medical scientist.
	Liliosa Mugari	Laboratory Logistics Unit Senior Manager, DLS, MoH.
	Agnes Juru	National microbiology HIV – AMR Reference Laboratory Coordinator. Coordinator New Technologies. (They evaluate new technologies coming into the country and decide which technologies are appropriate for each tier).

ANNEX 3: NATIONAL AND PROGRAMME DOCUMENTS INCLUDED IN THE QUALITATIVE STUDY

Note: If the same document has been revised, we only mention the latest version.

Country	# DOC	Names of documents that address laboratories and tiers	Date/years covered
Burkina Faso	1	*Direction des Laboratoires, juillet 2009 : Normes en Infrastructures, Equipements et Analyses de Biologie Médicale Essentielles des Formations Sanitaires Publiques*	2009
	2	*Guide de Bonne Exécution des Analyses de Biologie Médicale au Burkina Faso*, 2009	2009
	3	Malaria Operational Plan Fiscal Year 2019	2019
	4	*Liste Nationale des Médicaments et Consommables Médicaux Essentiels Burkina Faso ; Ministère de la Santé*, Burkina Faso	2014
Cameroon	1	*Plan Stratégique National de Développement des Laboratoires du Cameroun*	2018-2022
	2	*Organisation des Laboratoires Suivant la Pyramide Sanitaire au Cameroun*	2011
	3	*Plan Stratégique National de Lutte Contre le Paludisme*	2019-2023
Ethiopia	1	National strategic tuberculosis and leprosy plan (revision after midterm 2017)	2013-2022
	2	HIV strategic plan	2015-2020
	3	National strategic plan for malaria prevention, control, and elimination in Ethiopia (Draft)	2011-15
	4	Master plan for the public health laboratory system in Ethiopia; Second Edition)	2009-2013
	5	Pharmaceutical Fund and Supply Agency: Pharmaceutical procurement list, first edition, Addis Ababa, 2018	2018
Kenya	1	Kenya essential medical laboratory commodity list; published by the Ministry of Health, February, 2014	2014
Nigeria	1	Nigeria National Essential Diagnostic List 2021	2021
	2	Malaria strategic plan 2014-2020	2014-20
	3	Second national strategic health development plan 2:	
	4	Nigeria national laboratory services policy 2021-2025 (before 2015-2019) (not in QUANT)	2021-25
	5	Nigeria national laboratory strategic plan 2021-2025 (draft – not for reference – not in QUANT))	2021-25
	6	Medical Laboratory Science Council of Nigeria: Guidelines for in-vitro diagnostics 2018. [guidelines how to regulate IVDs, not the actual list of IVDs; not in QUANT)	2018
Uganda		Standard test menu, techniques, and list of supplies for health laboratories in Uganda (3rd edition, 2017-2020)	2017-20
Zimbabwe	1	UMARU, F.A. 2015. Laboratory harmonisation and standardisation in Zimbabwe: A framework for improving the quality of diagnostics services through standardisation of tiered network, tests techniques, methods, instruments, and human resources in Zimbabwe.	2015
	2	National health laboratory strategic plan (draft2) 2022-2026. Ministry of Health and Child Care	2022-26

ANNEX 4: COUNTRY PROGRESS IN DEVELOPING NEDLS, WITH RELEVANT DOCUMENTS

Country	Overall Country's progress by colour code and listing of documents
Nigeria	> Nigeria National Essential Diagnostics List 2021
Botswana	> Standardisation and Laboratory Logistics System Design for Botswana 2019
Burkina Faso	> Normes en Matière de Laboratoires d'Analyses de Biologie Médicale Juillet 2009
Cameroon	> Organisation des Laboratoires Suivant la Pyramide Sanitaire au Cameroun 2011
Ethiopia	> The Master Plan for the Public Health Laboratory System 2009-2013
Gabon	> Health Sector Standards 2012
Kenya	> Kenya Essential Medical Laboratory Commodity List 2014
Malawi	> Standardisation of Laboratory Tests, Techniques and Equipment 2009
Uganda	> Standard Test Menu, Techniques and List of Supplies for Health Laboratories in Uganda 2017-2020
Zimbabwe	> Laboratory Harmonisation and Standardisation in Zimbabwe 2015
Tanzania	> Standard Medical Laboratory Equipment Guideline 2018
Angola	> The National Health Development Plan 2012 – 2025
Benin	> Plan Stratégique National – Tuberculose 2015-2018 > President's Malaria Initiative Malaria Operational Plan 2016 > Integrated National Strategic Plan Oriented towards Elimination of HIV / AIDS, Tuberculosis, Malaria, Viral Hepatitis, STIs and Diseases with Epidemic Potential 2020-2024 > National Action Plan of the Benin's Health Security 2019-2021
Burundi	> Plan Stratégique de Lutte contre la Tuberculose 2011-2015
CAR	> Health District Standards in The Central African Republic 2009
Côte d'Ivoire	> Plan Stratégique National De Lutte contre la Tuberculose 2016-2020
DRC	> Recueil des Normes d'Organisation et Fonctionnement des Structures Sanitaires de la Zone de Santé République Démocratique du Congo, Juillet 2012
eSwatini	> Essential Health Care Package for Swaziland 2010
Ghana	> National Tuberculosis Health Sector Strategic Plan 2009-2013
Lesotho	> National Tuberculosis Programme Policy and Manual 2004
Liberia	> Essential Package of Health Services 2011 > Maternal and New-born Health Roadmap 2007 > National Standard Therapeutic Guidelines and Essential Medicines List, 2nd-Edition 2017 > National Health and Social Welfare Policy Plan 2011-2021
Mauritania	> Rapport d'Activités sur la Réponse au Sida en Mauritanie 2014
Mauritius	> National Response and Contingency Plan in the Eventuality of a Resurgence of Covid-19 Circulation 2021
Namibia	> Namibia Malaria Strategic Plan 2010-2016
Somalia	> Somalia National Strategic Plan for Malaria, 2011-2015
South Africa	> Primary Health Care Laboratory Handbook, May 2018
Zambia	> The National Tuberculosis and Leprosy Control Program 2017

Country	Overall Country's progress by colour code and listing of documents
Cape Verde	> IV Plano Estrategico Nacional VIH-SIDA 2020
Chad	> Plan Stratégique National de Lutte contre Le Paludisme 2019-2023
Djibouti	> National Malaria Control Strategy 2020-2024 > Report of the Review of the National Fight Against the Djibouti Tuberculosis 2018-2022
Equatorial Guinea	> National Health Development Plan 2021-2025
Guinea	> Communication Plan for the Fight Against Malaria 2018-2022 > National Committee of Struggle Against Aids 2013-2017 > National Strategic Plan for Maternal Health, of the New-born, of the Child, of the Adolescent and Youth 2016-2020 > National Strategic Plan to Combat Malaria 2013-2017 > President's Malaria Initiative 2018
Guinea Bissau	> Plan Stratégique Cholera Guinee Bissau, 2019-2013 > Plan Nacional do Desenvolvimento Sanitário 2008-2017
Madagascar	> Plan de Développement du Secteur Santé 2020-2024 > Plan-Stratégique-SISAL-2016-2020
Mozambique	> Health Sector Strategic Plan 2014-2019 > Implementing Laboratory Quality Management Systems in Mozambique 2011-2012 > Maternal and Child Health Integrated Program 2011-2015 > Mozambique Country Operational Plan for HIV COP 2021 > National Malaria Control Programme 2017-2022 > National Strategic Plan Tuberculosis Control 2018-2012 > NCD Joint Programming Mission 2015
Rwanda	> Malaria Strategic Plan 2020-2024 > Strategic Plan for HIV 2013- 2020 > Harmonised LMIS System Design Review and SOP Curriculum Development; Technical Report 2013 > Tuberculosis National Strategic Plan 2013-2018 > National Medical Laboratory Policy 2005
Sao Tome and Principe	> Comprehensive Multi-Year Plan 2016-2020 > Country Co-Operation Strategy 2010-2012 > Eliminating Malaria Briefing Document 2013 > Política Nacional de Saúde 2012
Seychelles	> National Health Strategic Plan 2022-2026
Sierra Leone	> Basic Package of Essential Health Services 2010 > National Leprosy and Tuberculosis Strategic Plan 2016-2020 > National Strategic Plan on HIV/AIDS 2016-2020 > Reproductive, Maternal, New born, Child and Adolescent Health Strategy 2017-2021 > Sierra Leone Malaria Control Strategic Plan 2016-2020 > Sierra Leone Non-Communicable Disease & Injuries Poverty Commission: Findings & Recommendation 2018-2022 > National Medical Laboratory Strategic Plan 2016-2020
South Sudan	> Guideline for Tuberculosis & HIV Prevention, Care and Control 2016 > National Health Policy 2016-2026 > National Reproductive Health Strategic Plan 2013-2016 > South Sudan Social and Behavioural Strategy for HIV and Aids Prevention, Care and Treatment 2018-2020

Country	Overall Country's progress by colour code and listing of documents
Sudan	> National Health Policy 2007 > National Health Sector Strategic Plan II 2012-2016 > Sudan Malaria Treatment Protocol 2017 > Sudan National Strategic Plan and Sectoral Plans on HIV/AIDS 2004-2009 > Sudan National Tuberculosis Management Guideline 2018
Congo	> National Strategic Framework for the Fight Against HIV / AIDs and STIs 2014-2018
Comoros	> Plan Stratégique de Lutte Contre le Paludisme 2007 – 2014 > Plan Stratégique National de Lutte Contre le VIH et le Sida 2015-2019 > Document de Stratégie Nationale de Prévention et de Lutte Contre les Maladies Non Transmissibles Mars 2013 > Plan National de Développement Sanitaire 2010-2014 > Politique Nationale de Sante (PSN) Février 2015 > Programme National de Lutte Contre La Tuberculose et la Lèpre Comores Nov 2011 > Plan Stratégique National (PSN) de Lutte Contre le VIH/le Sida 2011-2015
Niger	> Plan Stratégique National de la Recherche en Santé 2013 – 2020 > Politique Nationale de Santé 2016 > Plan Stratégique National du Système d'Approvisionnement en Produits de Santé 2019-2023

COLOUR CODE KEY

NEDL

Has document(s) aimed at standardising/harmonising testing across disease programmes

Has a document(s) that has defined testing per the tiered network

Has documents defining testing but not per the tiered network

Countries with documents addressing laboratories, but not testing

ANNEX 5: RECOMMENDED IVDS AT COMMUNITY AND FACILITY LEVEL IN WHO EDL 2

Disease/ Program	Tests for community settings and health facilities without laboratories	Tests for health care facilities with clinical laboratories on site
HIV	> HIV 1/2 antibody (RDT) > Combined HIV antibody/p24 antigen (RDT) > Qualitative HIV virological nucleic acid test (EID-PoC) > CD4 cell enumeration (POC) > Cryptococcal antigen-CrAg ((RDT)	> HIV 1/2 antibody (RDT/Immunoassay) > Combined HIV antibody/p24 antigen (RDT/ELISA) > Immunoglobulin plasma levels (IgG, IgA, IgM)- (RID/ELISA) > Qualitative HIV virological nucleic acid test (EID NAAT) > Quantitative HIV virological nucleic acid test-(VL NAAT) > Lymphocyte subtype enumeration: CD4, CD8, CD20 and CD15/26 cells (Flow Cytometry) > Cryptococcal antigen-CrAg (RDT/ELISA)
Tuberculosis	> Tuberculin skin (Mantoux) test	> TB (Microscopy) > TB Culture/DST > TB Nucleic Acid Test (Genexpert) > TB Nucleic Acid Test (TB LAMP) > M. tuberculosis DNA mutations associated with resistance (Molecular Line Probe Assay -LPA) > Lipoarabinomannan (LAM) antigen (RDT)
Malaria	> Malaria RDT	> Malaria – RDT > Malaria – Light Microscopy > Glucose-6- phosphate dehydrogenase (G6PD) activity > (Semi quantitative fluorescent spot test)
MNCH	> Syphilis (RDT)	> Syphilis (RDT/ELISA) > Antibodies to T. pallidum and to HIV-1/2 (RDT) > Non-treponemal rapid plasma reagin (RPR) test (Particle/ charcoal agglutination assay) > Non-treponemal venereal disease research laboratory (VDRL) test (Flocculation test) > T. pallidum haemagglutination (TPHA) test