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Diagnosis for all

Practical Guidance for the Development of National Essential Diagnostics Lists

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CONTENTS

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This document was developed by Pascale Ondoa, Michael Maina, Francis Ocen, Collins Otieno and Elisheba Mutegi (ASLM); Kekeletso Kao, Lucy Perrone, Mikashmi Kohli and Ezekiel Borro (FIND), and Winny Koster, Albert Gautier Ndione and Talya Underwood (consultants).

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ABBREVIATIONS AND ACRONYMS

Africa CDC	Africa Centres for Disease Control and Prevention
EDL	Essential diagnostics list
IVD	In vitro diagnostic
NEDL	National essential diagnostics list
NEML	National essential medicines list

1. PURPOSE OF THIS GUIDE

This guide is intended to provide countries in Africa with guidance around developing a national essential diagnostics list (NEDL) or revising their harmonisation documents on in vitro diagnostics (IVDs). The guide is intended as a companion to the World Health Organization's (WHO's) publication 'Selection of Essential In Vitro Diagnostics at Country Level', to provide practical guidance to African countries on developing an NEDL. The advice and tools provided within the guide will help countries develop NEDLs that are appropriate for their settings and aligned with universal health coverage goals and priorities for the continent as set out by the Africa Centres for Disease Control and Prevention (Africa CDC).

Recognising that countries will differ in the extent of their existing formal guidance around IVDs, this document provides guidance for developing, updating and revising NEDLs as required. This guide is intended for ministries of health, particularly those involved in IVD guidelines, policy- and decision-makers, and other stakeholders involved in developing guidelines around IVDs at the state and national level.

2. INTRODUCTION: THE IMPORTANCE OF A NATIONAL ESSENTIAL DIAGNOSTIC LIST

IVDs are medical devices that can detect diseases, conditions and infections.[1] IVDs can range from small, rapid point-of-care tests (for example, lateral flow tests) to more complex equipment conducted by trained personnel in a laboratory environment. An NEDL is a document that lists categories of IVDs that should be available, as a priority, at different levels of the national healthcare system.

NEDLs are key documents to help countries increase access to essential IVDs. An NEDL helps countries identify the most important IVDs to make available in the healthcare system for the national context and to support universal health coverage. An NEDL can also be used to allocate budgets for priority IVDs at different levels of the healthcare system. NEDLs are aspirational documents, as they allow countries to work towards achieving a target list of essential diagnostics.

In 2018, WHO published its first model essential diagnostics list (EDL), as an evidence-based list of essential IVD categories and recommended assay formats for those tests.[2] The model list provides guidance to countries on which tests are recommended and not recommended. A third edition of the model list was published in 2021.[3] In 2021, WHO also published a guide to using the WHO Model List to select essential IVDs at the country level.[4] In this guide, we provide contextualised guidance and resources to support African countries in developing and updating NEDLs in line with WHO guidance.

[1] World Health Organization. In vitro diagnostics.
Available from: https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1 (accessed 15 November 2022).

[2] World Health Organization. First WHO Model List of Essential In Vitro Diagnostics. 2018.
Available from: https://apps.who.int/iris/rest/bitstreams/1213140/retrieve (accessed 15 November 2022).

[3] World Health Organization. The selection and use of essential in vitro diagnostics. 2021.
Available from https://www.who.int/publications/i/item/9789240019102 (accessed 15 November 2022).

[4] World Health Organization. Selection of Essential In Vitro Diagnostics at Country Level. 2021.
Available from: https://www.who.int/publications/i/item/9789240030923 (accessed 15 November 2022).

3. DEVELOPMENT AND UPDATING OF A NATIONAL LIST OF ESSENTIAL IN VITRO DIAGNOSTICS

3.1 Guiding principles

Although processes for developing and updating NEDLs may vary by country, the following guiding principles are recommended to support the development of effective NEDLs:

Ensure political commitment and active involvement of the Minister of Health.

The Minister of Health can ask partners to financially support the development and implementation of an NEDL and ensure allocation of adequate resources to support the provision of IVDs in the NEDL.

Involve all relevant stakeholders in the NEDL development process.

Inclusion of stakeholders in decision-making discussions encourages involvement and ownership, and helps ensure that the outputs are relevant for the setting. Stakeholders for NEDL development should include laboratory scientists, regulatory bodies and procurement agencies.

Secure appropriately skilled personnel.

Leverage existing personnel with appropriate experience where possible, but consider recruiting local consultants to lead the process, to avoid overburdening Ministry of Health staff and enable the timely completion of the project. Appoint local laboratory scientists who are experts on IVDs and who are well respected in the country as part of the technical working group.

Utilise a systematic, evidence-based evaluation for developing and updating the NEDL.

Evaluations should start with assessing existing guidance around IVDs in the country.

Develop the NEDL in line with aspirational values.

The NEDL should include tests that will enable equitable access to testing for routine and outbreak care and support universal health coverage.

Plan and budget for the implementation of the NEDL.

Funding should be included for the validation, regulation and procurement of brands of the IVDs on the NEDL and the identification of necessary supplies, personnel and equipment.

Develop a framework to monitor and evaluate the NEDL.

Monitoring and evaluation are essential for ensuring the document remains up-to-date and relevant.

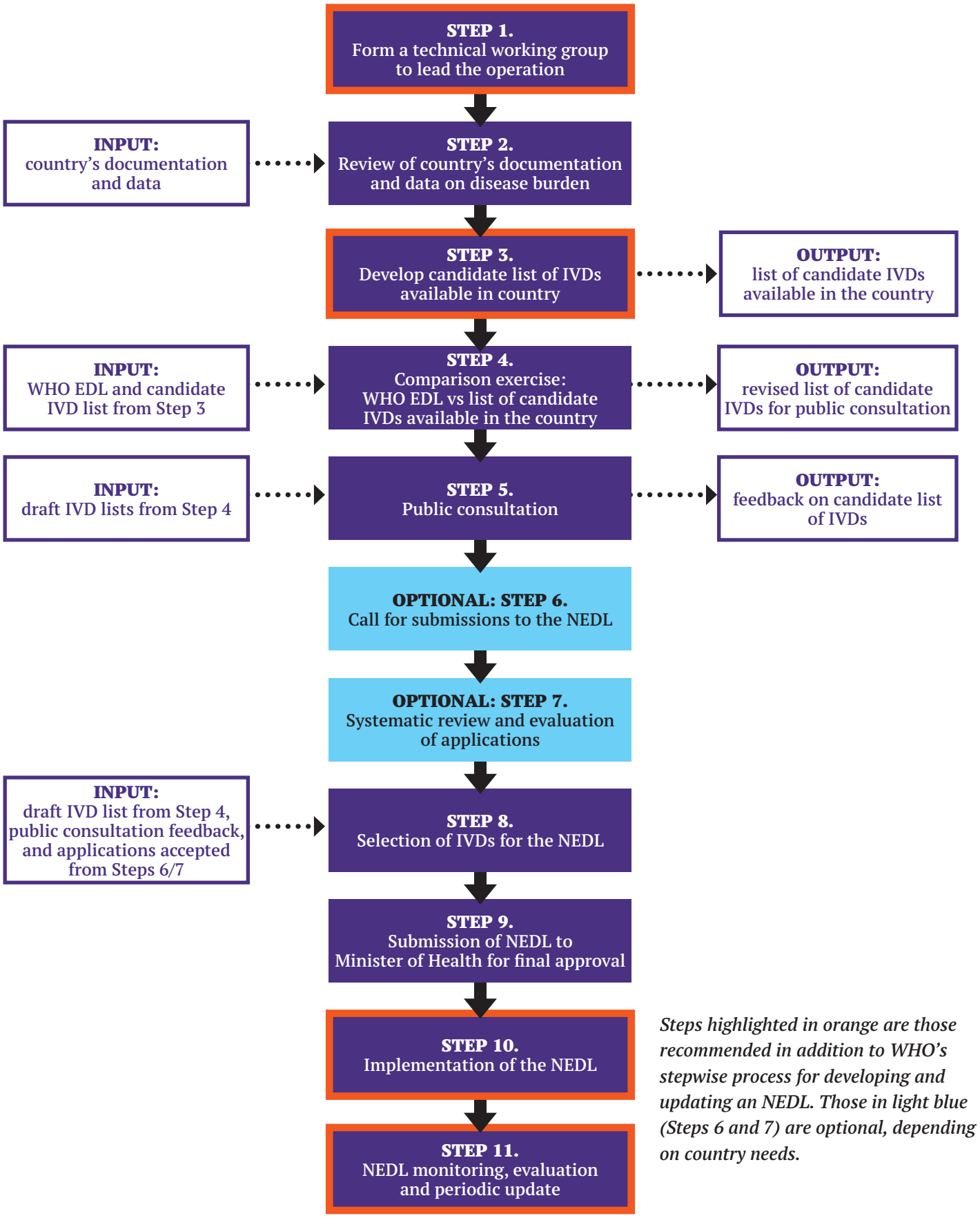
Periodically update the NEDL at pre-defined timepoints.

Periodic updates allow countries to incorporate changes to priority diseases (e.g., new outbreaks), new evidence and new IVDs.

3.2 Process

Figure 1 outlines the key steps involved in developing or updating an NEDL and the key inputs/outputs at each step. If countries wish to update their laboratory harmonisation documents, rather than develop a standalone NEDL, the guidance provided here can be applied broadly to guide the revision of the harmonisation document.

Figure 1. Key steps for developing or updating an NEDL



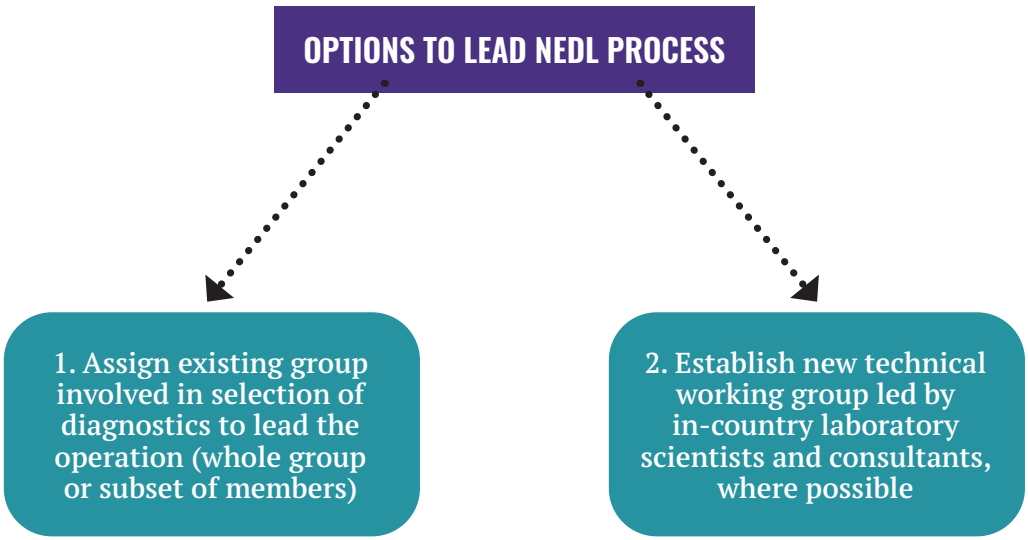
Steps highlighted in orange are those recommended in addition to WHO's stepwise process for developing and updating an NEDL. Those in light blue (Steps 6 and 7) are optional, depending on country needs.

Step 1. Formation of technical working group to lead the operation

RECOMMENDATION: The Minister of Health should appoint a technical working group to lead the development or updating of an NEDL, or assign an existing group (e.g., national laboratory technical working group), if they have suitable experience and bandwidth.

The process of developing or updating an NEDL requires the commitment and active involvement of the country's Minister of Health. Prior to beginning work on the NEDL, agreement from the Minister of Health for the project should be established, alongside a draft budget.

To develop or update an NEDL, the Minister of Health should either form a technical working group for this purpose or use an existing group responsible for selecting diagnostics, if they have suitable experience and bandwidth. In countries where there is an established national laboratory technical working group, this group can be assigned to lead the operation, with relevant stakeholders co-opted as needed. Where new working groups are established, respected in-country laboratory scientists who are familiar with IVDs should be appointed to lead the process. Working groups can also include stakeholders from national reference laboratories, and from disease programmes (e.g., from the tuberculosis and HIV programmes, and non-communicable disease programmes). Where possible, consultants who understand the country context should be recruited to lead the process to ensure the timely completion of tasks.



Step 2. Review of country's documentation and data on disease burden to identify testing gaps and needs

RECOMMENDATION: Evaluate the country's existing policies and documentation around IVDs, laboratory services, etc., or conduct a formal survey of the laboratory landscape to identify testing gaps and needs. Review data on disease burden and identify priority diseases that require IVDs based on epidemiological data and Africa CDC risk ranking tool.

The first step in developing or updating an NEDL/harmonisation document requires evaluation of the country's existing policies and documentation around IVDs, national laboratory services, national health programmes and health system tiers to understand the ecosystem within which the document will operate. It is also important to review data on disease burden to ensure that prioritisation of IVDs is tailored to the specific epidemiological setting, to ensure coverage of diseases prevalent in the country beyond priority diseases (e.g., tuberculosis and HIV). The NEDL should also be aligned with the national healthcare/laboratory delivery structure. This includes

considering the different tiers of the health system and the location of laboratory services across these tiers (for example, which levels of the health system/types of facilities have access to multiplex testing devices like GeneXpert, and consideration of the capabilities of community health workers). It is also essential that the NEDL is informed by the national essential medicines list (NEML) to ensure that treatments are available for the conditions covered by the NEDL. Together, evaluation of these factors will ensure each country can develop an NEDL appropriate for their context, disease priorities, epidemiology, health facility structure and laboratory network.

Countries may wish to undertake a formal survey of the laboratory landscape at this stage, if there are sufficient resources available for such a project and it is deemed important to fully characterise the laboratory landscape. This formal survey should cover questions such as IVDs currently used at the different laboratories, priority diseases, human resources, equipment, infrastructure and barriers to access IVDs. The survey should aim to capture input from laboratories across the health system (e.g., public and private laboratories at primary, secondary and tertiary levels). Findings from the survey should be analysed using a systematic approach. However, if it is felt that a full landscape survey is not needed or not feasible, the technical working group can conduct a desk review of laboratory policies and documentation around IVDs.

Key documents to review include those related to the selection and prioritisation of diagnostic tests, including local policies and national reference documents, such as laboratory standardisation and harmonisation guidelines. It is also important to consider when the documents were last updated and to what extent they may be out of date.

Documents most likely to contain information on diagnostic availability by level include:

Annex 1 provides examples of such documents for selected African countries, identified as part of a review conducted by ASLM.

Published data on disease epidemiology should also be reviewed to enable understanding of existing and emerging diseases to guide the selection of IVDs. Both communicable and non-communicable diseases should be ranked as a function of prevalence, morbidity and mortality, based on local epidemiology data, if available. If information on local epidemiology is not available, the WHO list of priority disease can be consulted instead.[5]

The Africa CDC, in collaboration with the European Centre for Disease Prevention and Control, has recently developed a risk ranking process that can also be applied for this task. This methodology allows risk ranking for infectious diseases of epidemic potential to identify priority diseases for emergency preparedness and response.[6] **Table 1** shows the 19 criteria categorised across four groups developed as part of this process, which countries can apply to rank the risk of infectious diseases in their settings.

Table 1. Criteria for evaluating the risk of infectious diseases of epidemic potential in Africa

Category	Criteria
Risk trajectory	**1.** Probability of the pathogen circulating among humans in the African region in the next five years. **2.** Probability that the risk increases in the next five years in Africa.
Epidemic potential	**3.** Transmissibility of the pathogen in comparison with other pathogens being prioritised. **4.** Population susceptibility: how many regions in Africa have high pools of susceptible populations, in comparison with the other pathogens being prioritised. **5.** Probability of the pathogen causing a cross-country outbreak: what is the likelihood, compared with other pathogens being prioritised, that the pathogen could lead to a cross-country outbreak?
Disease severity	**6.** Peak infection fatality rates. **7.** Proportion of cases that lead to severe disease. **8.** Estimated economic impact of an outbreak of the disease in comparison with other pathogens being prioritised. **9.** Estimated economic impact of an outbreak of the disease in comparison with other pathogens being prioritised. **10.** Estimated social impact of an outbreak of the disease in comparison with other pathogens being prioritised.
Preparedness and countermeasures	**11.** Level of public health preparedness to deal with an outbreak of the pathogen in comparison with other pathogens being prioritised. **12.** Vaccines (availability of vaccines, effectiveness of vaccines, anticipated societal acceptance of vaccines). **13.** Pharmaceutical countermeasures: **13a.** Availability of pharmaceutical countermeasures, **13b.** Effectiveness of pharmaceutical countermeasures, **13c.** Anticipated societal acceptance of pharmaceutical countermeasures. **14.** Public health and social measures, particularly non-pharmaceutical interventions: **14a.** Availability of non-pharmaceutical measures for controlling an outbreak (e.g., case isolation, contact tracing, mosquito-nets, etc.), **14b.** Effectiveness of non-pharmaceutical measures for controlling an outbreak, **14c.** Anticipated social acceptance of non-pharmaceutical measures.

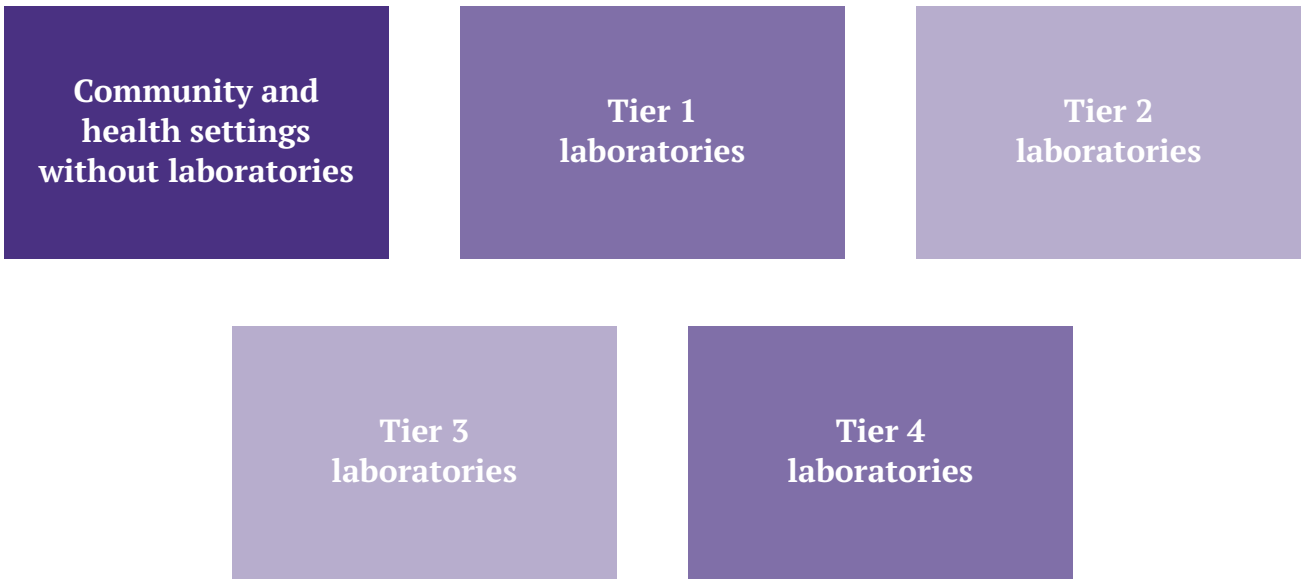
[5] World Health Organization. Prioritizing diseases for research and development in emergency contexts. Available from: https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts (accessed 15 November 2022).

[6] Africa Centres for Disease Control and Prevention. Risk ranking and prioritisation of epidemic-prone diseases first edition (DRAFT). 2022. Available at (link to be added once published).

Step 3. Development of candidate list of IVDs available in the country

RECOMMENDATION: **Develop a candidate list of IVDs available in the country using information from country documentation and the existing NEDL if available. Assign IVDs to tiers based on the laboratory network, as shown below.**

From the evaluation of country documents conducted in Step 2, a candidate list of IVDs available in the country should be developed. For countries with an existing NEDL, the candidate list should include IVDs on the existing NEDL and any other IVDs recommended in other country documentation. Because laboratory tiers are not always consistent across levels of the health system, it is recommended that laboratory tiers, rather than healthcare tiers, be used when assigning IVDs as part of the NEDL. As such, it is recommended that the candidate list of IVDs in the country is structured by the categories shown below:[7]



IVDs should be assigned to these different tiers using the information gathered from the initial review (e.g., in terms of where IVDs are currently used and where IVDs could be used based on available infrastructure). Annex 2 provides a template that can be used to develop the candidate list of IVDs.

[7] World Health Organization. The selection and use of essential in vitro diagnostics. 2021. Available from https://www.who.int/publications/i/item/9789240019102 (accessed 15 November 2022).

Step 4. Comparison exercise: WHO EDL versus list of candidate IVDs available in the country and development of draft NEDL for public consultation

RECOMMENDATION: **Compare the candidate list of IVDs available in the country with the WHO EDL to identify those that match and can therefore be recommended. Consider which IVDs on the WHO EDL, currently not included in the candidate list, would be suited for the country's context, disease burden and public health priorities. Update the candidate list accordingly to create a draft aspirational list of IVDs.**

Once the list of candidate IVDs has been created, this should be compared against the WHO EDL list to identify those that match in terms of test category, test purpose and assay format. The template provided in Annex 2 includes a column for this step, where users can record whether the IVD is included on the WHO EDL list. Candidate IVDs that match those listed in the WHO EDL may be considered for the NEDL without further evidence. For candidate IVDs not listed in the WHO EDL, countries may wish to seek further evidence to support their inclusion, unless their value is already well demonstrated in the country. IVDs currently included in country guidance but not recommended by WHO (those listed under the 'Do Not Do recommendations' section), should be removed from the candidate list.[8]

In this step, the country's NEDL working group should also consider the test categories and specific IVD formats listed in the WHO EDL, not currently in the candidate list, that would be suited for their country's context, disease burden and public health priorities. To improve access to diagnostic tests, consideration should also be given to IVDs that can be conducted at or near the point of care by lower-level healthcare workers (e.g., community healthcare workers). A template is provided in Annex 3 for developing a draft NEDL for public consultation, which includes both candidate IVDs available in country and those identified from the WHO EDL as important to include.

[8] World Health Organization. The selection and use of essential in vitro diagnostics. 2021. Available from https://www.who.int/publications/i/item/9789240019102 (accessed 15 November 2022).

Step 5. Public consultation

RECOMMENDATION: **Submit the draft NEDL list from Step 4 for public consultation on relevant websites and through dissemination to recommended stakeholders to obtain comprehensive feedback on proposed IVDs.**

The outputs from Step 4 should be posted for public consultation on relevant national websites and disseminated to key stakeholders, allowing sufficient time for review (four weeks recommended). This step is important to ensure that key stakeholders involved in the various aspects of recommending, procuring and testing with IVDs can provide input into the NEDL.

Key stakeholders for consultation may include:

Ministry of Health

- Including medical directors and other senior officials

Public and private sector laboratory services

- Managers and directors in charge of public and private sector laboratories

Professional health associations

- For microbiologists, medical doctors, laboratory staff

Disease surveillance and epidemiology personnel

Research groups and academic institutions

Implementing partners

- For example: Clinton Health Access Initiative, Elizabeth Glaser Pediatric AIDS Foundation, Amref Health Africa, Fondation Mérieux, Médecins Sans Frontières

Regulatory and procurement agencies

Technical partners

- For example: World Health Organization, United States President's Emergency Plan for AIDS Relief (PEPFAR), Africa Centres for Disease Control and Prevention

Funding agencies

- For example: The Global Fund to Fight AIDS, Tuberculosis and Malaria; PEPFAR; Bill & Melinda Gates Foundation

Other government departments

- For example: Departments for gender, children and social protection, Ministry of Youth and Sports

Other key stakeholders:

- Traditional medicine representatives
- Civil society organisations
- Faith-based organisations
- General public
- Political leaders

OPTIONAL:
Step 6. Call for submissions to the NEDL

The technical working group may wish to allow submissions to the NEDL for IVDs not listed in the WHO EDL or not currently available in the country, but deemed relevant for the country's public health priorities and epidemiology. This step may be useful if it is felt that there is a specific diagnostic need not met by IVDs currently available in the country or recommended by the WHO EDL. If undertaken, countries should follow the guidance issued by WHO for this step in the guide 'Selection of Essential In Vitro Diagnostics at Country Level' (covered on page 13).

OPTIONAL:
Step 7. Systematic review and evaluation of applications

If countries call for submissions to the NEDL, a process should be developed for systematically reviewing and evaluating applications. Countries should refer to the guidance issues by WHO for this step in the guide 'Selection of Essential In Vitro Diagnostics at Country Level' (covered on pages 13-14).

Step 8. Selection of IVDs for the NEDL

» **RECOMMENDATION: The technical working group should develop an initial NEDL based on the draft list, feedback from public consultation and successful applications (if optional steps are undertaken) and based on the key considerations discussed in this section. The initial list should be developed by the core NEDL technical working group, before being shared with the wider group and key stakeholders for review and finalisation.**

The selection of IVDs for the NEDL should be based on the draft list produced in Step 4 of the process shared for public consultation, feedback from the public consultation and the results of the systematic evaluation of applications in Step 7 (if undertaken). The core NEDL working group should subsequently organise meetings for the full working group to discuss and agree upon IVDs for the NEDL.

Recommended considerations for selecting IVDs by laboratory tier are shown in **Table 2**:

Table 2. Considerations for selecting IVDs for the NEDL.

1.	The types and capacities of laboratory and clinical personnel present at each healthcare tier.
2.	Laboratory infrastructure and amenities at each tier of the healthcare system, including access to electricity, reagent-grade water, phlebotomy and specialised human resources.
3.	IVDs already present at different levels of the healthcare system.
4.	Disease burden and priority healthcare needs of the population, particularly where IVDs have a clear impact on the diagnosis and management of a condition.
5.	Which IVDs are required for critical supportive tests, such as complete blood count and C-reactive protein, to support diagnosis and monitoring.
6.	Existing vertical disease programmes and their needs (e.g., tuberculosis, malaria, HIV).
7.	Accessibility of healthcare facilities and laboratories, and existing sample referral networks to assess the practicality of transporting diagnostic samples.
8.	Which IVDs can be used at the community level and in facilities without an on-site laboratory to expand access to testing.
9.	Which tests enable safe and rational use of the NEML.
10.	Price and affordability of recommended IVDs.

Once the NEDL technical working group has developed an initial draft of the NEDL, workshops should be arranged with key stakeholders to obtain feedback on the draft document. Key stakeholders for reviewing the NEDL should include personnel from different Ministry of Health departments, laboratory specialists, representatives from different healthcare tiers, regulatory bodies, professional associations, implementing partners, civil society, and international funding and technical partners.

Step 9. Submission of NEDL to Minister of Health for final approval

» **RECOMMENDATION: Submit the finalised NEDL to the Minister of Health and any other national/governmental/legal bodies for approval as required by the country's legislation.**

Finalised NEDLs should be sent to the Minister of Health for final approval and endorsement. Depending on the local context, the NEDL may need approval from the Prime Minister's office, the National Assembly, or a Directorate of Legal Affairs and Litigation (if legal approval is required). Following approval, the NEDL should be embedded as policy.

Step 10. Implementation of the NEDL

» **RECOMMENDATION: Develop a plan for implementing the NEDL, which includes the specific brands of IVDs and other material to be procured, a budget for approval by the Minister of Health, plans for the procurement of specified IVDs, and training of personnel to conduct testing (among other factors).**

Plans for implementing an NEDL must be developed early on in the process to ensure plans are feasible and aligned with existing health programmes and infrastructure.

Key steps in implementing an NEDL are listed in **Table 3**, although the specific process will need to be adapted to the local context.

Table 3. Recommended steps for implementation of NEDL

Step No.	Recommended step
1.	**Selection of specific brands of IVDs** to be used in the country and **identification of required equipment, reagents and consumables** for the tests listed on the NEDL. This equipment should be verified and validated by the national laboratory team.
2.	**Costing of the NEDL** and preparation of a budget for approval by the Minister of Health.
3.	**Anchoring of the NEDL in legislation** to mandate that the Ministry of Health, disease programmes and private laboratories should use the NEDL.
4.	**Organisation and coordination of bulk procurement** of selected IVDs, consumables and reagents.
5.	**Alignment with key stakeholders** from different states, governmental departments, national disease programmes and the public/private healthcare sector on IVD policies and implementation.
6.	**Training and recruitment of qualified personnel to conduct testing** where required (e.g., if new IVDs are introduced, if additional personnel are required to conduct expanded testing).

WHO has issued guidance around the procurement of IVDs and related equipment that can be used to guide procurement decisions. The list of WHO-prequalified IVDs should also be consulted regarding which IVDs have been assessed by WHO and deemed acceptable for procurement by United Nations agencies.

Beyond the development of a general NEDL, countries may also wish to recommend specific brands of IVDs and equipment. In this case, key considerations should include the following **(Table 4)**:

Table 4. Key considerations if recommending specific brands of IVDs and equipment

Topic	Key consideration
Safety	Demonstrated and acceptable safety in expected way of use for healthcare workers and patients.
Quality	Products should comply with internationally acceptable quality standards, as recognised by national or other recognised regulatory bodies.
Performance	Sensitivity and specificity should meet the WHO requirements for each product.
Comparative cost-benefit	Products should have a favourable cost-benefit ratio (in terms of use) compared with alternative products.
Local suitability	Preference should be given to a test or supplies with which laboratory staff are familiar, and those that are reliably available in the local setting.
Local manufacture	Priority should be given to tests manufactured locally or regionally to improve availability and reduce costs (and dependence on global supply chains).

Step 11. NEDL monitoring, evaluation and periodic update

RECOMMENDATION: **Monitor and evaluate the NEDL to assess the suitability of IVDs on the list for the country context. Update the NEDL periodically to ensure the list remains appropriate.**

To ensure the NEDL remains useful and reflective of a country's priorities, plans also need to be developed to monitor, evaluate and periodically update the NEDL. Existing monitoring and evaluation systems for the laboratory network can be applied to assess the suitability and performance of the IVDs on the list. The NEDL should be reviewed at periodic intervals (e.g., annually) by the technical working group to ensure that the list remains appropriate and to capture any changes around available IVDs and disease priorities (e.g., as a result of new outbreaks).

FURTHER READING

WHO resource page on IVDs:

World Health Organization. In vitro diagnostics.
Available from: https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1
(accessed 15 November 2022).

Third WHO EDL list:

World Health Organization. The selection and use of essential in vitro diagnostics. 2021.
Available from https://www.who.int/publications/i/item/9789240019102
(accessed 15 November 2022).

WHO guide to selection of essential IVDs at a country level:

World Health Organization. Selection of Essential In Vitro Diagnostics at Country Level. 2021.
Available from: https://www.who.int/publications/i/item/9789240030923
(accessed 15 November 2022).

WHO guidance for the procurement of IVDs and related equipment:

World Health Organization. Guidance for procurement of in vitro diagnostics and related laboratory items and equipment. 2017. Available from:
https://www.who.int/publications/i/item/9789241512558
(accessed 15 November 2022).

WHO list of prequalified IVDs:

World Health Organization. Prequalified In Vitro Diagnostics.
Available from: https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists
(accessed 15 November 2022).

ANNEX 1. EXAMPLE NATIONAL AND PROGRAMME DOCUMENTS THAT ADDRESS IVDS BY TIERS OF THE LABORATORY SYSTEM FROM SELECTED AFRICAN COUNTRIES

Country	Name of document and link	Date/years covered
Burkina Faso	Liste Nationale des Médicaments et Consommables Médicaux Essentiels Burkina Faso; Ministère de la Santé, Burkina Faso. *Link*	2014
	Malaria Operational Plan Fiscal Year 2019. *Link*	2019
Ethiopia	HIV/AIDS National Strategic Plan for Ethiopia. *Link*	2021–2025
	Master Plan for The Public Health Laboratory System In Ethiopia (Second Edition). *Link*	2009–2013
	Pharmaceutical procurement list, first edition, Addis Ababa, 2018. *Link*	2018
Kenya	Kenya Essential Medical Laboratory Commodity List; Published by the Ministry of Health – 2019. *Link*	2019
Nigeria	Nigeria National Essential Diagnostic List 2021	2021
	Medical Laboratory Science Council of Nigeria: Guidelines for In-Vitro Diagnostics Regulation in Nigeria. *Link*	2018
Uganda	Standard test menu, techniques, and list of supplies for health laboratories in Uganda (3rd edition, 2017–2020). *Link*	2017–2020

ANNEX 2. TEMPLATE FOR CANDIDATE LIST OF IVDS CURRENTLY USED IN COUNTRY

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type	Included in WHO EDL? Yes/No
Community and health settings without laboratories:					
Blood typing*	A, B and O blood groups and Rhesus factor	To determine blood group types (A, B and O) and Rhesus type	Slide agglutination test	Capillary whole blood Venous whole blood	Yes
Tier 1 laboratories					
Tier 2 laboratories					
Tier 3 laboratories					
Tier 4 laboratories					

*Example entry (taken from WHO EDL guide, World Health Organization. The selection and use of essential in vitro diagnostics. 2021. Available from https://www.who.int/publications/i/item/9789240019102).

ANNEX 3. TEMPLATE FOR DRAFT NEDL FOR PUBLIC CONSULTATION

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	Supporting documents (national and WHO)
Community and health settings without laboratories:						
IVDs from candidate list						
Other IVDs from WHO EDL deemed a priority for country						
Tier 1 laboratories						
IVDs from candidate list						
Other IVDs from WHO EDL deemed a priority for country						
Tier 2 laboratories						
IVDs from candidate list						
Other IVDs from WHO EDL deemed a priority for country						
Tier 3 laboratories						
IVDs from candidate list						
Other IVDs from WHO EDL deemed a priority for country						
Tier 4 laboratories						
IVDs from candidate list						
Other IVDs from WHO EDL deemed a priority for country						