Open session
5th meeting of the Strategic Advisory Group of Experts on IVDs

World Health Organization

25 November 2024
Geneva, Switzerland

Introductory remarks by Dr Yukiko Nakatani, Assistant Director-General, Access to Medicines and Health Products

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Open session
5th meeting of the Strategic Advisory Group of Experts on IVDs

Housekeeping rules

- Please share your questions and comments through the Q&A feature
- Questions and comments will be addressed online as well as orally (as time permits) during the webinar Q&A session
- Questions not answered during the time of the open session will be addressed afterward and posted on the WHO website
- This webinar will be recorded, and the link will be available on the WHO website

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Meeting objectives

The objective of the 5th SAGE IVD meeting is to discuss and make recommendations on policies and strategies related to in vitro diagnostics and the WHO model list of essential in vitro diagnostics (EDL), including:

- Present the work of the EDL Secretariat and colleagues on improving access to in vitro diagnostics (IVDs) and collect input from stakeholders during the open session
- Review the submissions received for addition of IVDs for the fifth edition of the EDL (EDL 5)
- Make recommendations for EDL 5
- Discuss current strategies and make recommendations on the way forward to increase availability, access, and proper use of in vitro diagnostics

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Agenda

Time	Session	Speaker
09h00 – 09h05	Welcoming remarks	Dr Yukiko Nakatani, ADG MHP
09h05 – 09h10	Housekeeping rules. Introduction to fifth SAGE IVD meeting objectives	Dr Francis Moussy
09h10 – 09h30	Introduction to SAGE IVD and its members	Dr Francis Moussy
09h30 – 09h50	Overview of the WHO model list of essential in vitro diagnostics (EDL): scope and methodology for its review and update	Dr Ana Aceves Capri
09h50 – 10h00	What is new for EDL 5?	Dr Ana Aceves Capri
10h00 – 10h15	WHO essential diagnostic tests for bacterial and fungal infections and AMR	Dr Sriram Raghu
10h15 – 10h30	EDL for Emergencies and Humanitarian Crises	Dr Philomena Raftery
10h30 – 11h00	Coffee break	
11h00 – 11h30	Update on National EDLs	Dr Francis Moussy Dr Antonio Villanueva (ERIA)
11h30 – 11h40	The WHO model list of essential medicines (EML) and its relationship with the EDL	Ms Bernadette Capello
11h40 – 11h50	MeDevIS, the UHC Compendium and the electronic EDL: improving access to diagnostic tools	Ms Adriana Velazquez
11h50 - 12h00	The WHA 76.5 resolution on strengthening diagnostics capacity and the WHO Diagnostics Task force	Ms Adriana Velazquez
12h00 – 13h00	Discussion/comments from stakeholders	Stakeholders
	End of open session	

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Strategic Advisory Group of Experts on in vitro diagnostics

- The **SAGE IVD** was conceived in 2018 as an advisory body on matters of global policy and strategy related to IVDs, including advising WHO on the tests to be included in the EDL

    - 15 SAGE IVD members serve in their personal capacities and represent the broad range of disciplines required to advise on the many aspects of IVDs and other clinical laboratory related activities
    - Geographical representation: experts from all the WHO regions
    - Gender balance
    - Conflict of interest is managed according to rules and procedures from the WHO Office of Compliance, Risk Management and Ethics

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2023 SAGE IVD panel

Dr Amina Hançali, Morocco

Dr Itsuki Hamamoto, Japan

Dr Runa Jha, Nepal

Dr Dario Trapani, Italy

Dr Sadia Shakoor, Pakistan

Dr François-Xavier Mbopi Keou, Cameroon

Dr Daniel Mukadi-Bamuleka DRC

Dr Christophe Peyrefitte, France

Dr Patricia J. García, Peru

Mr Paulinus Offutalu, Nigeria

Dr Kenneth Fleming, United Kingdom

Dr Mandira Varma Basil, India

Dr Michael Wilson, USA

Dr William Sewell, Australia

Dr Lyu Yunfeng, China

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https://www.who.int/groups/who-strategic-advisory-group-of-experts-on-in-vitro-diagnostics

The WHO model list of essential in vitro diagnostics (EDL):

- Scope and structure
- Methodology for its review and update
- What's new for EDL 5

Dr Ana Aceves Capri
Technical Officer, EDL Secretariat
MDD, WHO HQ

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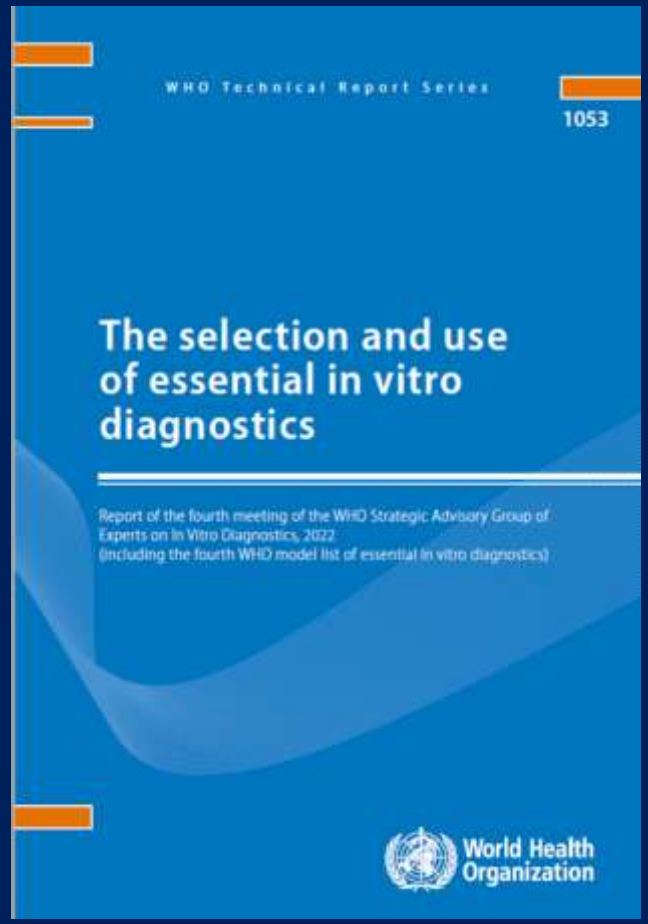
WHO Model list of essential in vitro diagnostic (EDL)

- List of IVD tests categories and recommendations on the assay format, test purpose, specimen type and health care setting
- Health policy document, based on scientific evidence
- The EDL 4 (last version) was published in October 2023 and includes 156 IVD tests categories



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Scope of EDL 4

- The EDL does not list commercial products but categories of IVD tests
- The EDL includes general tests and disease-specific tests for non-communicable diseases (NCD) and infectious diseases
- Most tests are recommended for medical care
- Some tests for surveillance and for use in public health labs

General tests	Disease-specific
Anatomical pathology	Aspergillosis
Blood typing	Cancer
Clinical chemistry	Cardiovascular diseases
Clinical microbiology	Chagas disease
Clinical pathology	Cholera
Haematology	COVID-19
Pregnancy testing	Diabetes mellitus
	Endocrine disorders
	Hepatitis B, C and E
	HIV
	Human papillomavirus
	Influenza
	Malaria
	Neglected tropical diseases
	Pneumocystis pneumonia
	Primary immunodeficiencies
	Streptococcal pharyngitis
	Sickling disorders
	Sexually transmitted infections
	Syphilis
	Tuberculosis
	Vaccine preventable diseases
	Visceral leishmaniasis
	Zika virus

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Structure of the EDL

- The EDL is organized in two levels, and each level is organized in subsections: general tests and disease specific tests
- The list also includes a special section titled Do Not Do recommendations (from EDL 3 onwards)

I. Community settings and health facilities without laboratories

I.a General tests (*arranged by discipline*)
I.b Disease-specific tests (*arranged by disease*)

II. Health care facilities with clinical laboratories

II.a General tests (*arranged by discipline*)
II.b Disease-specific tests (*arranged by disease*)
II.c Bloods screening tests

Do Not Do recommendations

Refer to test categories recommended for discontinuation based either on evidence of harm or lack of benefit

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Example of EDL 4 listing

II.b. Disease-specific IVDs recommended for use in clinical laboratories *continued*

Disease	IVD test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Diabetes mellitus	Glucose	To diagnose and monitor[39] type 1 and type 2 diabetes mellitus To diagnose impaired fasting glucose/ impaired glucose tolerance To screen for type 2 diabetes mellitus and impaired fasting glucose/impaired glucose tolerance *Note: When used for emergency or critical care, results are time-sensitive.*	Optical methods, automated chemistry analyser if available	Serum Plasma	N/A	HEARTS-D: diagnosis and management of type 2 diabetes (2020) https://apps.who.int/iris/handle/10665/331710
	Haemoglobin A1c (HbA1c)	To diagnose and monitor diabetes mellitus	Immunoassay	Venous whole blood	N/A	HEART-D: diagnosis and management of type 2 diabetes (2020) https://apps.who.int/iris/handle/10665/331710

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Objective of the EDL and recommended uses

- The objective of the EDL is to support IVD policy development
- The EDL is being used to prioritize and select IVD tests, and to support the development and update of national EDLs (NEDL) at country level
- EDL and NEDLs can inform universal health coverage-priority benefits packages (UHC-PBP)
- EDL and NEDL can help decision makers define the tests that should be available at different levels of the health system as per the context and needs of each country
- Ideally, the EDL should be used within the scope of integrated clinical laboratory testing services and laboratory networks → With the proper implementation of a NEDL, patients can have better and greater access to IVD tests

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Review and update of the EDL

- The review of the EDL is a rigorous evidence-based process that is collaborative and transparent
- The EDL is updated every 2 years through a call for submission of applications

✓Applications can be submitted by:

- Stakeholders such as MOH officials, members of academia, member of professional organizations, NGOs, companies in the IVD industry
- WHO
- UN specialized agencies with significant role in health-related topics: UNICEF, UNAIDS, UNFPA

- The **EDL secretariat** oversees the process, and the **SAGE IVD** is responsible for reviewing the applications and making recommendations

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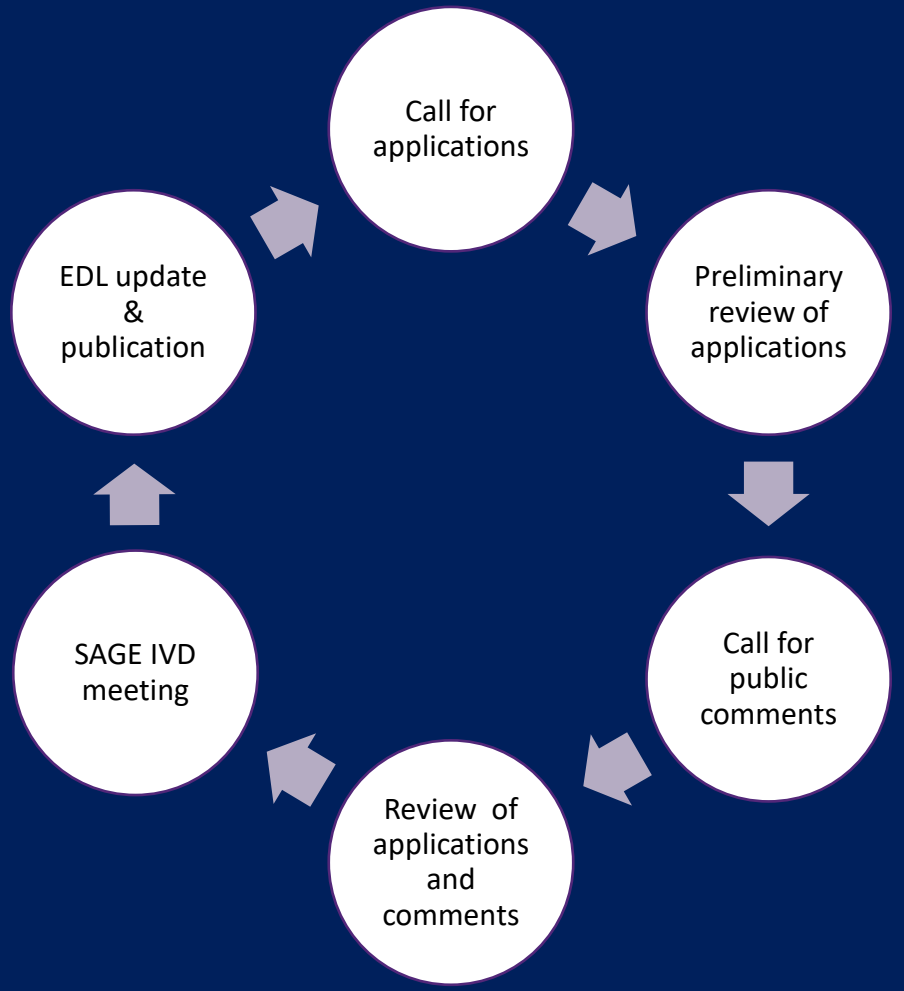
Review and update of the EDL



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Criteria for selection and listing of test categories in the EDL

- Public health impact of the disease and the test category
- Availability of published evidence on clinical utility
- Availability of published evidence on diagnostic accuracy
- Availability of commercial IVD products, as confirmed by adequate data on quality, safety, performance and regulatory status
- Operational characteristics and infrastructure required, such as intended user(s), training requirements, specimen type, storage conditions, energy requirements and associated equipment
- Availability of evidence on cost–effectiveness
- Equity and human rights issues
- Ethical considerations

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https://www.who.int/publications/i/item/9789240030923

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[Call for submission - Submissions for the fifth WHO model list of essential in vitro diagnostics (EDL 5)]

Tests identified as high priority to inform EDL 5 call for applications:

- *Entamoeba* antigen test
- Free light-chain test (in serum)
- IgM antibodies against scrub typhus
- IgM antibodies against *Leptospira*
- Immunofixation electrophoresis
- IVDs for *Bordetella pertussis*
- IVDs for Hepatitis delta (RDT, EIA and NAT)
- IVDs for Hepatitis A
- IVDs for poliovirus
- IVDs for rotavirus
- Lead (blood lead concentration)
- NAT for Neisseria meningitidis - single plex (follow up to EDL 4 application)
- NAT for diphtheria
- Protein electrophoresis (in serum and urine)
- Serology tests for yellow fever
- therapeutic drug monitoring, Amikacin
- therapeutic drug monitoring, Gentamicin
- therapeutic drug monitoring, Phenytoin
- therapeutic drug monitoring, Lithium
- therapeutic drug monitoring, Methotrexate
- Total testosterone

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Call for submission - Submissions for the fifth WHO model list of essential in vitro diagnostics (EDL 5)

Review and update of the EDL

- Prospective applicants submit an expression of interest by email describing the type of application, and the IVD category and assay format
- There are five different types of applications:
    1. Addition of a new IVD category/assay format
    2. Edits to the current list
    3. Remove an IVD from the current list
    4. Submit additional evidence for IVDs conditionally listed
    5. Addition of do not do recommendations
- Expressions of interest are considered against WHO programmatic priorities and EDL's high priority IVD categories to invite a submission

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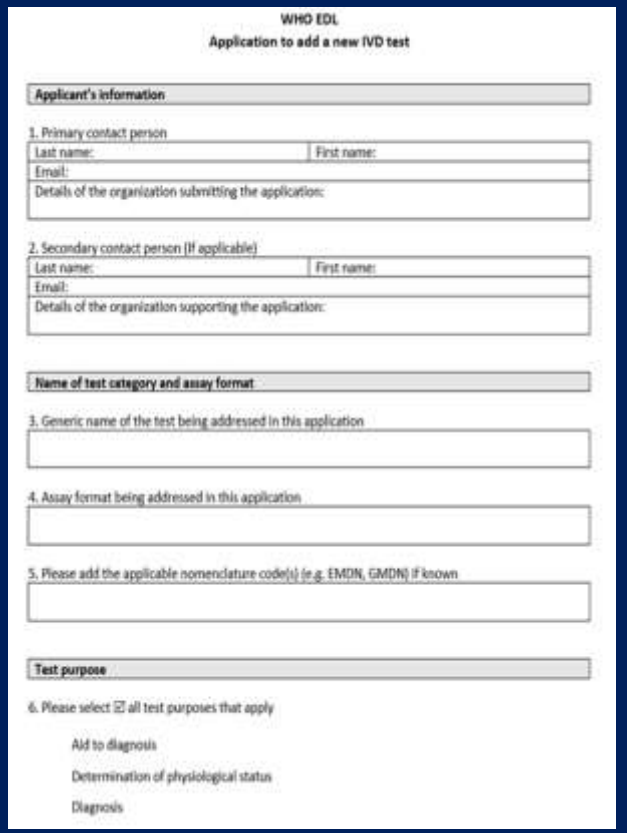
Review and update of the EDL

- The secretariat shares the application form and related instructions with the applicants
- While the applicants works in completing the application the secretariat remains available to clarify questions. All communications are via email
- Completed application form, and **supporting evidence** are then submitted to the secretariat via email



WHO EDL

Application to add a new IVD test

Applicant's information

1. Primary contact person

Last name: | First name:

Email:

Details of the organization submitting the application:

2. Secondary contact person (If applicable)

Last name: | First name:

Email:

Details of the organization supporting the application:

Name of test category and assay format

3. Generic name of the test being addressed in this application

4. Assay format being addressed in this application

5. Please add the applicable nomenclature code(s) (e.g. EMDN, GMDN) if known

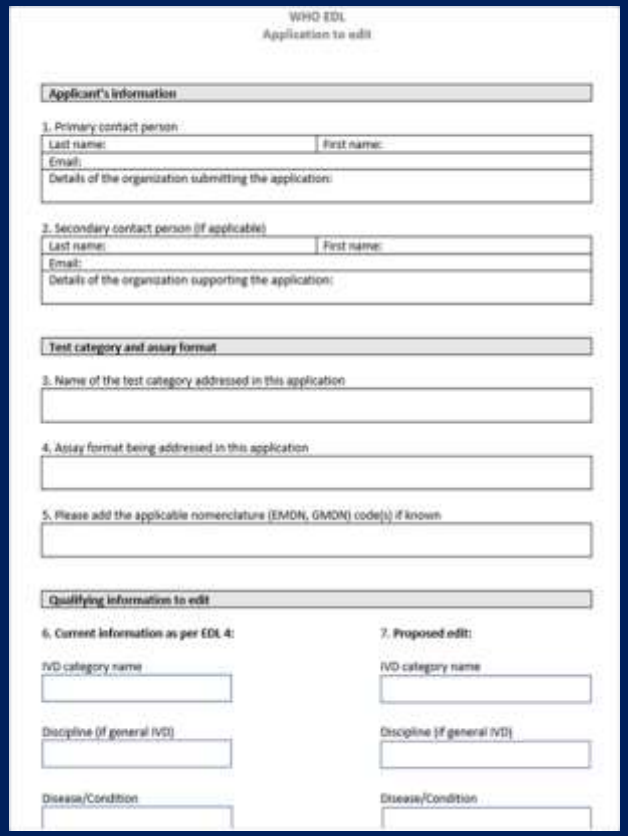
Test purpose

6. Please select ☑ all test purposes that apply

Aid to diagnosis

Determination of physiological status

Diagnosis



WHO EDL

Application to edit

Applicant's information

1. Primary contact person

Last name: | First name:

Email:

Details of the organization submitting the application:

2. Secondary contact person (If applicable)

Last name: | First name:

Email:

Details of the organization supporting the application:

Test category and assay format

3. Name of the test category addressed in this application

4. Assay format being addressed in this application

5. Please add the applicable nomenclature (EMDN, GMDN) code(s) if known

Qualifying information to edit

6. **Current information as per EDL 4:** | 7. **Proposed edit:**

IVD category name | IVD category name

Discipline (if general IVD) | Discipline (if general IVD)

Disease/Condition | Disease/Condition

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Supporting evidence

- **Peer reviewed publications, systematic reviews, and guidelines on:**
  - IVD test performance: sensitivity, specificity, PPV, NPV, likelihood ratio, area under the ROC curve, diagnostic odds ratio
  - Clinical utility: acceptability, appropriateness, availability of treatments/interventions
  - Cost-effectiveness studies

✓ A team of methodologists assess the evidence regarding its quality and strength and prepare an assessment summary

- Information about commercially available IVD products, including package inserts/instructions for use

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Review and update of the EDL

- The secretariat reviews all submitted applications for completeness, if necessary, the application is returned to the applicant
  - Applications are accepted if they are complete and deemed as high programmatic priorities by EDL secretariat and/or WHO technical teams
    - Applications and supporting evidence are shared with the methodologists who prepare the evidence assessment summary
      - Each application is reviewed by at least two members of the SAGE IVD, who prepare preliminary reviews for consideration by the full SAGE IVD

✓ SAGE IVD members have access to the submissions, the supporting evidence, and to the evidence assessment summaries

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- All applications
- SAGE IVD preliminary reviews
- Evidence assessment summaries

- When the call closes, the secretariat shares all the comments submitted with the SAGE IVD

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https://www.who.int/news-room/articles-detail/call-for-public-comments---applications-to-the-fifth-who-model-list-of-essential-in-vitro-diagnostics-(edl5)

Review and update of the EDL

- Each expert reviews all the preliminary reviews by the other SAGE IVD members, all the evidence assessment summaries by the methodologists, and all the comments by the public

- To support the decision-making process, each expert completes an individual selection table before **the SAGE IVD meeting**

Nr.	Test category submitted	Proposed wording for the test with regards to: • Diagnostic test name • Test purpose • Assay format • Specimen type (As per the application and harmonized to EDL 4 wording)	Health facility level as per WHO EDL* 1. Community and health facilities without laboratories 2. Health care facilities with clinical laboratories	1	2	3	4	Please provide the reasons for your selection (mandatory).	Any proposed changes Please give reasons (mandatory) • Are all claims aligned with the evidence provided? • Is the wording misleading or incorrect? • Is the health care facility level incorrect?
1.	Protein electrophoresis (PEP), gel electrophoresis	**Diagnostic test:** Protein electrophoresis (PEP) **Test purpose:** To aid in the diagnosis, monitoring, and prognosis of monoclonal gammopathies. **Assay format:** gel electrophoresis **Specimen type:** Serum, urine	Health care facilities with clinical laboratories (II.b.)						

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The SAGE IVD meeting

- The experts present their preliminary recommendations for each application to the full SAGE IVD for discussion
- Methodologists comment on the quality, strength and availability of the evidence
- SAGE IVD members reach a decision for each application by consensus. The reasons for their decision and their final recommendations are documented

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After the SAGE IVD meeting

- The secretariat drafts the report of the SAGE IVD meeting and updates the EDL table
- Final version of EDL table is reviewed by SAGE IVD
- Final version of the EDL is approved by ADG MHP
- The technical report and the EDL are published
- The secretariat begins the update of the electronic version of the EDL

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What is new for EDL 5?

EDL 5 applications: 11 additions of new IVD categories, 5 additions of new assay formats*, 2 edits+

1) Protein electrophoresis, gel electrophoresis
2) Protein electrophoresis, capillary electrophoresis
3) Immunofixation electrophoresis, gel electrophoresis
4) Immunofixation electrophoresis, capillary electrophoresis
5) Free light chains, immunoassay
6) Immunoglobulin levels (IgG, IgA, IgM), immunoassay+
7) Qualitative HIV, NAT+
8) *Bordetella pertussis*, NAT
9) Total testosterone, immunoassay
10) Estrogen receptor, NAT*
11) Progesterone receptor, NAT*
12) Human epidermal growth factor receptor 2 (HER-2), NAT*
13) *Clostridioides difficile* combined GDH and toxins A and B, RDT
14) Lead, Anodic stripping voltammetry (ASV)
15) Cholesterol, point-of-care test*
16) Creatinine, point-of-care test*
17) Total anti-HDV antibody, immunoassay
18) HDV NAT

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What is new for EDL 5?

- Clinical microbiology tests will be re-named to provide greater level of detail and to align better with the “WHO essential diagnostic tests for bacterial and fungal infections and AMR”
- Subset of the EDL tailored to emergency situations as per the mandate of the resolution WHA 76.5 on Strengthening diagnostics capacity
- Updates to the STI section (internal edits by STI programme)
- Electronic EDL (eEDL) will include codes from the European Medical Device Nomenclature (EMDN) system and the Global Medical Device Nomenclature (GMDN) system, in accordance with the WHA75(25) decision on nomenclature of medical devices

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Thank you

For more information, please contact:

Dr Ana Aceves Capri
Technical officer, MDD, WHO HQ
acevesa@who.int

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Essential diagnostic tests for bacterial and fungal infections and AMR

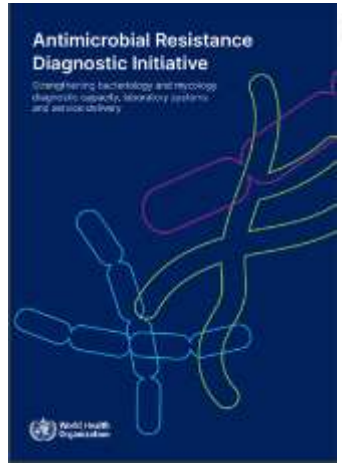
Dr Sriram Raghu

Technical officer
AMR surveillance, evidence and laboratory strengthening,
Antimicrobial Resistance Division,
WHO/HQ

sriramr@who.int

Consultation with SAGE IVD , 25 November 2024

The AMR Diagnostic Initiative



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Goals

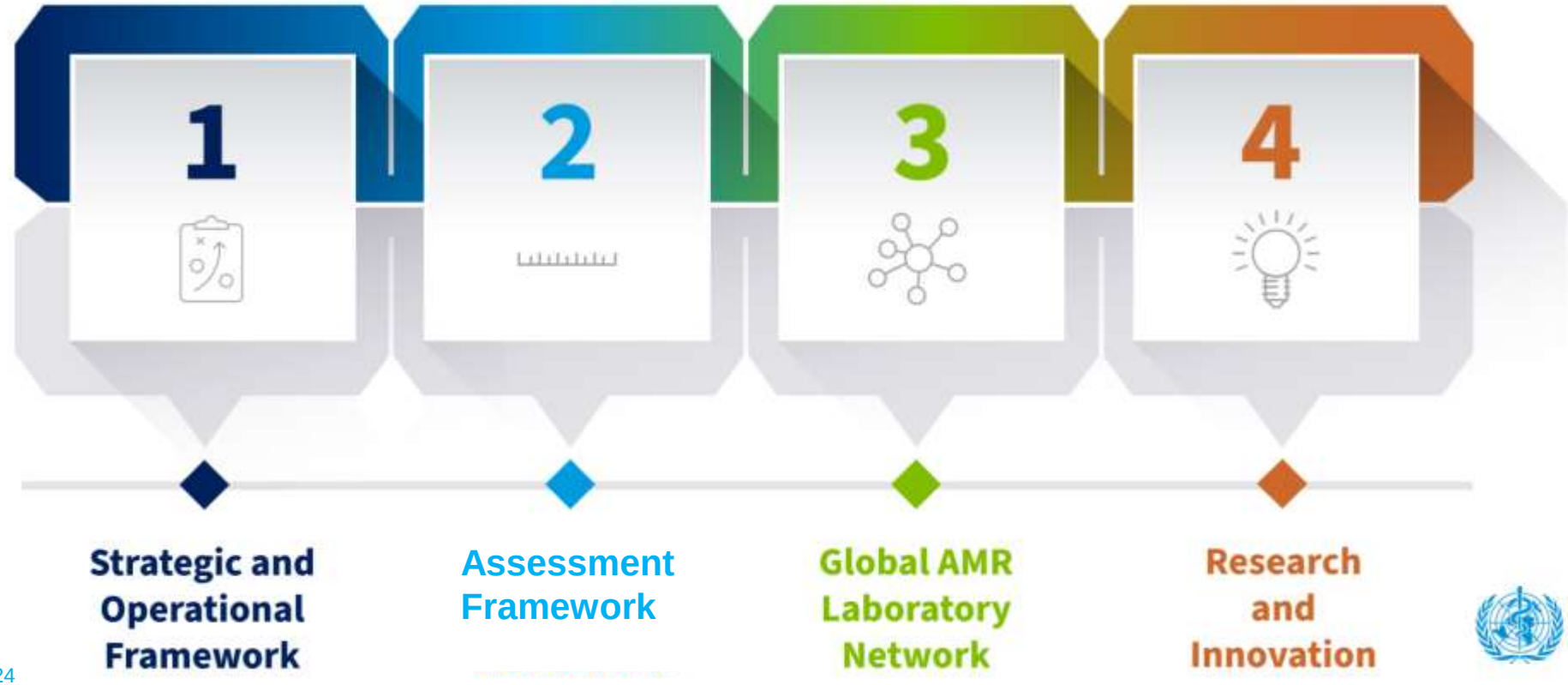
1. To **bring diagnostics to the forefront of the global AMR response**.
2. To **achieve equitable access to quality testing** for common bacterial and fungal pathogens and associated antimicrobial resistance **across all levels of the health system.**

Objective

Strengthen bacteriology and mycology diagnostic capacity, laboratory systems and service delivery

The AMR
Diagnostic Initiative

Four building blocks



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Strategic and Operational Framework

1. Strengthen **governance and resource allocation** to enhance bacteriology and mycology diagnostic services
2. Provide **equitable access** to bacteriology and mycology diagnostic services across the health system
3. Ensure **quality** bacteriology and mycology diagnostic services
4. Ensure **optimal utilization** of the bacteriology and mycology laboratory services and test results

Essential diagnostic tests for bacterial and fungal infections, and AMR

Aim: to expand access to essential diagnostic tests for bacterial and fungal infections

Objective: to provide countries with a minimal package of essential tests for bacterial and fungal infections, and susceptibility testing which should be **accessible** to **health care workers and patients at each level of** the health system**.**

Purpose: to guide clinical management, antibiotic use, and inform IPC measures.

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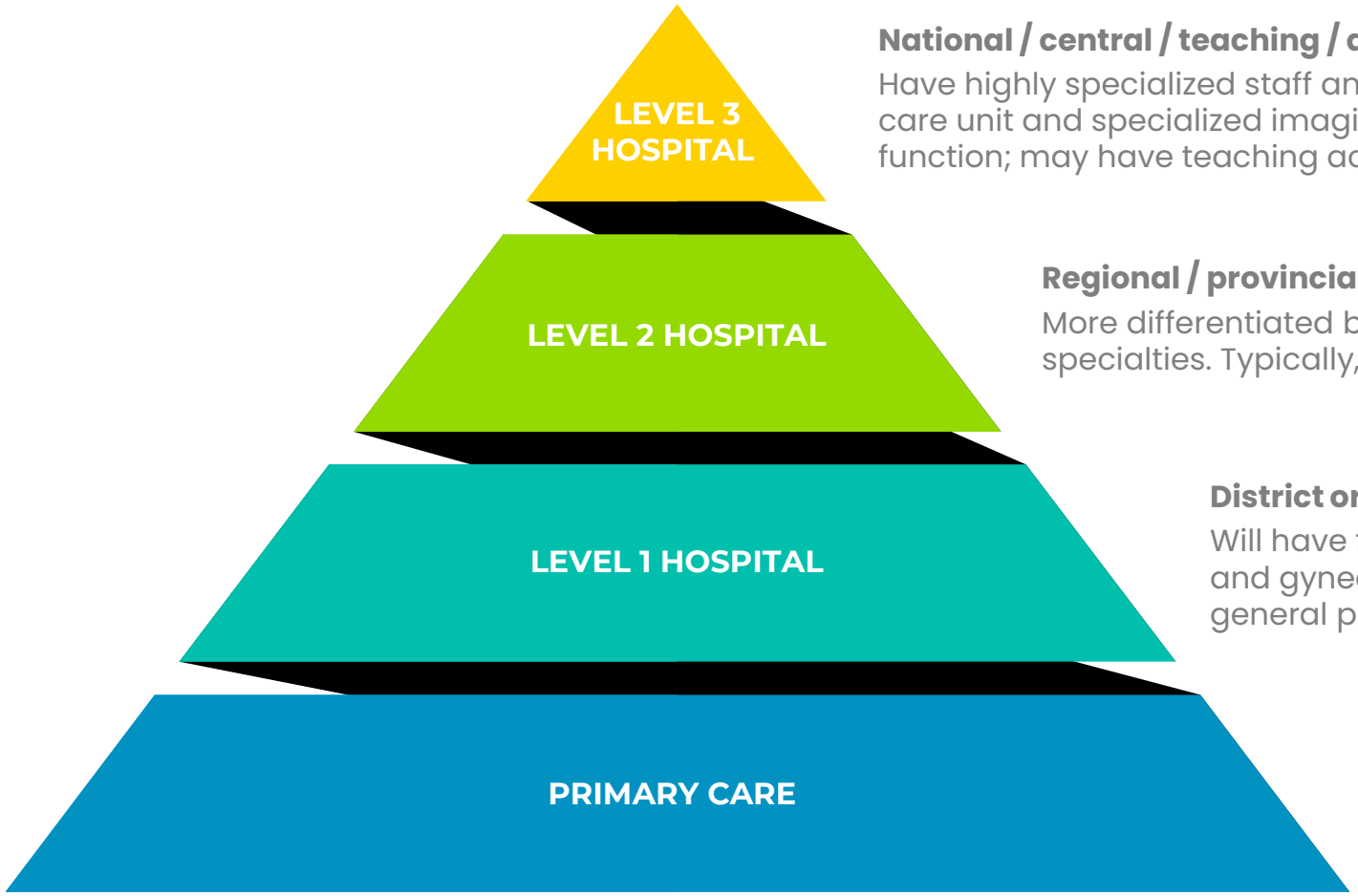
Scope and approach to develop the list

- **Inclusion**: bacteriology, mycobacteriology, mycology tests, including susceptibility testing
- **Exclusion**: biomarkers; tests for viral infections
- **WHO EDL**: leverage and complements the EDL
- **Accessibility**
  - List identifies the tests that should be **accessible** to healthcare workers and patients **at each level the health system** through on-site testing or specimen referral
  - List does **not** dictate the level at which tests should be **performed**

LEVELS OF THE HEALTH SYSTEM



National / central / teaching / academic hospitals

Have highly specialized staff and technical equipment, for example, cardiology, intensive care unit and specialized imaging units; clinical services are highly differentiated by function; may have teaching activities. Typically, 300 to 1500 beds.

Regional / provincial hospitals

More differentiated by function, with as many as 5 to 10 clinical specialties. Typically, 200–800 beds.

District or community hospitals

Will have few specialties, mainly internal medicine, obstetrics and gynecology, pediatrics and general surgery, or just general practice. Typically, 50-250 beds.

Health post, community clinic or health centre

General non-specialist out-patient medical care, often delivered by nursing staff, may include antenatal services

Rationale for developing the list to complement the WHO EDL

Facilities classified as "with" and "without" a laboratory

At what levels of the health system should the test be *available for health care workers and patients?

II.a. General IVDs recommended for use in clinical laboratories *continued*

Discipline	IVD test	Test purpose	Assay format	Specimen type
Blood typing	ABO blood groups and Rhesus (Rh) factor typing	To determine ABO groups and Rh factor	Slide agglutination t	enous whole blood
Clinical microbiology	Staining procedures	For the presumptive identification of pathogens and for determination of microbial morphology	Microscopic examination of slides which may use different types of microscopes and stains	Disease-appropriate specimens (e.g. sputum, venous whole blood, urine, stool, body fluids, cerebrospinal fluid or cultures)
	Culture	Initial step in detection and identification of bacterial and fungal species for selection of appropriate antimicrobial regimens	Culture on growth media plates or broth in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)	Disease-appropriate specimens (e.g. urine, stool, sputum, body fluids, e.g. cerebrospinal fluid, etc.)
	Blood culture	To detect bacterial and fungal bloodstream infections (sepsis)	Blood culture bottle in an incubator followed by recovery of isolates (traditional manual techniques or automated equipment)	Venous whole blood
	Genus and species identification of bacteria and fungi	To identify the genus or species of bacteria or fungi from microbial isolates	A range of biochemical tests that may be performed manually or on automated equipment	Bacteria or fungal isolates

Microscopy, with no specification of types of stains
No indication of specimen type

Which stains (Gram stain/KOH/ India ink etc.)?
Which specimen types?

Culture, with no differentiation of specimen

Level of complexity varies with specimen type

Rationale for developing the list to complement the WHO EDL

II.a. General IVDs recommended for use in clinical laboratories *continued*

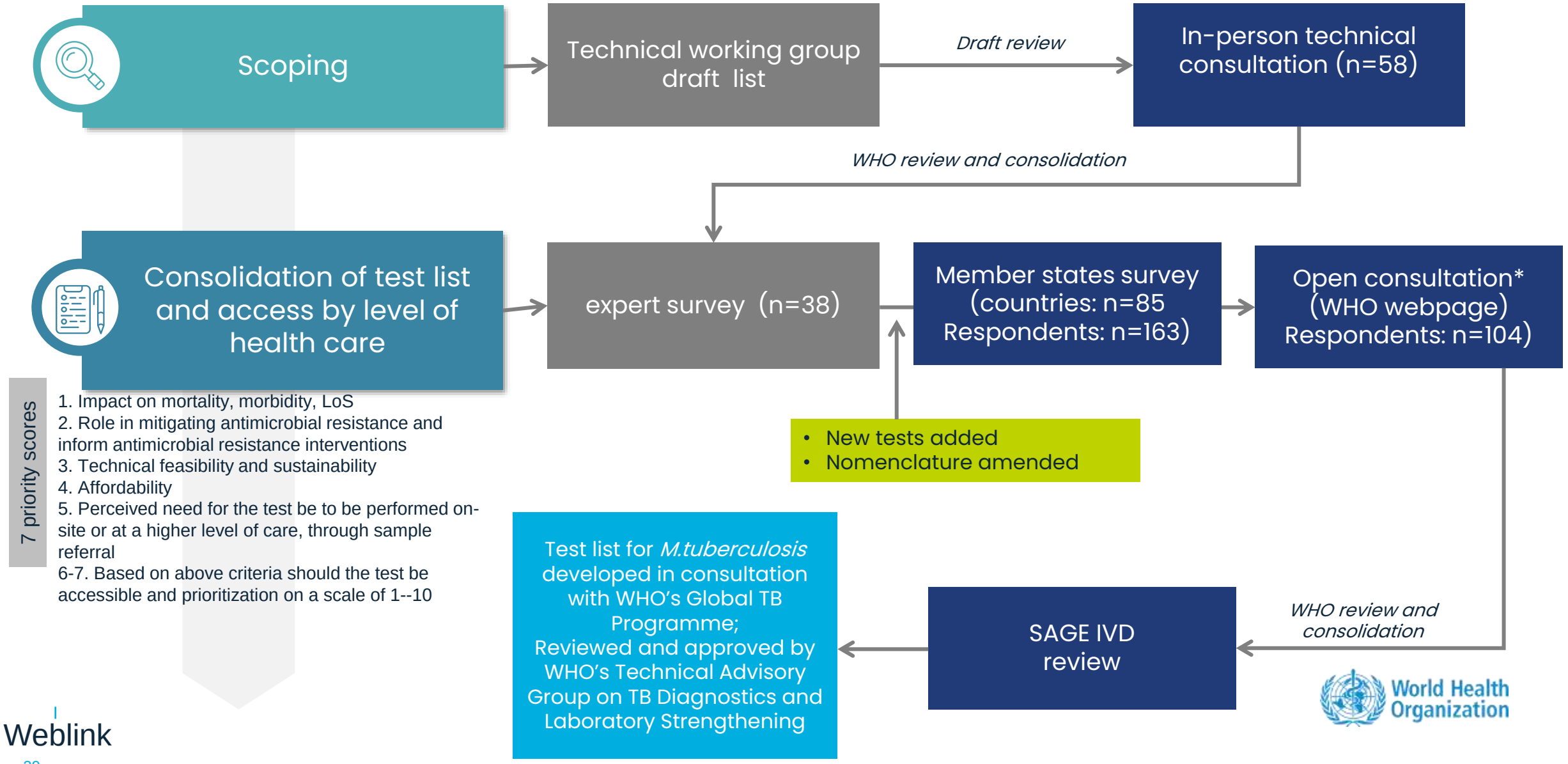
Discipline	IVD test	Test purpose	Assay format	
Clinical microbiology *continued*	Antimicrobial susceptibility testing (AST)	Final step in selection of appropriate antibiotics after species identification and interpretation by EUCAST[21] and CLSI guidelines[22] Note: WHO regards the development of antimicrobial resistance (AMR) as a high-priority global health issue. See WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS): https://www.who.int/activities/facilitating-global-surveillance-of-antimicrobial-resistance	Antimicrobial susceptibility testing of isolates may be done manually (by disc diffusion, gradient tests and broth microdilution), or by automated platforms	Bacteria isolates

Antimicrobial susceptibility testing only of bacteria

Antifungal susceptibility testing included

Methods

Snapshot of methods to develop list of essential diagnostic tests for bacterial and fungal infections and AMR



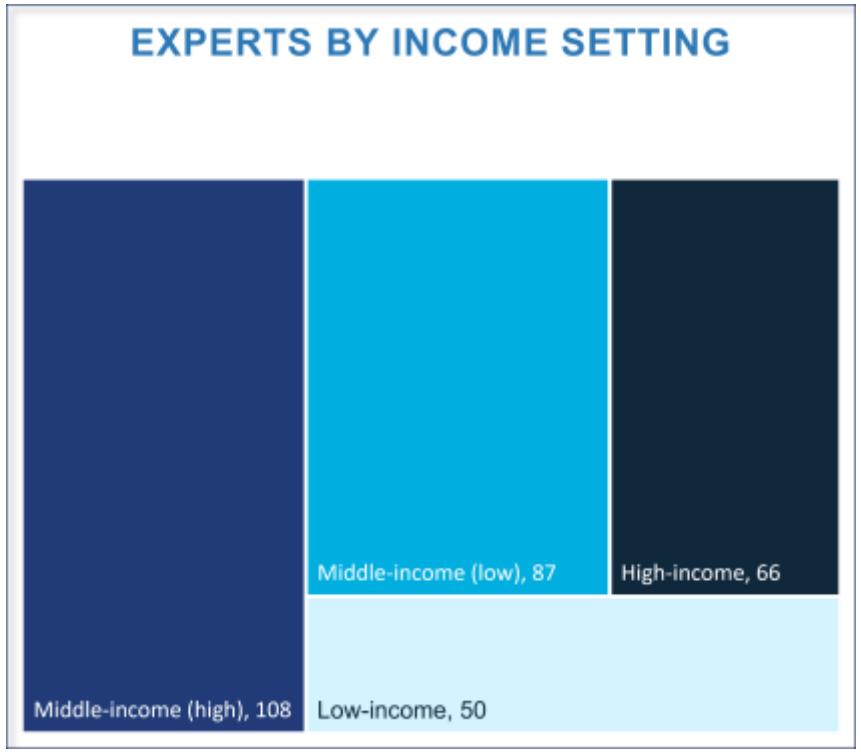
* Weblink

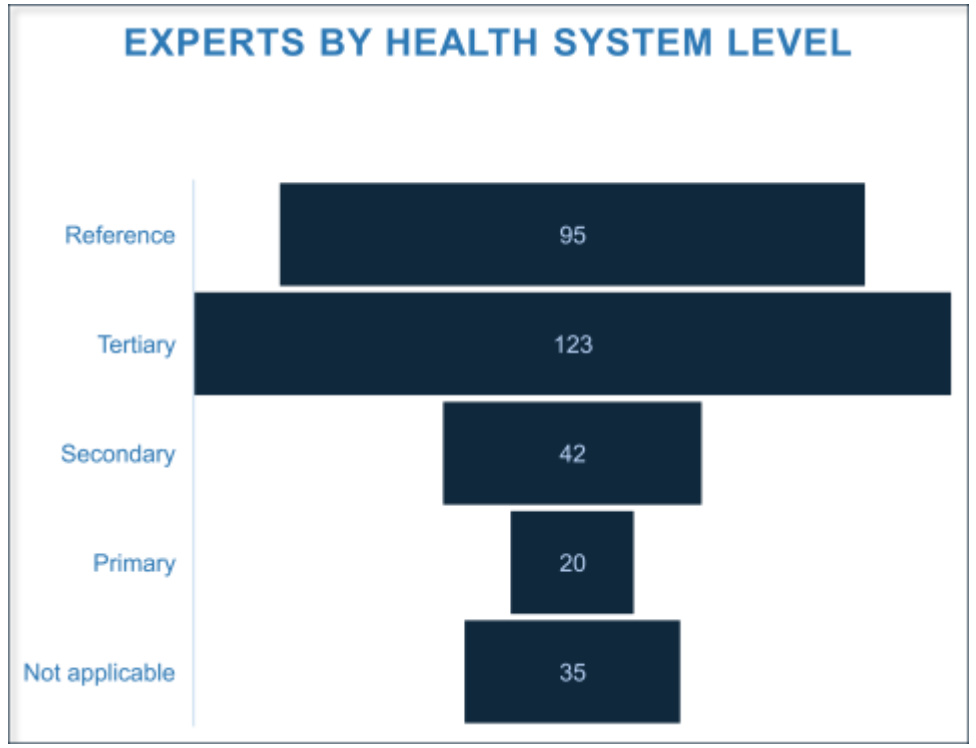
Consolidation of test list and access by level of care

Survey uptake

Survey respondents: n = 315

Countries: n = 85





Essential diagnostic tests for bacterial and fungal infections and AMR

PRIMARY CARE TESTS

SPECIMENS PROCESSED	MICROBIOLOGY TESTING
BLOOD	Syphilis serological test (rapid)
URINE	Dipstick test for urinary tract infection or asymptomatic bacteriuria
STOOL	Rapid test for V. cholerae (endemic regions)
THROAT SWAB	Rapid Group A Strep test
WHOLE BLOOD (OR SERUM/PLASMA)	Cryptococcal antigen test

LEVEL 1 HOSPITAL TESTS

SPECIMENS PROCESSED All tests on specimens processes in Primary care plus	MICROBIOLOGY TESTING
URINE	• Microscopy (cell count)
URETHRAL SWAB OR URINE SEDIMENT	• Gram stain for leukocytes and intracellular diplococci
CSF	• Microscopy (cell count), • Gram stain, • Cryptococcal antigen test (CrAg)
BLOOD CULTURE	• Direct Gram stain • Culture for bacteria and yeasts (automated or manual), • Bacterial and yeast isolates: Gram stain, Identification(ID) • Bacterial isolates: AST
STERILE FLUID CULTURE **(CSF, PLEURAL ASPIRATE, OTHER)**	
SERUM	• Syphilis serology (treponemal plus non-treponemal tests)

LEVEL 2 HOSPITAL TESTS

All tests on specimens processes in Primary care and Level 1 hospitals plus

SPECIMENS PROCESSED	MICROBIOLOGY TESTING
URINE	• Culture (bacteria, yeasts), • Bacterial and yeast isolates: Gram stain and ID • AST (bacteria only) • Histoplasma rapid antigen test
TISSUE	• Gram stain, • Potassium hydroxide (KOH) stain • Culture (bacteria, yeasts), • Bacterial and yeast isolates: Gram stain and ID • AST (bacteria only)
PUS	• Gram stain, • Culture (bacteria, yeasts), • Bacterial and yeast isolates: Gram stain and ID • AST (bacteria only)
SPUTUM / RESPIRATORY	• Gram stain, • Culture (bacteria, yeasts) • Bacterial and yeast isolates: Gram stain and ID • AST (bacteria only) • Microscopy for pneumocystis (Bronchoalveolar lavage samples only)
STOOL	• Microscopy for red and white cells • Culture for selected bacteria, • Selected bacterial isolates: Gram stain, ID and AST, • C. difficile rapid test
STOMACH BIOPSY OR STOOL	• H. pylori urease test on biopsy or ELISA antigen test on stool
VAGINAL DISCHARGE	• Microscopy for bacterial vaginosis scoring and candida
BLOOD	• Aspergillus antibody testing

LEVEL 3 HOSPITAL TESTS

SPECIMEN	TESTS
All tests on specimens processes in Primary care, Levels 1 and 2 hospitals plus	
TISSUE, PUS, RESPIRATORY, STERILE SPECIMENS	• Culture and ID (phenotypic or genotypic) for filamentous fungi • Culture, ID (phenotypic or genotypic) and AST for difficult to identify bacteria • Culture and ID (phenotypic or genotypic) for bacteria of critical public health importance or those that pose threat of laboratory-acquired infection • Staining and culture for Actinomyces and Nocardia
UROGENITAL SWABS / URINE FOR STIS	• N. gonorrhoeae culture and AST, • Rapid molecular testing for N. gonorrhoea and C. trachomatis
BRONCHIOALVEOLAR LAVAGE	• *Nucleic acid amplification test for Pneumocystis jirovecii*
SELECTED BACTERIAL OR FUNGAL ISOLATES	• Bacterial and yeast Minimum inhibitory concentration (MIC) testing (gradient diffusion or agar dilution or broth microdilution), • Antifungal susceptibility testing for filamentous fungi
SELECTED BACTERIAL ISOLATES	• Phenotypic (preferred) and/or genotypic detection of key bacterial resistance mechanisms
THROAT SWAB	• C. diphtheriae
BLOOD/DEEP RESPIRATORY SAMPLES	• Galactomannan antigen test for Aspergillus

TB tests for

Primary care: Health post, community clinic or health centre

Specimens	Microbiology testing	Notes
Sputum	WRD for TB, including diagnosis of RR	People with RR-TB at this level should have access to additional appropriate molecular or culture-based drug susceptibility testing.
Sputum	Culture for M. tuberculosis for people with a negative WRD and ongoing clinical presentation suggestive of TB	TB culture should not be the first-line test but should be available for people with a negative WRD and ongoing clinical presentation suggestive of TB. See above note on DST for TB.
Stool	WRD for TB in children, including diagnosis of RR	See above note on DST for TB.
Urine	Lateral flow test for lipoarabinomannan for diagnosis of active TB in adults, adolescents and children with HIV who have signs or symptoms or screened positive for TB, or are seriously ill, or have advanced HIV disease	Refer to WHO recommendation. Should be done in parallel with WRD or culture of respiratory sample to obtain RIF result. Note that this is very specific to certain epidemiological settings, and is not appropriate for all settings.
Skin or blood test	Test for LTBI (either Tuberculin skin test (TST) or TB-specific skin test (TBST) or IGRA)	Should be available for testing household or other close contacts of people with TB
NPA	WRD for TB in children, including diagnosis of RR	See above note on DST for TB.

- DST should be based on existing WHO treatment guidelines for different levels of resistance.
- At country level, phenotypic or genotypic comprehensive DST (including at least INH, RIF, FQ, BDQ, LZD) should be available in most countries, either through referral of specimens or *M. tuberculosis* isolates, or through patient referral.
- Referral of isolates or specimens is preferred, since this may reduce diagnostic delay and minimize patient transfers. However, since treatment decisions for resistant TB are less likely to be made at lower levels, decisions on which specimens/isolates should be referred for comprehensive DST may be made using laboratory-implemented algorithms or at higher levels of the health system

Proposed TB tests for level 1 and above

District hospitals

Specimens	Microbiology testing	Notes
Sterile fluid culture (CSF, pleural aspirate, other)	Culture for *M. tuberculosis* for people with a negative WRD and ongoing clinical presentation suggestive of TB	See note on DST for TB
Induced sputum or gastric aspirate or NPA	Culture for *M. tuberculosis* for children with a negative WRD and ongoing clinical presentation suggestive of TB	See note on DST for TB

- DST should be based on existing WHO treatment guidelines for different levels of resistance.
- At country level, phenotypic or genotypic comprehensive DST (including at least INH, RIF, FQ, BDQ, LZD) should be available in most countries, either through referral of specimens or *M. tuberculosis* isolates, or through patient referral.
- Referral of isolates or specimens is preferred, since this may reduce diagnostic delay and minimize patient transfers. However, since treatment decisions for resistant TB are less likely to be made at lower levels, decisions on which specimens/isolates should be referred for comprehensive DST may be made using laboratory-implemented algorithms or at higher levels of the health system

Acknowledgements

WHO core secretariat: Sriram Raghu, Mark Nicol, Chad Centner, Silvia Bertagnolio (Unit of AMR Surveillance, Evidence and Laboratory strengthening, Antimicrobial Resistance Division, WHO/HQ)

WHO Steering Group

Expert consultation members

Special thanks to the survey respondents

World Health Organization

Thank you

Essential Diagnostics List for Humanitarian and Public Health Emergencies

5th SAGE IVD meeting

25 Nov 2024

Dr Philomena Raftery

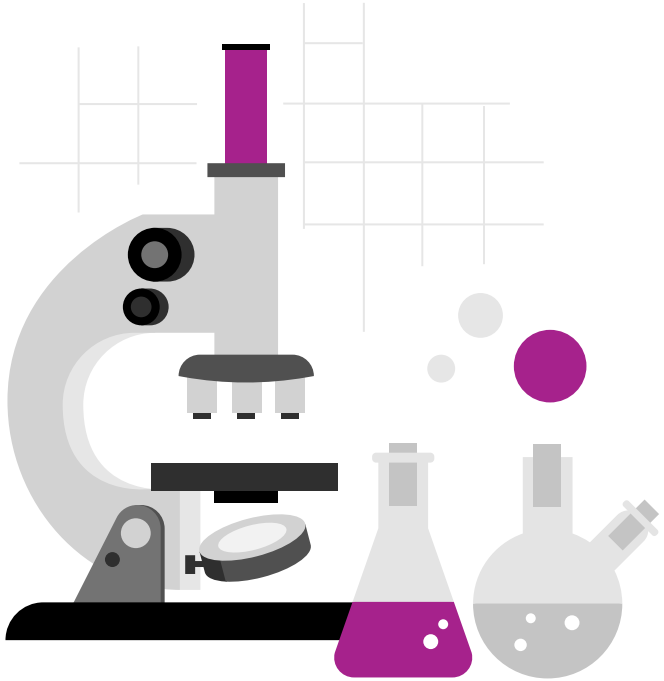
Senior Technical Officer

Public Health Laboratory (PHL) Unit

WHO Health Emergencies Programme, Lyon office

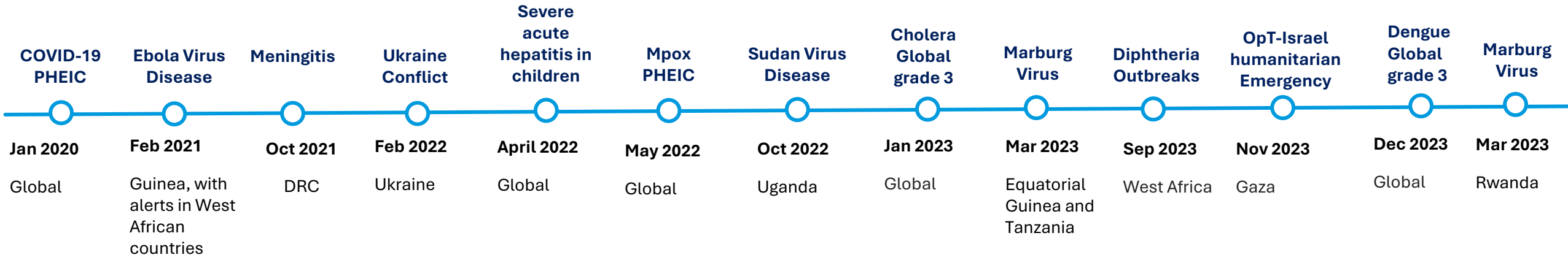
World Health Organization

Background and Rationale



- Access to good quality, affordable, and appropriate health products is indispensable to advance UHC, address health emergencies, and promote healthier populations
- Recognizing the importance of access to safe diagnostic tools and services, WHA76.5 resolution on “Strengthening Diagnostics Capacity” was adopted by the 76th WHA in May 2023
- One of the requests of the WHA76.5 was “to categorize a subset of the WHO Model list of Essential In Vitro Diagnostics (EDL) as tailored to emergency situations, including the Interagency Emergency Health Kits”
- Gap in understanding of what in vitro diagnostics (IVD), and other diagnostics such as imaging, should be available in areas affected by emergencies as the emergency evolves over time, as well as how these needs vary by geographic region and season

Access to diagnostics is a key component in responding to all types of health emergencies



- Range of geographic regions – Globall, regional, national
- Range of emergency types – Outbreaks, Humanitarian, Complex emergencies

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Background and Scope

Development of EDL for emergencies is a joint project between the EDL Secretariat and WHE Laboratory and Diagnostic team

WHO has established a working group comprised of members of the WHO Strategic Advisory Group of Experts on IVDs (SAGE IVD) and WHO staff to draft the EDL subset list for emergencies

Complementary list to the EDL that will include IVDs and other types of diagnostics

- Propose to also involve the Strategic and Technical Advisory group on Medical Devices (STAG MEDEV)

Prioritization and a staged approach - First phase should focus on IVDs, and diagnostic imaging included in Phase 2

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Scope of EDL - need to take into consideration the wide variability in diverse emergencies

Public health emergencies

Outbreaks, epidemics, pandemics

Environmental or natural disasters

Earthquakes, hurricanes, tsunamis, floods

Complex humanitarian crises and armed conflicts

Conflict, refugee/ internal displacement, migration

Additional variables

- Geographical distribution
- Assay format (NAAT/EIA/RDT)
- Specimen type
- Level of health facility (EDL_I/EDL_2)

All phases of emergency cycle

- Preparedness
- Acute
- Protracted
- Recovery

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Diagnostics services in emergency settings need cover a broad spectrum of test types

Initial health care response - trauma, obstetric, and general acute surgical care

General adult and pediatric medical care

Maternal and child health

Detection and surveillance of priority infectious diseases and AMR

Detection and monitoring of communicable diseases – TB, HIV, STIs etc

Protracted crises, include diagnostic services to ensure continuity of essential health care, including NTDs

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Methodology - combined Scoping review and Delphi approach

Gather and synthesize evidence on diagnostic services needs and priorities in emergencies including relevant lists of diagnostics

Perform a scoping review

Identify key stakeholders with knowledge and operational experience in emergency and humanitarian crises settings

Gather evidence and information through interviews, and surveys

Initial EDL for Humanitarian and Public Health Emergencies will be drafted as a subset of those already in the EDL 4

World Health Organization

Plan for Scoping Review

Research question

“What diagnostics are considered essential in public health and humanitarian emergencies across all phases of the emergency management cycle?”

Search Terms

Key terms
Essential diagnostics
OR laboratory diagnostics
OR laboratory tests
OR in-vitro diagnostics
AND emergencies
OR humanitarian crisis
OR humanitarian emergency
OR public health emergency
OR outbreak
OR pandemic
OR natural disaster
OR conflict

Inclusion criteria

Exclusion criteria

Systematic search

Database search
Web of Science, Scopus, PubMed, Medline, EMBASE, and Global Health

Selection through screening

Additional search
- Engage key stakeholders in interviews
- Grey literature
- IVD lists not in the public domain

Data extraction, analysis, and interpretation

EDL draft

Mapping variables
- Diagnostic services
- Geographical distribution
- Assay format
- Specimen type
- Facility

Consultation

Convene meetings with expert group to review and discuss IVDs and tests

List of priority infectious diseases common during natural disasters and humanitarian crises

Type_of_disease	Syndrome	Disease	Infectious agent
Bacterial diseases	Diarrhea	Enteric fever (Typhoid)	*Salmonella paratyphi A*
		Cholera	*Vibrio cholerae*
		Infectious bloody diarrhea	*E.coli 0157*
		Shigellosis	*Shigella dysentery*
	Jaundice	Leptospirosis (Weil's disease)	*Leptospira*
	Muscular contractions	Tetanus	*Clostridium tetani*
	Meningitis	Meningitis	*Neisseria meningitidis*
	Respiratory and cutaneous	Melioidosis	*Burkholderia pseudomallei*
		Diphtheria	*Corynebacterium diphtheriae*
	Respiratory	Legionellosis	*Legionella*
		Tuberculosis	*Mycobacterium tuberculosis*
Viral diseases	Fever	West Nile Fever	*West Nile virus*
	Respiratory	Acute Respiratory infection	*Influenza viruses*
		COVID-19	*SARS-CoV-2*
	Parotitis	Mumps	*paramyxovirus*
	Cutaneous	Measles	*Measles virus*
		Rubella	*Rubella virus*
		Mpox	*Monkeypox virus*
	Jaundice	Hepatitis	*Hepatitis B*
			Hepatitis A, E
	Haemorrhagic fever	Dengue fever	*Dengue virus*
		Lassa fever	*Lassa virus*
		Marburg	*Marburg virus*
		Crimean-Congo hemorrhagic fever	*Tick-borne virus (Nairovirus)*
		Ebola	*Ebola virus*
		Rift Valley Fever	*Rift Valley fever virus*
	Fever diarrhea opportunistic infections	AIDS	*Human immunodeficiency virus*
	Paralysis	Poliomyelitis (polio)	*Poliovirus*
Parasitic diseases	Fever	Malaria	*Plasmodium spp.*
	Cutaneous	Leishmaniasis	*Leishmania parasites*
Fungal diseases	Cutaneous	Cutaneous mucormycosis	*Mucormycete Apophysomyces trapeziformis*
Antimicrobial resistant infections			

World Health Organization

Tests available in 4th EDL for infectious pathogens

Type of disease	Syndrome	Disease	Infectious agent	Geographical region	Type strain
Bacterial diseases	Diarrhea	Enteric fever (Typhoid)	Salmonella paratyphi A	Worldwide (developed countries, Asia, and Subsharan Africa)	All
		Cholera	Vibrio cholerae	Worldwide (poverty and poor hygienic practices)	All
		Infectious bloody diarrhea	E.coli 0157	Worldwide (developed countries)	Infectious disease & Humanitarian
		Shigellosis	Shigella dysentery	Worldwide (overcrowding and poor hygienic practices)	Humanitarian
	Jaundice	Leptospirosis (Weil's disease)	Leptospira	Worldwide (where rats are common, flooding)	Natural
	Muscular contractions	Tetanus	Clostridium tetani	Worldwide	Natural & humanitarian
	Meningitis	Meningitis	Neisseria meningitidis	Worldwide (overcrowding)	Natural & humanitarian
	Respiratory and cutaneous	Melioidosis	Burkholderia pseudomallei	Tropical and subtropical (Southeast Asia Australia)	Natural & humanitarian
		Diphtheria	Corynebacterium diphtheriae	Worldwide (common in children)	All
	Respiratory	Legionellosis	Legionella	Worldwide	Natural & humanitarian
		Tuberculosis	Mycobacterium tuberculosis	Worldwide (mostly in South-East Asia, Africa and the Western Pacific)	Humanitarian (conflict)
Viral diseases	Fever	West Nile Fever	West Nile virus	Worldwide	Natural & humanitarian
	Respiratory	Acute Respiratory infection	Influenza viruses	Worldwide (overcrowding)	All
		COVID-19	SARS-CoV-2	Worldwide	Infectious disease & Humanitarian
	Parotitis	Mumps	paramyxovirus	Worldwide (common in children)	All
	Cutaneous	Measles	Measles virus	Worldwide (developed countries)	All
		Rubella	Rubella virus	Worldwide (common in children)	All
		Mpox	Monkeypox virus	Africa (West and Central)	Infectious disease & Humanitarian
	Jaundice	Hepatitis	Hepatitis B	Worldwide (endemic areas)	Humanitarian
			Hepatitis A, E	Worldwide	All
	Haemorrhagic fever	Dengue fever	Dengue virus	Tropical and subtropical (South and southeast Asia, South America)	Humanitarian
		Lassa fever	Lassa virus	Africa (West and Central)	Infectious disease
		Marburg	Marburg virus	Africa	Infectious disease
		Crimean-Congo hemorrhagic fever	Tick-borne virus (Nairovirus)	Africa, Asia (west and central), Europe (Balkans and Greece)	Infectious disease
		Ebola	Ebola virus	Africa (central)	Infectious disease & Humanitarian
		Rift Valley Fever	Rift Valley fever virus	Africa	Infectious disease
	Fever diarrhea opportunistic infections	AIDS	Human immunodeficiency virus	Worldwide (subsaharn Africa and Asia	Humanitarian
	Paralysis	Poliomyelitis (polio)	Poliovirus	Worldwide (Pakistan, Afghanistan, Nigeria not vaccinated)	All
Parasitic diseases	Fever	Malaria	Plasmodium spp.	Worldwide, Tropics	Humanitarian
	Cutaneous	Leishmaniasis	Leishmania parasites	Tropical and subtropical (Africa, Southern europe, Middle east)	Humanitarian
Fungal diseases	Cutaneous	Cutaneous mucormycosis	Mucormycete Apophysomyces trapezifo	Europe, America, Asia	Natural & humanitarian
Antimicrobial resistant infections					

Not available in EDL

Available in EDL

No laboratory test

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Methodology – Commission evidence-based submissions

For those diagnostics not already in the EDL

Need to be added as new complementary list via the rigorous process used for the EDL, including relevant public consultations

Evidence based submissions will be commissioned for these diagnostics

For IVDs, SAGE IVD will make recommendations

For non-IVD diagnostics, STAG MEDEV will make recommendations on the additions of these tests

Final version based on recommendations from both SAGE IVD and STAG MEDEV will be published alongside EDL 6

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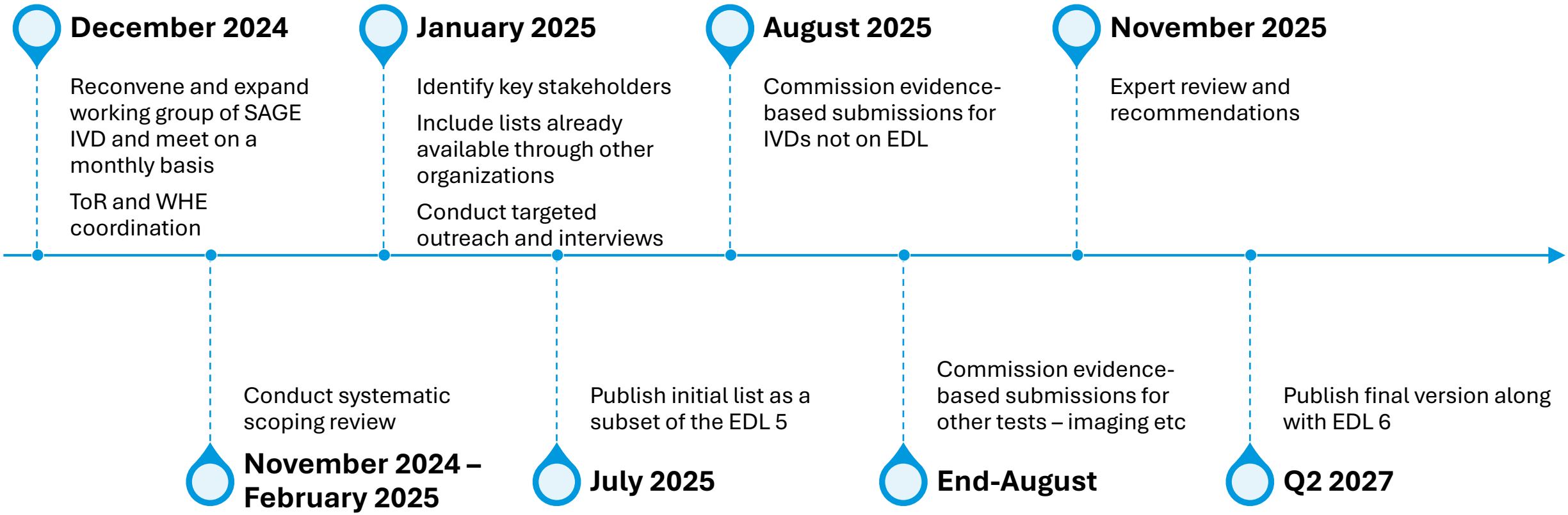
Timeline for Development of EDL Emergencies



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Thank you

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30-minute comfort break

Please, rejoin us at 11:00 CET/Geneva time for an update on the work on National EDLs at country level

World Health Organization

Update on national EDLs

Dr Francis Moussy, WHO
Dr Antonio Villanueva, ERIA

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Context matters, and each country can decide the type of NEDL they want to develop

NEDL

Implementation:

With proper implementation of a NEDL, health professionals can have the tests they need where they need them

Patients can access these tests when they need them

World Health Organization

NEDL development and implementation efforts

- India and Nigeria currently working in implementation
- Nepal and Ethiopia have recently finalized their NEDL
- Pakistan and Timor Leste: NEDL final development phase
- Honduras has recently started NEDL development
- NEDLs under development in Kenya, Malawi, South Africa, the Gambia, Zimbabwe, Viet Nam and Indonesia

Kao K, Kohli M, Gautam J, Kassa H, Acellam S, Ndungu J, Albert H. Strengthening health systems through essential diagnostic lists and diagnostic network optimization. PLOS Glob Public Health. 2023 Mar 30;3(3):e0001773. doi: 10.1371/journal.pgph.0001773. PMID: 36996019; PMCID: PMC10062591.

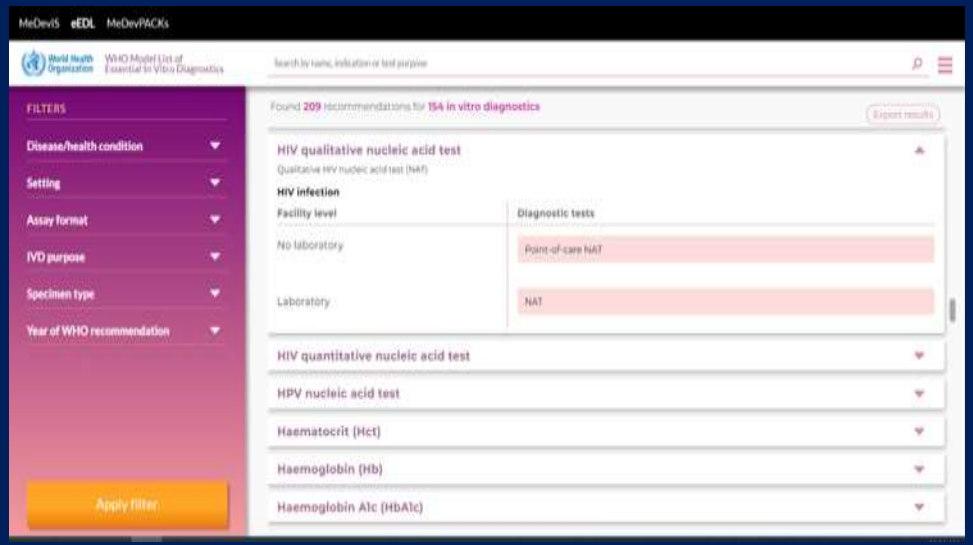
- Also, early stage, development for Cambodia, the Philippines and Thailand
- Burkina Faso, Madagascar, South Sudan: have also finalized NEDL development

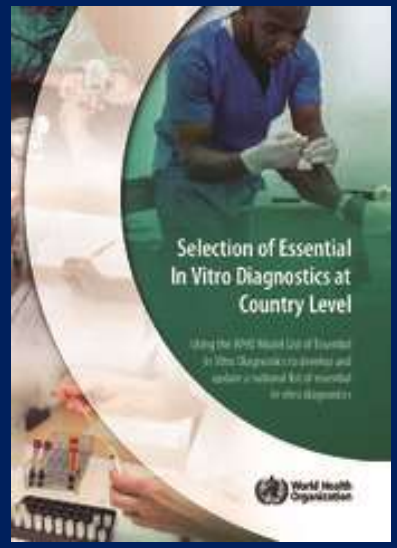
World Health Organization

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10062591/

Tools to support countries

1. WHO Technical Report Series The selection and use of essential IVDs including the EDL
2. Electronic EDL (eEDL)
3. Selection of essential in vitro diagnostics at country level: using the WHO Model List of Essential In Vitro Diagnostics to develop and update a national list of essential in vitro diagnostics
4. Technical specifications to support selection and procurement of IVD products *(added to the eEDL)*





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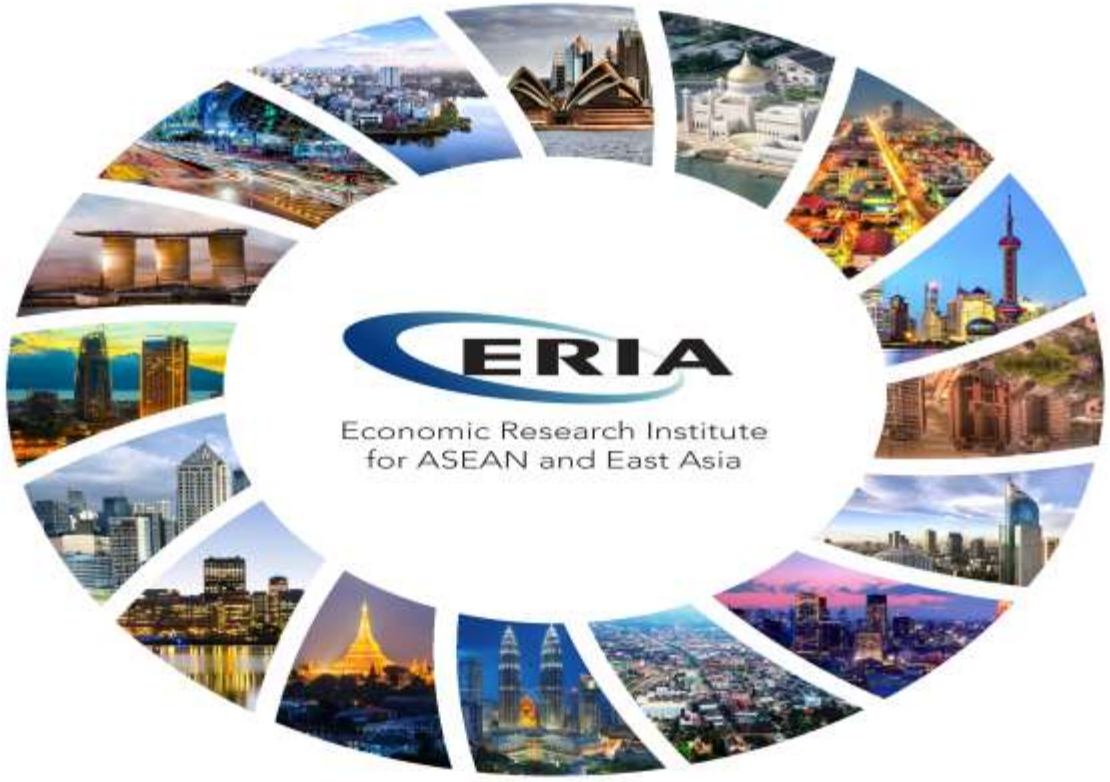


WHO EDL for AMS Project Brief

5th Meeting of the Strategic Advisory Group of Experts on IVDs
2024 November 25

ERIA Healthcare Unit NEDL team:
Dr. Manami Uechi, Director
Dr. Yasuyuki Mitsuhashi, Senior Policy Fellow
Dr. Antonio Villanueva, Senior Research Fellow, Lead
Mr. Narihiro Hirai, Chief Programme Manager
Dr. Achmad Solikhin, Health Programme Manager
Ms. Nanda Putri, Project Coordinator

Disclaimer

The opinions expressed in this presentation and on the following slides are based on currently available data as well as status of events and discussions with stakeholders and may therefore undergo modification in the future.

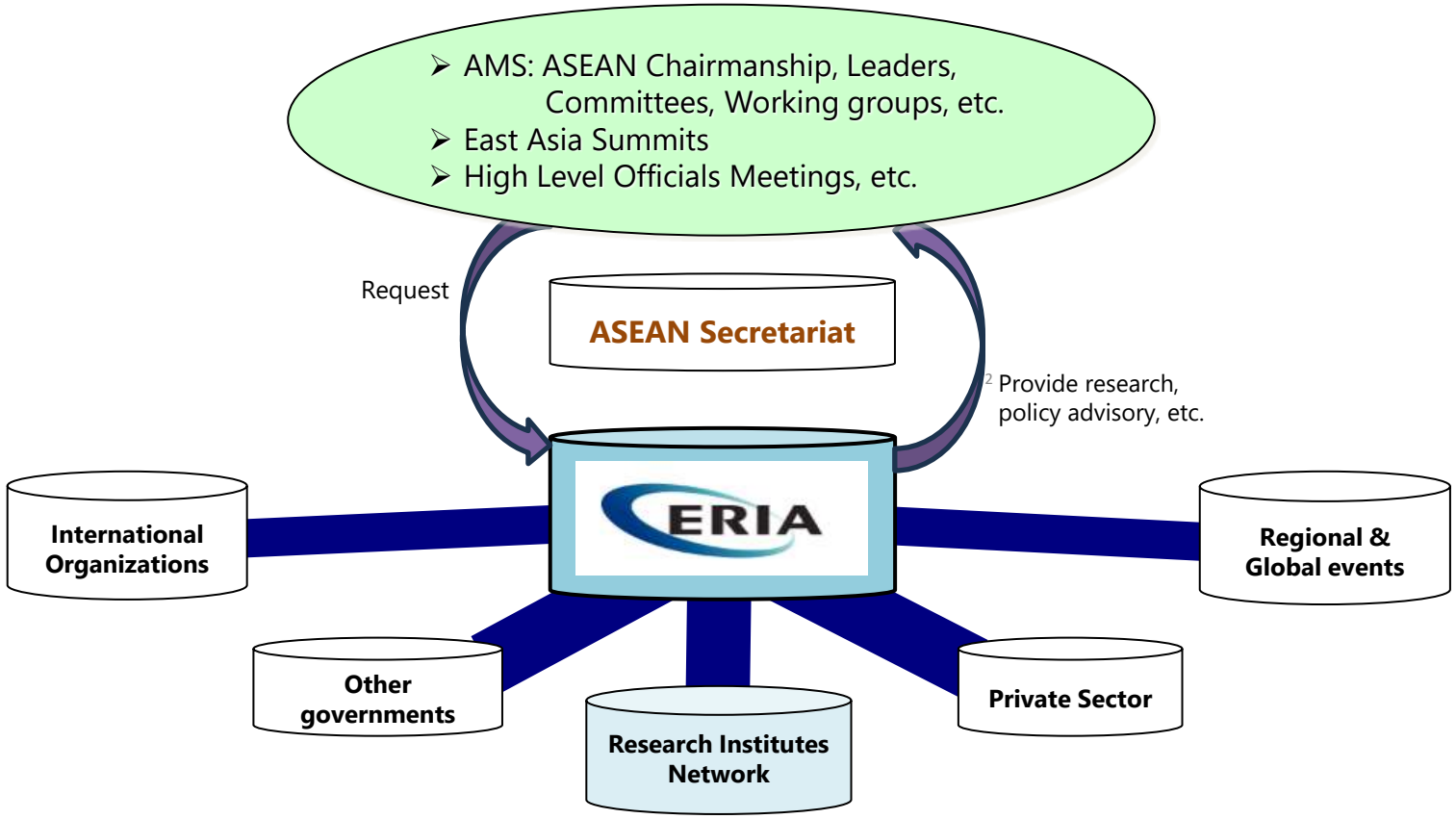
The Collaboration:

WHO ERIA ASEAN

What is ERIA?

- The Economic Research Institute for ASEAN and East Asia is an international research organization and an economic think tank that conducts research to produce evidence-based policy recommendations in supporting ASEAN and wider community building
- Established in 2007 by a formal agreement of the leaders of 16 East Asia Summit member countries.
- Member States:
  - ASEAN: Association of Southeast Asian Nations (10 countries)
  - Plus 6: Australia, China, India, Japan, New Zealand, South Korea
- HQ: The ASEAN Secretariat
  - Annex Office: Senayan, Jakarta, Indonesia

Our Network


AMS: ASEAN Chairmanship, Leaders, Committees, Working groups, etc.
East Asia Summits
High Level Officials Meetings, etc.
Request
ASEAN Secretariat
Provide research, policy advisory, etc.
ERIA
International Organizations
Regional & Global events
Other governments
Research Institutes Network
Private Sector

Commitment & Programmes

Support regional initiatives for sustainable growth & quality of life for the people in ASEAN and East Asia

ASEAN Chairmanship	**Healthcare Unit**	**ERIA Digital Innovation & Sustainable Economy Centre**
Asia CCUS Network (clean coal technology and carbon capture, utilisation, and storage)	**Capacity Building Programme**	**Asia Zero Emission Center**
ERIA School of Government	**Regional Knowledge Centre for Marine Plastic Debris**	**ASEAN/East Asia non-tarrif measures (NTM) Database**

10 ASEAN Member States

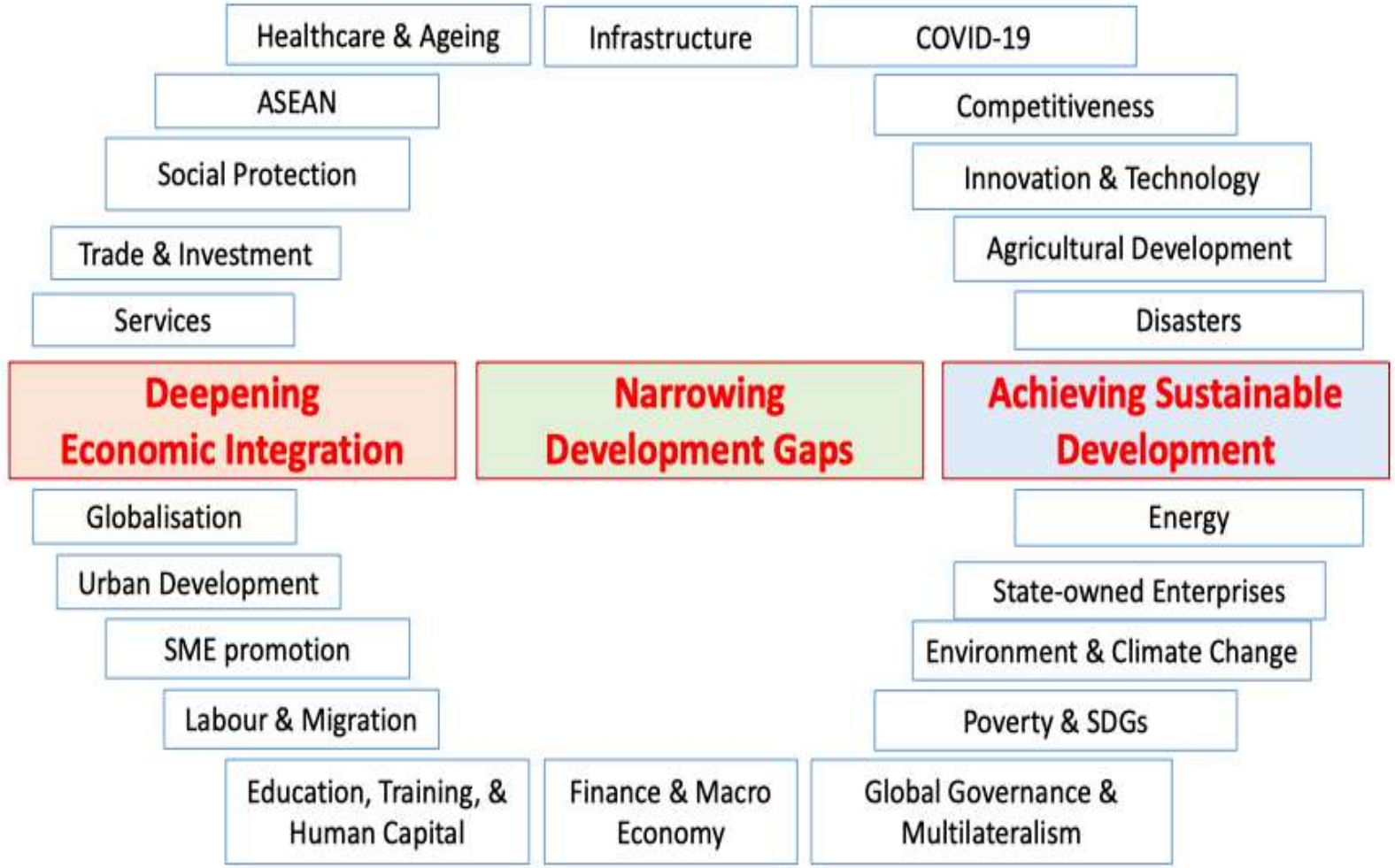
Brunei Darussalam	(WPRO)
Cambodia	(SEARO)
Indonesia	(SEARO)
Lao PDR	(WPRO)
Malaysia	(WPRO)
Myanmar	(SEARO)
the Philippines	(WPRO)
Singapore	(WPRO)
Thailand	(SEARO)
Viet Nam	(WPRO)
Observer Timor-Leste	(SEARO)

Getting to Know the WHO EDL for AMS Project

1 RATIONALE

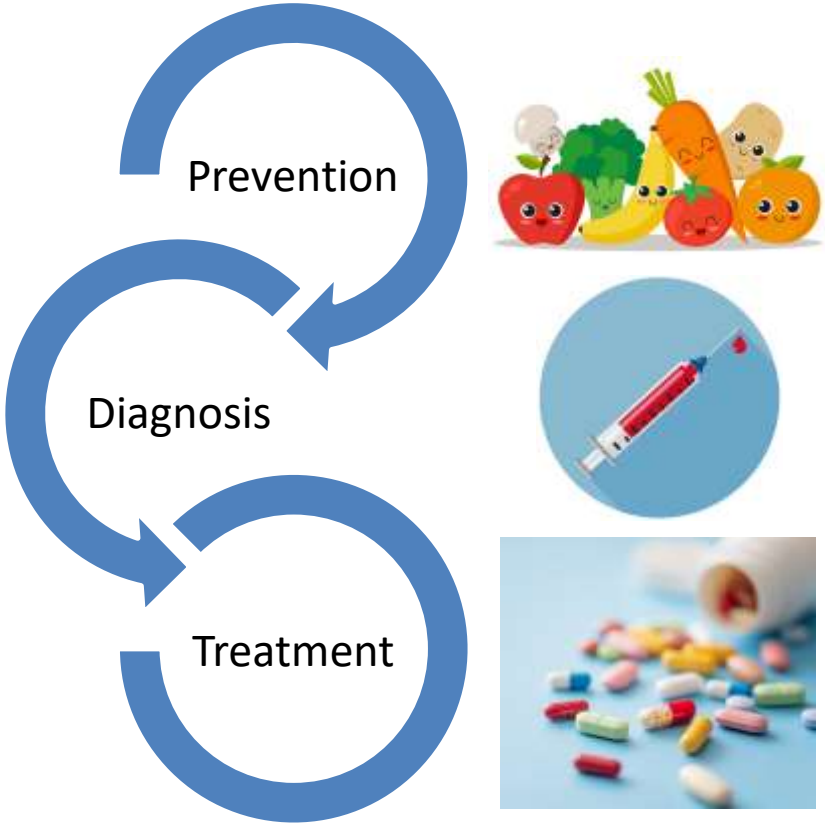
OF WHO ESSENTIAL DIAGNOSTICS LIST IN ASEAN MEMBER STATES

Research & Policy: Pillars & Areas



ASEAN: “We need support in diagnostics”

- To enhance UHC, 3 approaches to harmonised healthcare initiatives in ASEAN follow a patient-centered approach which track patients through the basic clinical model of healthcare:
  - Prevention, Promotion (Advocacy-Awareness), *e.g., vaccines*
  - Diagnosis/Detection
  - Treatment, Management, Rehabilitation



ASEAN Diagnostic initiatives

- *Example 1*: ACPHEED (ASEAN Center for Public Health Emergencies and Emerging Diseases)
  - Prevention, led by Viet Nam
  - Detection, led by Indonesia
  - Response, led by Thailand

- *Example 2*: A-SSR (ASEAN Security and Self-Reliance initiatives)
  - ASEAN Vaccine Security and Self-Reliance (AVSSR), led by Thailand
  - ASEAN Diagnostic Security and Self-Reliance (ADxSSR), led by Indonesia
  - ASEAN Drug Security and Self-Reliance (ADSSR), led by Malaysia

Essential Lists as baselines

- Among AMS, created decades ago were:
  - National Essential Medicines Lists, followed later by
  - National Essential Vaccines Lists.
  - The majority, however, do not yet have a unified National Essential Diagnostics List (NEDLs), which is the latest of the 3 essential lists released by WHO.

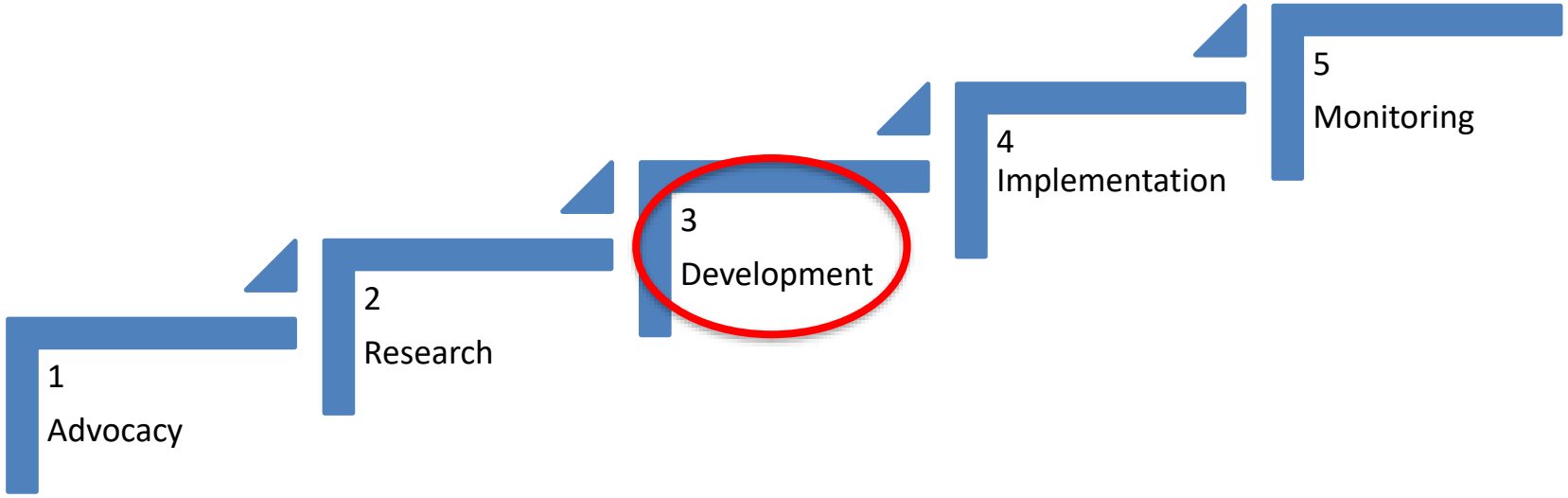
Advantages of a regional (ASEAN) NEDL development effort

- Advocates awareness of diagnostics at the regional (ASEAN) level, in accordance with WHA 76.5
- Models regional efforts toward global health security
- Serves as a foundation for ADxSSR
- Serves as a reference for ACPHEED (detection)
- Enhances UHC and Emergency Preparedness within ASEAN, more so for those ASEAN Member States (AMS) in need of improving health service delivery
- Improves procurement, supply chain logistics, equipment maintenance, quality assurance, regulatory affairs, and R&D of diagnostics at the national levels while providing evidence-based guidance on regional needs
- Regional meetings can streamline the sharing of NEDL development into regional guidance toward more effective implementation

2 TIMELINE

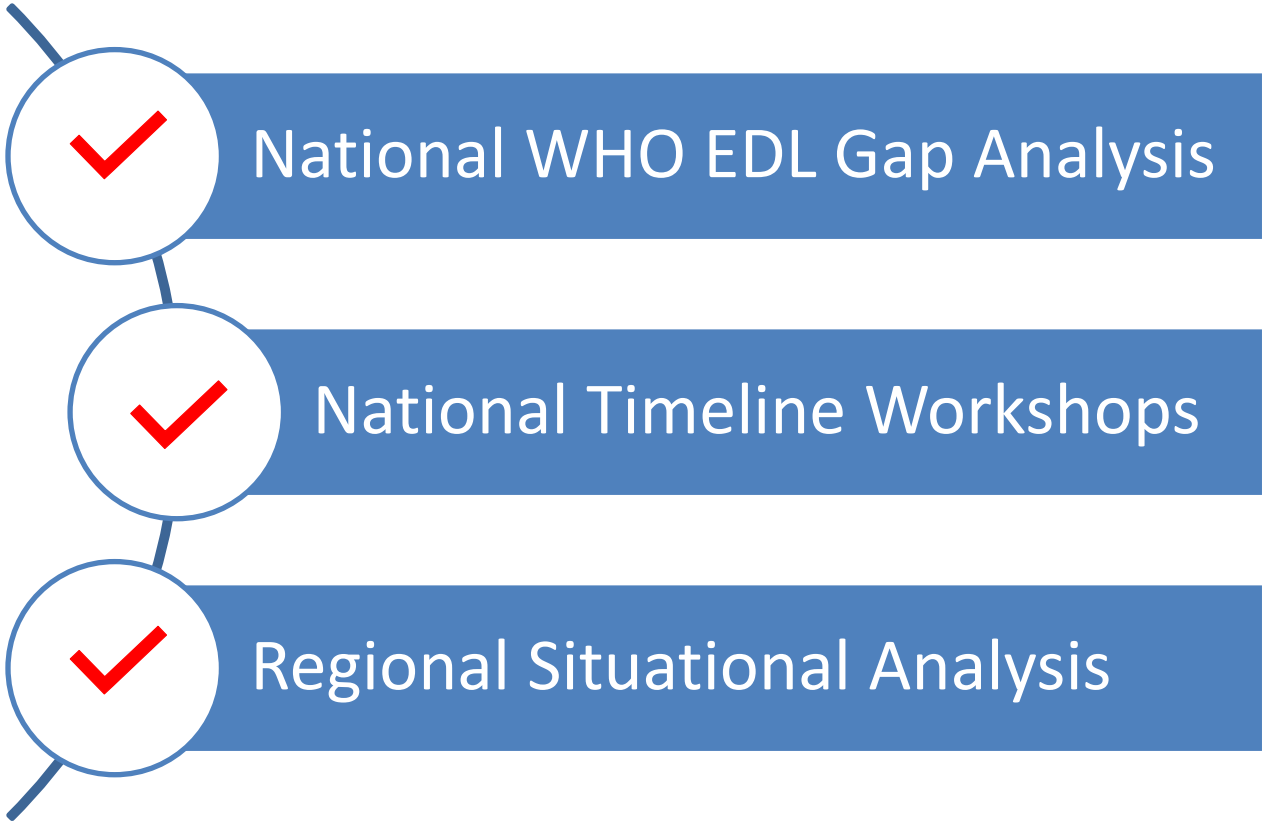
EDL FOR AMS PROJECT

Overview of Steps toward Effective NEDLs



Advocacy of WHO EDL for AMS

Research on WHO EDL for AMS

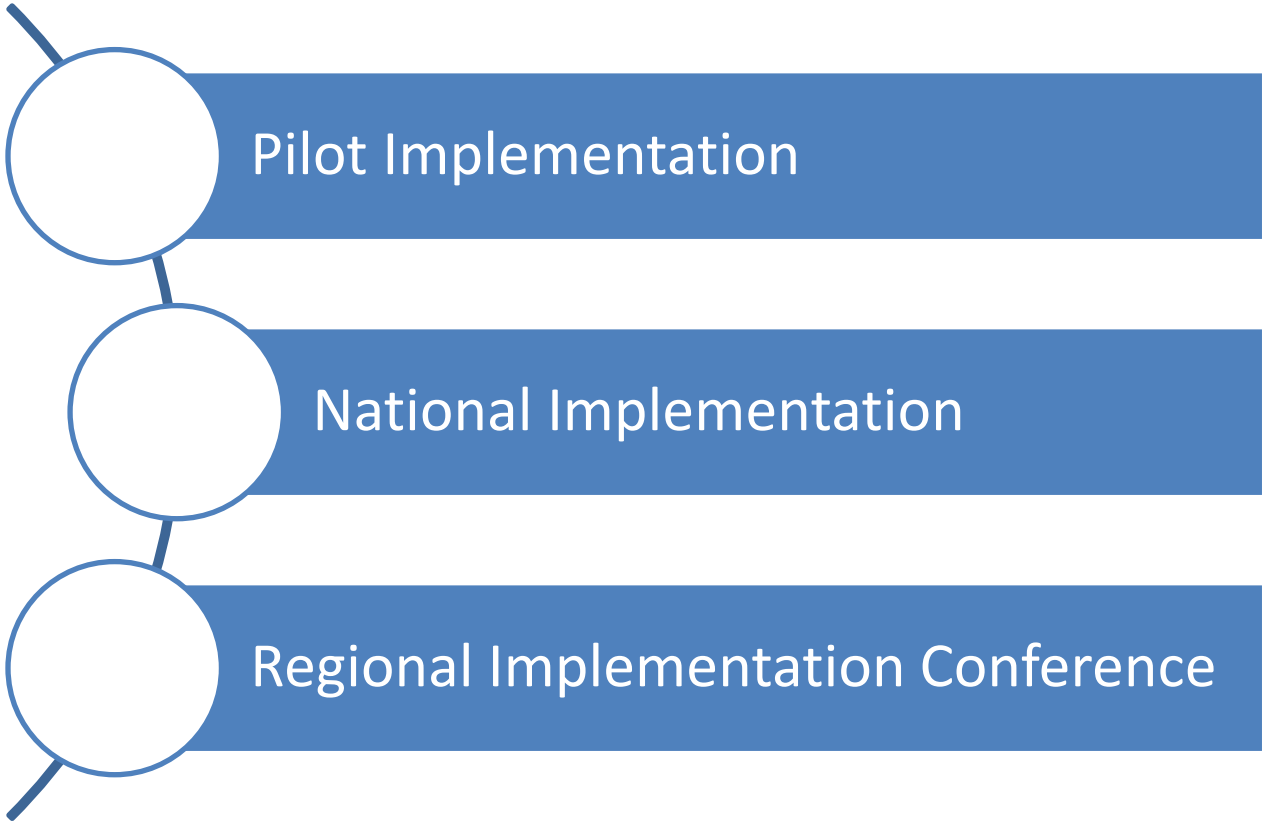


Development of Regional NEDLs

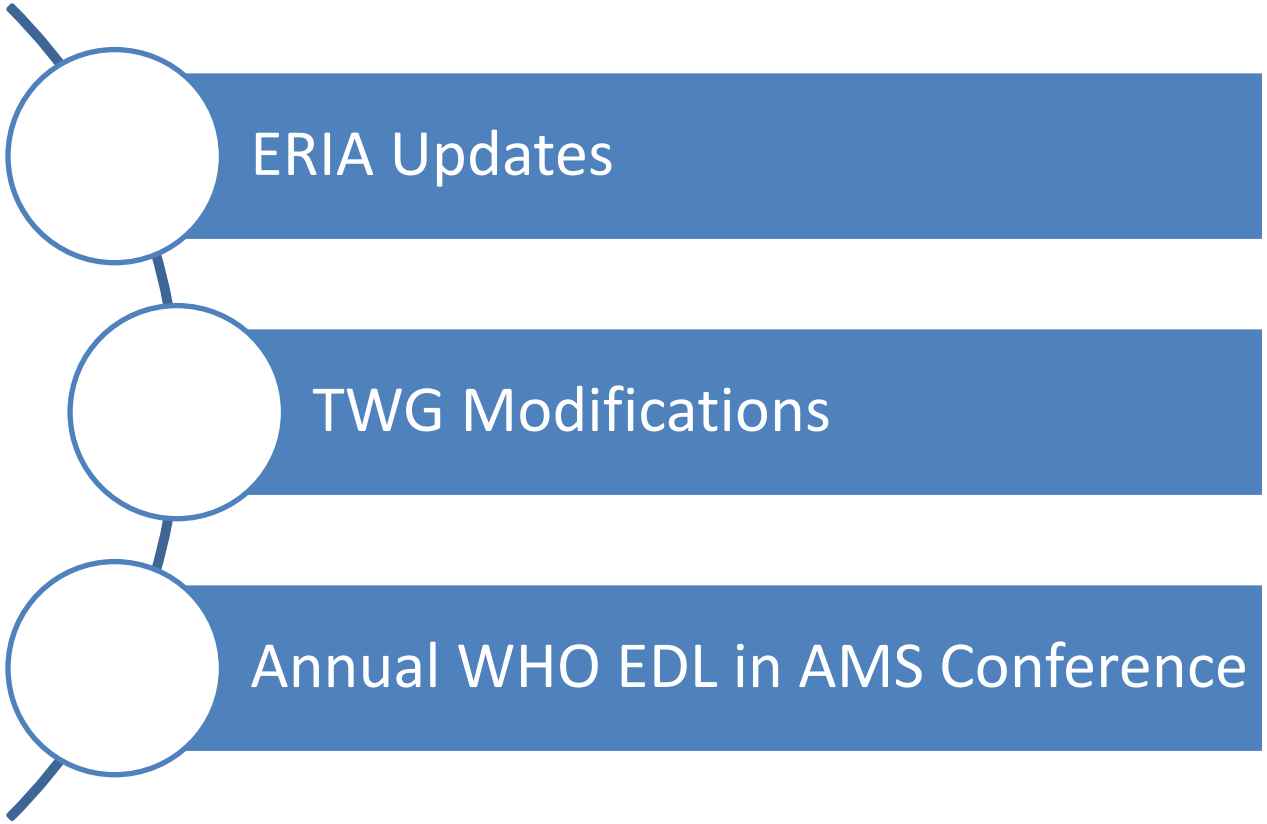
Why an NEDL Regional Advisory Committee

- As is the case of all proposed ASEAN projects, the lead country must have the support of AMS
- Varied healthcare systems exist within AMS, therefore while no one country can be a model for all, sharing updates on NEDL development among progressing AMS can benefit each other and other AMS
- Countries who have observable and progressive interest and continuous activity in NEDL development include Indonesia, the Philippines, Thailand
- NEDL is aligned with the scope of ADxSSR, meaning the NEDL lead collaborates with the ADxSSR lead for the betterment of regional diagnostic initiatives
- RAC may include representative experts from WHO, FIND, ERIA-NCGM, ASEC and others with a target as model for other developing regions
- The intent of the RAC does not involve power but rather emphasizes sharing of experiences and expert resources; there are no voting rights involved

Implementation of NEDLs



Monitoring of NEDL Implementation



3 STATUS

OF WHO EDL IN AMS

Map of NEDL Activity in AMS

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G

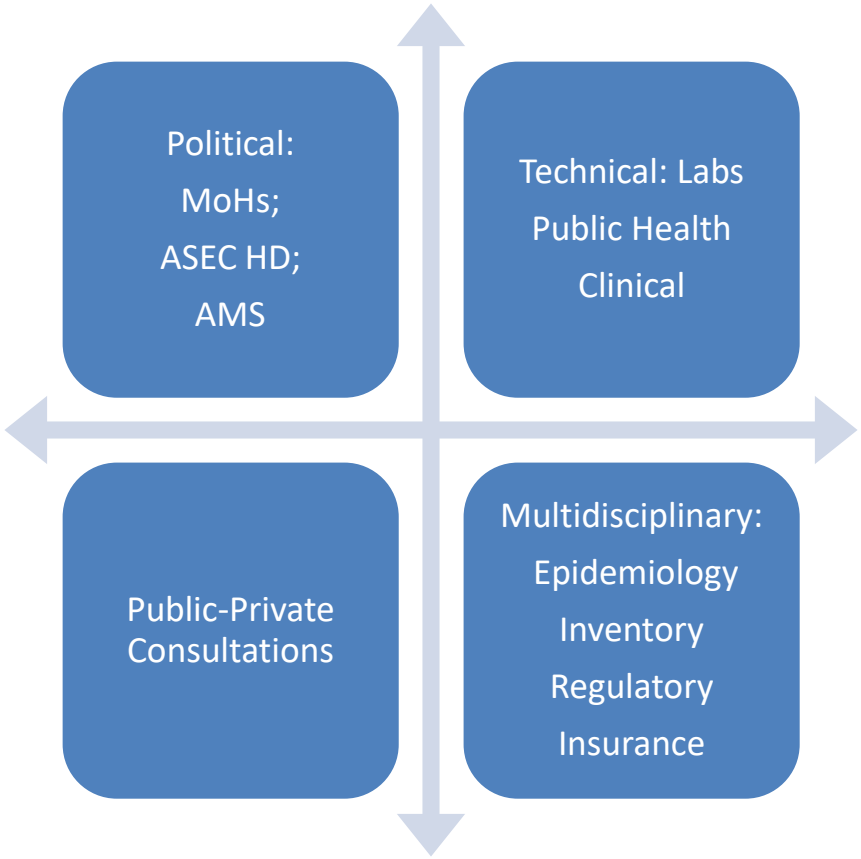
For approval 1

For approval 3

4 FOCUS ON DEVELOPMENT

TECHNICAL KNOW-HOW
ON DEVELOPMENT OF AN NEDL IN AMS:
NEXT STEPS

Matrix on How to Streamline Development of an NEDL in AMS



ERIA-DoH PH to co-host 2nd RCM on Development of NEDL for AMS in Manila on December 17-18, 2024

Time	Event	PIC
8:30-9:00	Registration	ERIA and DoH-Philippines
9:00-9:15	Opening Remarks (15 mins) • ERIA Managing Director for Policy Design and Operations • WHO Lead, Secretariat of the WHO Model List of Essential In Vitro Diagnostics (the EDL) • Department of Health Philippines (DoH) Undersecretary/Assistant Secretary	 Dr. Aladdin Rillo Dr. Francis Gabriel Moussy *(online)* *(TBC)*
9:15-9:30	Photo session (all participants)	DoH-Philippines
9:30-9:50	Presentation • ERIA and ADxSSR The Scope of Diagnostics Lists	Dr. Antonio Villanueva Dr. Roy Himawan
9:50-10:10	Presentation • NCGM Objectives of Developing an NEDL	Dr. Masami Fujita *(TBC)*
10:10-10:30	Presentation • WHO Guide to NEDL Development (Part I) - WPRO	Dr. Jinho Shin
10:30-10:50	Tea/Coffee Break	
10:50-11:10	Presentation: • WHO Guide to NEDL Development (Part II) - SEARO	Dr. Mohammad Ameel
11:10-11:30	Presentation: • Independent Consultants The Purpose of a WHO EDL Gap Analysis	Ms. Vivian Fensham and Mr. Fabrice Gerard
11:30-12:00	Presentation: • Observer Presentation of a Completed NEDL	Dr. Nevio Sarmento *(TBC)*
12:00-12:30	• Q&A	ERIA
12:30-14:00	Lunch	
14:00-14:30	Interactive Presentation • WHO Headquarters Familiarity with e-EDL	Dr. Ana Aceves *(online)*
14:30-15:00	Interactive Presentation • WHO Headquarters Familiarity with e-MeDeVis	Dr. Adriana Velazques Berumen *(online)*
15:00-15:15	Tea/Coffee Break	
15:15-16:45	Breakout Session 1 • Roundtable Consultations on How to Implement the WHO Roadmap on Development of an NEDL	AMS and Consultants
16:45-17:00	• Recap and Announcements	ERIA
17:00-19:00	***Free time***	
19:00-20:30	***Welcome Dinner (Casual Attire)***	

Time	Event	PIC
8:30-9:00	Registration	ERIA and DoH
9:00-9:10	Review of Day 1 and Expectations for Day 2	ERIA
9:10-10:10	Presentations • Progress of NEDL Development (20 mins each)	DoH-Philippines MoH-Indonesia MoH-Thailand
10:10-10:30	Tea/Coffee Break	
10:30-12:00	Breakout Session 2 • Roundtable Consultations on How to Implement the WHO Roadmap on Development of an NEDL	AMS and Consultants
12:00-13:30	Lunch	
13:30-15:10	Reports from AMS Delegates • on Moving Forward after this RCM (10 mins each)	ERIA
15:10-15:30	Tea/Coffee Break	
15:30-16:30	Plenary • Draft the Summary and Recommendation/Guidelines	ERIA & DoH-PH
16:30-16:45	Closing Remarks • ERIA Director of Healthcare Unit • DoH/PH – HFMB OHL NEDL-PH Lead	 Dr. Manami Uechi Ms. Nette Marayag
16:45-17:00	***Administrative and Logistical Matters including Distribution of Certificates and Per-diem***	***ERIA***

Focus: Forming a Technical Working Group

- Based on the OTMFM
- *Objectives as TWG Members Framework Matrix*
- *What are your national objectives for developing an NEDL / Who will use it?*

- Map the epidemiologic BoD
- Map the inventory, noting procurement and supply history
- Note the diagnostic requirements for UHC, emergency preparedness, priority programs including EML
- Check national health insurance coverage
- Specify requirements for regulatory and setup

- Compare/customise from WHO EDL and MeDevIS diagnostics with existing vs ideal lists

- Send TWG invitations to:
- *(depending on national objectives)*

- Epidemiologist/Surveillance
- Local authority for Procurement
- Policymaker for UHC/emergency preparedness/priority programs
- Technical EML/EVL
- Representative for national health insurance coverage
- Regulatory on diagnostics
- Regulatory on set up of health facilities
- Specialist on diagnostic specifications, maintenance, and quality assurance
- Designers of existing lists

- Gather information/collect data
- Set consultation period with local health system expert and EDL/MeDevIS expert

Sample TWG Invitation Letter

October 14, 2024

National Epidemiology Center
Ministry of Health
Country

- Dear Dr Epidemiologist who works on Burden of Disease/Surveillance,
- Decades ago our Ministry developed an Essential Medicines List followed later by an Essential Vaccines Program. Only recently in 2018, the WHO released the Model Essential Diagnostics List as well, which serves as a guide for the development of a National Essential Diagnostics List. Post-pandemic, ASEAN also realised the need for diagnostic security and created the ASEAN Diagnostic Security and Self-Reliance (ADxSSR) initiative. Further, in line with WHA Resolution 76.5 (May 2023) which mandates for attention to diagnostics including the update on progress of NEDL development by 2025, our Ministry supports the creation of an NEDL Technical Working Group led by NEDL lead unit. To support the objectives of our NEDL, may we invite you to become a TWG member because of your expertise in identifying geographic burden of disease-based needs of our population.
- In this regard, we would appreciate your attendance at our first meeting to be held at PLACE on WHEN. The objectives of the NEDL and a strategic plan on how to move forward will be discussed. In total, there will be 3 to 4 meetings over the course of the next 4 months. Please confirm your attendance through WHO CONTACT INFO, or you may nominate a fellow expert.
- Thank you for your attention and we look forward to your significant contribution in this landmark national document.
- Sincerely yours,
- Signed

Readings

- EDL for AMS Regional Consultative Meeting Concept Note/Proposal, Agenda, List of Delegates, Summary and Recommendations

- Review WHO EDL PowerPoint on Impact of EDL
- Review WHO EDL document & electronic versions: https://iris.who.int/bitstream/handle/10665/373322/9789240081093-eng.pdf
- https://edl.who-healthtechnologies.org/ (EDL)
- https://medevis.who-healthtechnologies.org/ (MeDevIS)

- Review WHO EDL PowerPoint & Publication on How to Develop a National EDL
- https://www.who.int/publications/i/item/9789240030923

Thank you　អរគុណ　謝謝
धन्यवाद　Terima kasih

ありがとうございました

감사합니다　ຂອບໃຈ

ကျေးဇူးတင်ပါတယ်　NGĀ MIHI
Salamat po　ขอบคุณ
感谢　Cảm ơn bạn

The WHO Model Lists of Essential Medicines & Essential In-vitro Diagnostics

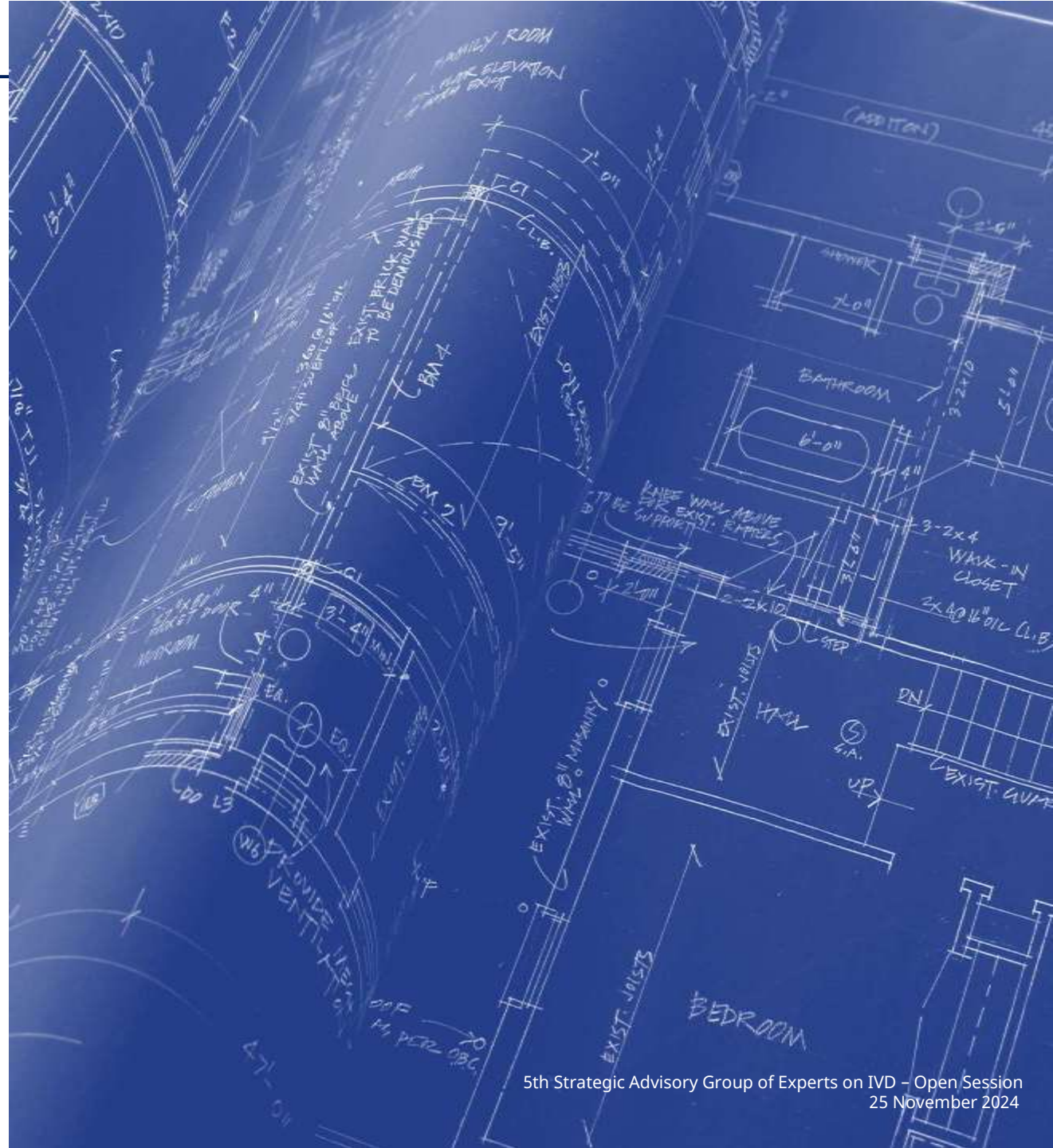
Bernadette Cappello
Technical Officer, Essential Medicines
Department of Health Products Policy & Standards

World Health Organization

5th Strategic Advisory Group of Experts on IVD – Open Session
25 November 2024

The WHO Model Lists

The primary purpose of the WHO Model Lists is to provide a blueprint for national authorities to adopt or adapt in accordance with local priorities and treatment guidelines for the development and updating of national EMLs / EDLs.



World Health Organization

Essential medicines:

- ✓ Satisfy the priority health care needs of the population
- ✓ Selected considering disease prevalence / public health relevance, evidence of efficacy and safety, comparative cost and cost-effectiveness
- ✓ Should be available within functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at affordable prices for individuals and the community

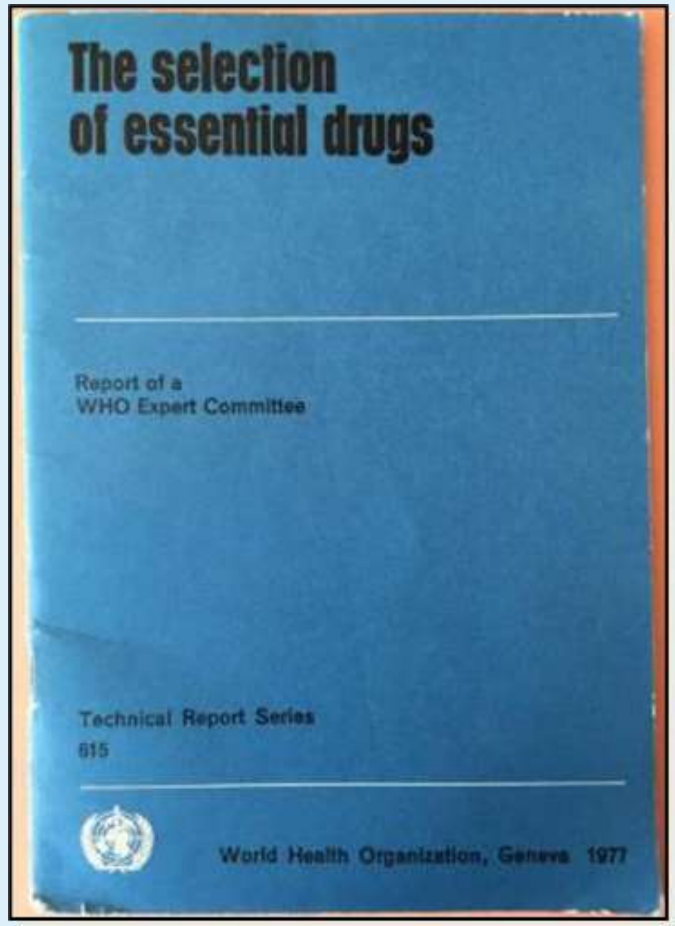
World Health Organization

Essential medicines concept:

- ✓ A limited range of carefully selected medicines leads to better health care, better medicines management and lower costs
- ✓ Accepted as a powerful means to promote health equity and achieve universal health coverage
- ✓ Incorporates the need to regularly update medicines selection to reflect new therapeutic options and changing therapeutic needs

WHO Model Lists of Essential Medicines

- First published in 1977, containing 208 medicines
- Introduced the idea that “some medicines are more important than others”
- Complemented in 2007 by the Model List of Essential Medicines for Children
- In 2023: 502 and 361 medicines on EML and EMLc, respectively
- Next update in May 2025



World Health Organization

Essential medicines and companion diagnostics:

In vitro diagnostics provides essential information for the safe and effective use of a medicine or biological product.

- ✓ Identify patients who are **most likely to benefit** from treatment
- ✓ Identify patients likely to be at **increased risk of adverse effects**
- ✓ Monitor **response to treatment**

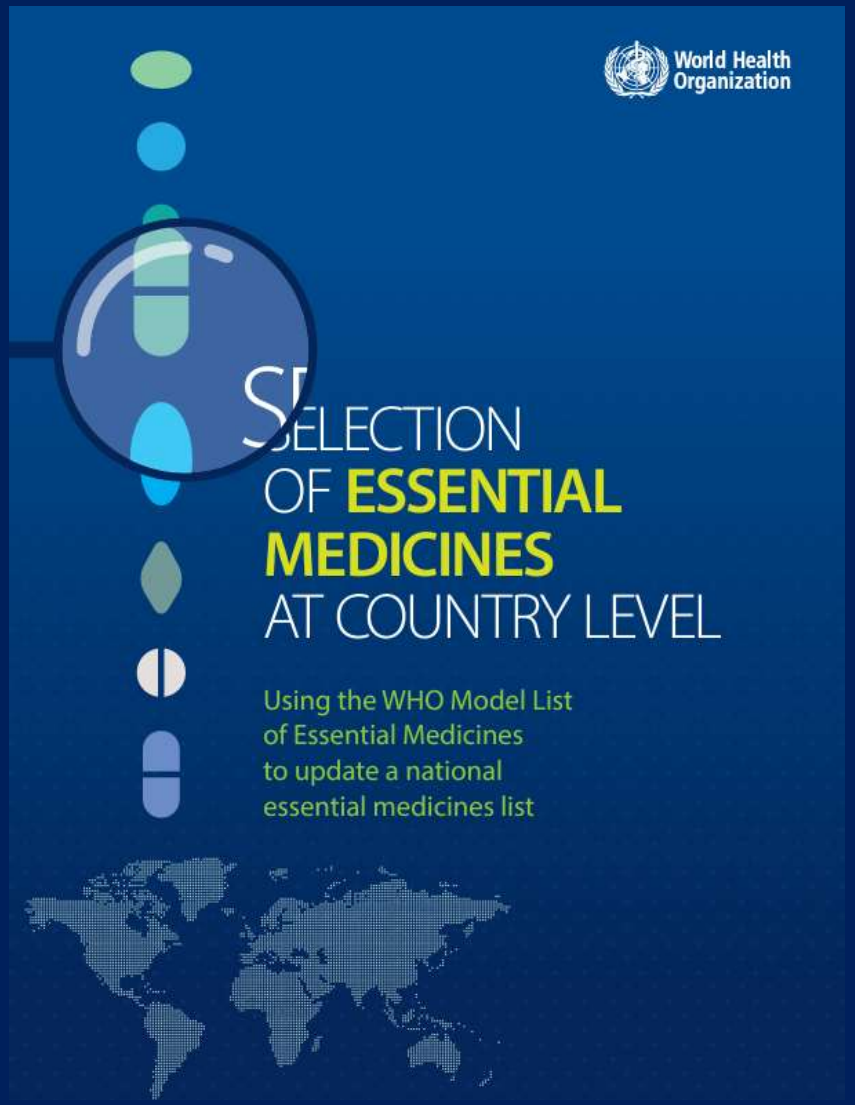
World Health Organization

The WHO Model Lists and national EMLs / EDLs:

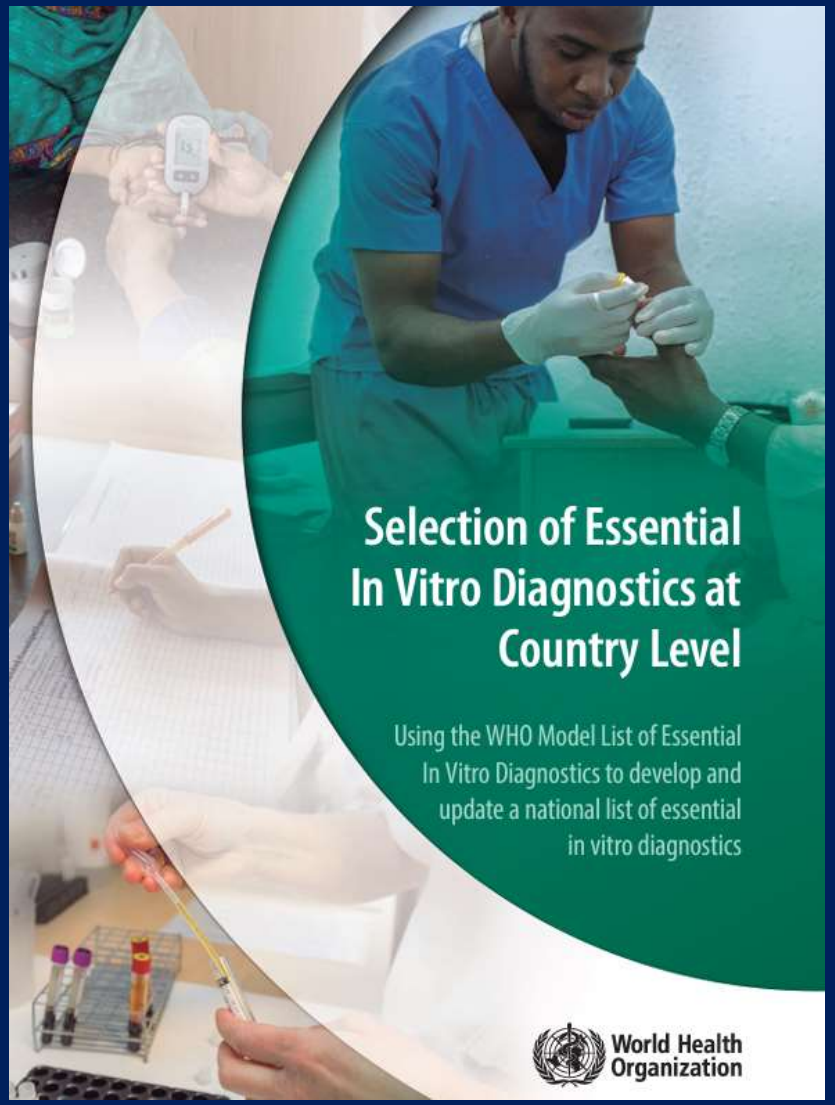
How can essential medicines and IVDs evaluation by WHO assist countries in national selection?

- *When a medicine/IVD is listed on the WHO Model Lists, it becomes a priority for access and reimbursement*
- *A recommendation NOT to include a medicine on the WHO Model List should also have implications at country level (e.g. deprioritize ?)*

World Health Organization



https://iris.who.int/handle/10665/330898



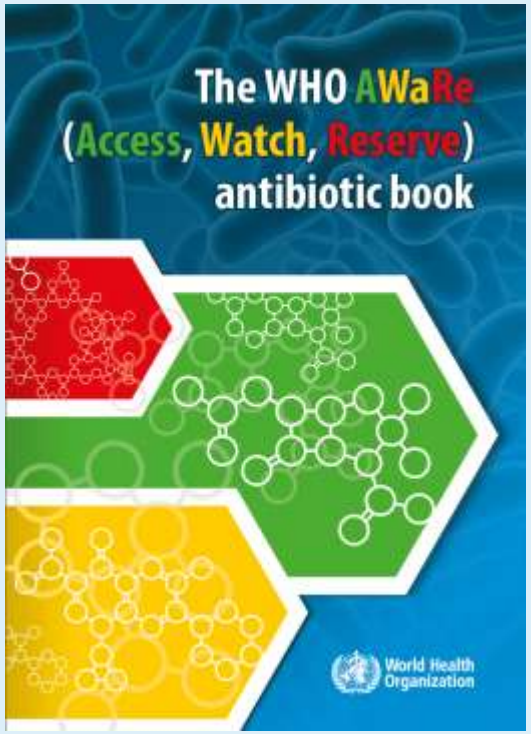
https://iris.who.int/handle/10665/343385

World Health Organization

“Treatment without diagnosis is a form of quackery”

Paris J. Can Psychiatr Assoc J. 1975 Jun;20(4):305-7.

EML, EDL, and AWaRe



https://iris.who.int/handle/10665/365237

Table 23.2 – Microbiology tests to consider for diagnosis of lower urinary tract infections as indicated in the WHO EDL *(6)*

Diagnostic test	Purpose of the test	Settings where the test should be available
Urine culture[a] and antimicrobial susceptibility testing	Initial step to detect and identify bacterial and fungal species for selection of appropriate antimicrobial regimens	Health care facilities with clinical laboratories

EDL: Model List of Essential In Vitro Diagnostics.

[a] **A positive urine culture in an asymptomatic patient indicates bacterial colonization and does not require treatment except in pregnant women or in patients undergoing urological procedures in which bleeding is anticipated.** Bacterial colonization of the urine is a common finding, especially in women, the elderly (both sexes) and individuals with underlying urological abnormalities. Of note, the absence of urine leukocytes has a good negative predictive value but the positive predictive value of leukocyturia is poor.

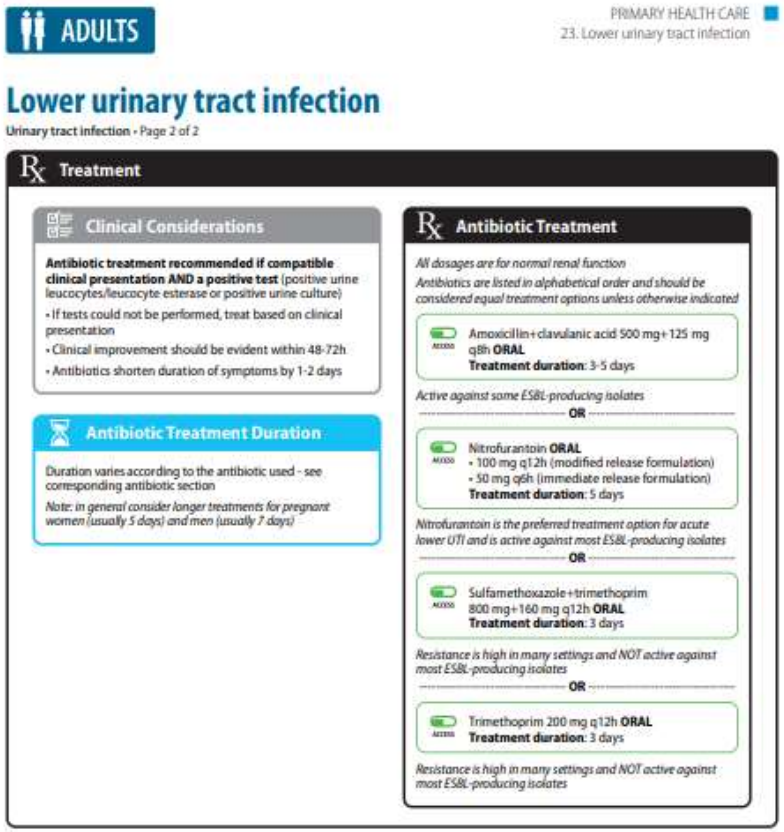
In patients with symptoms of a UTI, a urinalysis (dipstick or microscopy) may be done to detect the presence of bacteriuria and pyuria (Table 23.3), while blood tests are not generally used to confirm infection – tests results would be normal in case of lower UTI. In a symptomatic patient, leukocyturia (> 10 leukocytes/µL, 0.01 x 10^9/L), the presence of leukocyte esterase and/or positive nitrites are indirect signs of infection. Of note, leukocyturia or the presence of leukocyte esterase without symptoms is not an indication for antibiotic treatment.

Table 23.3 – Laboratory tests to consider for diagnosis of lower urinary tract infections as indicated in the WHO EDL *(6)*

Diagnostic test	Purpose of the test	Settings where the test should be available
Urinalysis test strips	To detect urinary tract infections	Community settings and health facilities without laboratories[a]

EDL: Model List of Essential In Vitro Diagnostics.

[a] Community and health settings without laboratories are settings such as health posts and centres, doctors' offices, outreach clinics and ambulatory care. These tests are also assumed to be available at health care facilities with laboratories.


ADULTS

PRIMARY HEALTH CARE
23. Lower urinary tract infection

Lower urinary tract infection

Urinary tract infection • Page 2 of 2

Treatment

Clinical Considerations

Antibiotic treatment recommended if compatible clinical presentation AND a positive test (positive urine leucocytes/leucocyte esterase or positive urine culture)
- If tests could not be performed, treat based on clinical presentation
- Clinical improvement should be evident within 48-72h
- Antibiotics shorten duration of symptoms by 1-2 days

Antibiotic Treatment Duration

Duration varies according to the antibiotic used - see corresponding antibiotic section

Note: in general consider longer treatments for pregnant women (usually 5 days) and men (usually 7 days)

Antibiotic Treatment

All dosages are for normal renal function

Antibiotics are listed in alphabetical order and should be considered equal treatment options unless otherwise indicated

Amoxicillin+clavulanic acid 500 mg+125 mg q8h **ORAL**
Treatment duration: 3-5 days

Active against some ESBL-producing isolates

OR

Nitrofurantoin **ORAL**
- 100 mg q12h (modified release formulation)
- 50 mg q6h (immediate release formulation)

Treatment duration: 5 days

Nitrofurantoin is the preferred treatment option for acute lower UTI and is active against most ESBL-producing isolates

OR

Sulfamethoxazole+trimethoprim 800 mg+160 mg q12h **ORAL**
Treatment duration: 3 days

Resistance is high in many settings and NOT active against most ESBL-producing isolates

OR

Trimethoprim 200 mg q12h **ORAL**
Treatment duration: 3 days

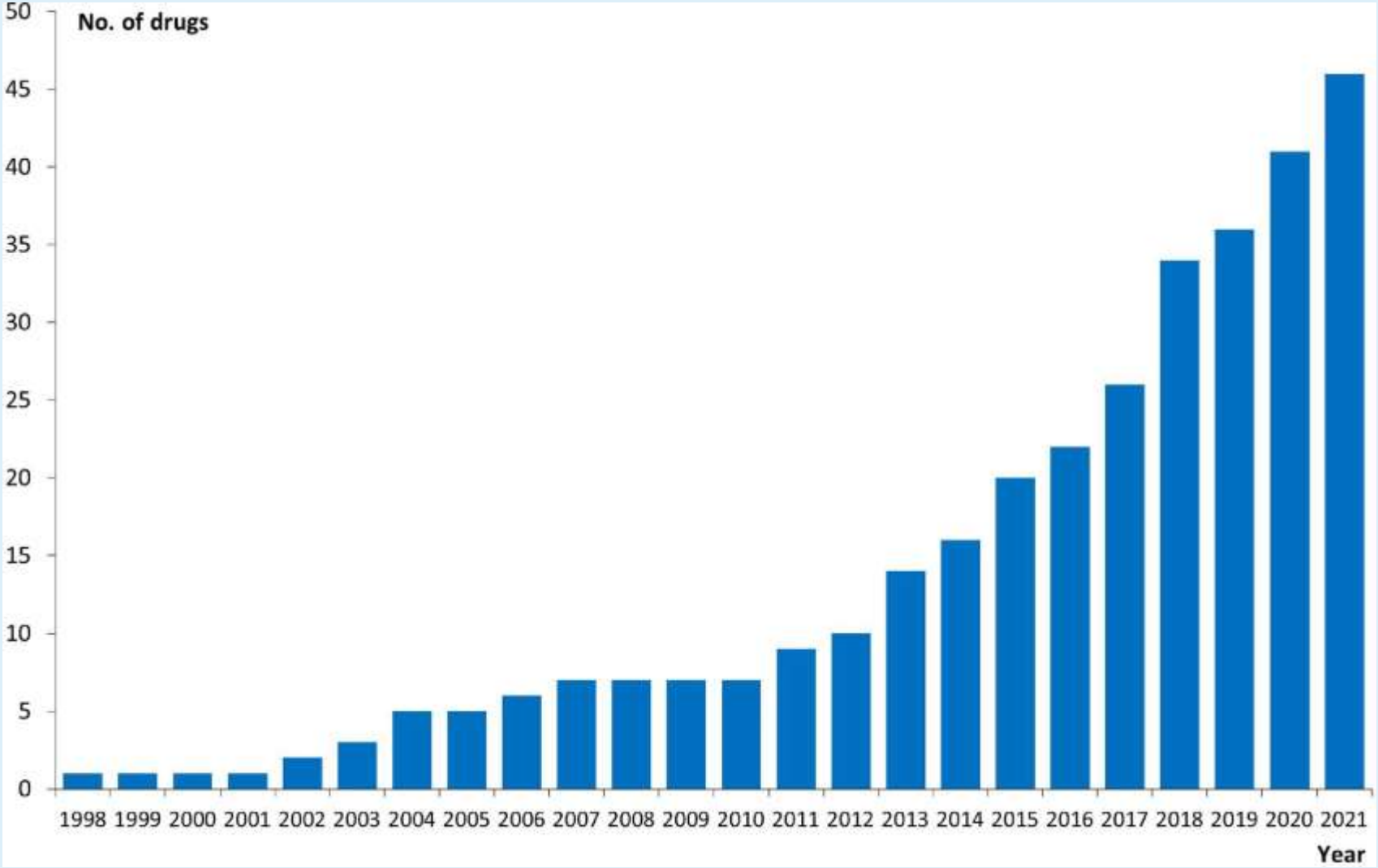
Resistance is high in many settings and NOT active against most ESBL-producing isolates

World Health Organization

“Since the mapping of the human genome in 2003, the development of biomarker targeted therapy and clinical adoption of “personalized medicine” has accelerated.”

Merlin T et al. Med Decis Making. 2013 Apr;33(3):333-42

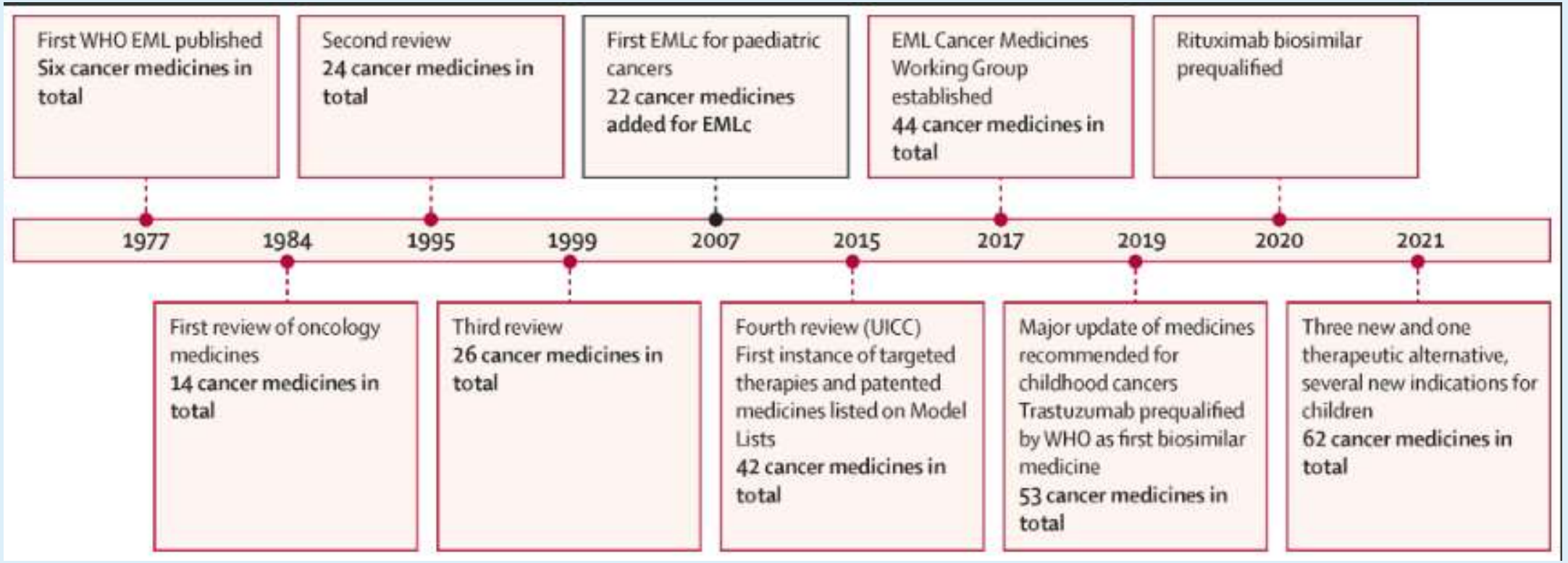
Cumulative number of FDA-approved oncological and hematological medicine companion diagnostic combinations by year.



Jørgensen JT. Cancer Treat Res Commun. 2021;29:100492

World Health Organization

EML, EDL, and cancer medicines



Jenei et al. Lancet Glob Health. 2022 Dec;10(12):e1860-e1866

World Health Organization

EML cancer medicines and companion diagnostics

Year	# applications for cancer medicines	% applications where cancer medicines would potentially require a companion diagnostic
2017	5	60 %
2019	13	54 %
2021	24	54 %
2023	12	67 %
2025	??	??

World Health Organization

2025 EML update

- Application period closed on **1 November 2024**
- Applications to be published on the WHO website for comments on **1 February 2025**
- Meeting of the Expert Committee on Selection and Use of Essential Medicines from **5-9 May 2025**
- **Release of updated EML in July/August 2025**
  - (implications of EML recommendations for future EDL updates communicated to EDL Secretariat)

World Health Organization

Thank you

For more information, please contact:

Bernadette Cappello
Technical Officer, Essential Medicines
Department of Health Products Policy & Standards

cappellob@who.int

‘We Go Together’ – Grease, 1978
https://www.youtube.com/watch?v=kx2P1bSFOTo

World Health Organization

*The WHA 76.5 resolution on Strengthening diagnostics capacity

*MeDevIS, the UHC Compendium and the electronic EDL: improving access to diagnostic tools

*WHO Diagnostics Task Force

Ms Adriana Velazquez
MDD Team lead
WHO HQ

World Health Organization

WHA mandates on Diagnostics

Monday, 25th November 2024

World Health Organization

Agenda

World Health Assembly mandates related to Diagnostics

1. **WHA60.29 Health technologies, in particular medical devices**
2. **Essential in vitro diagnostic list and Priority Medical Devices**
3. **MeDevIS and EDL databases**
4. **WHA75.25 Standardized medical devices nomenclature**
5. **WHA76.5 Strengthening Diagnostics Capacity**
6. **Diagnostics taskforce and Diagnostics Consortium**
7. **Use of essential in vitro diagnostics and priority medical devices in other databases**

Next events:

DxCo and 5th Global Forum Medical devices to June 2025.

World Health Organization

WHA60.29

In vitro diagnostics are a type of medical devices

WHA60.29 Health technologies[1]

The Sixtieth World Health Assembly,

Having considered the report on health technologies;[2]

Recognizing that health technologies equip health-care providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation and attainment of internationally agreed health-related development goals, including those contained in the Millennium Declaration;

Acknowledging the need for Member States and donors to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies, in particular medical devices, on the basis of their impact on the burden of disease, and to ensure the effective use of resources through proper planning, assessment, acquisition and management;

Noting the need to expand expertise in the field of health technologies, in particular medical devices;

WHO has been developing the medical devices technical series as a mandate from WHA60.29 to support Member States.

World Health Organization

There are 10,000 thousands of types of medical devices… including in vitro diagnostics

used at all levels of health care.

In vitro diagnostic, laboratory

Medical equipment

Surgical instruments

Single use medical devices

Implantable medical devices

Some assistive devices

Some personal protective equipment

Software as medical device

World Health Organization

5 elements towards improving access to safe, quality, affordable medical devices, towards increased quality of health care everywhere

1. Nomenclature of medical devices

2.R&D

Academia and industry
- Innovation
- Manufacturing

3. Regulation

National regulatory agencies
- Lists of approved MD for marketing in the country

4. Assessment

Ministries of Health (policies, HTA-different in every country)
- Selection of National Lists of MDs for reimbursement or procurement
- Health care benefit packages, national policies,

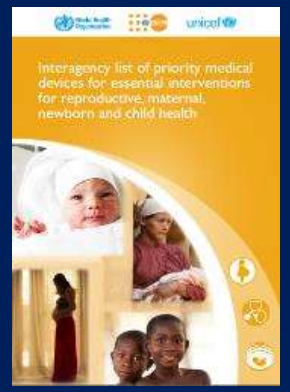
5. Management

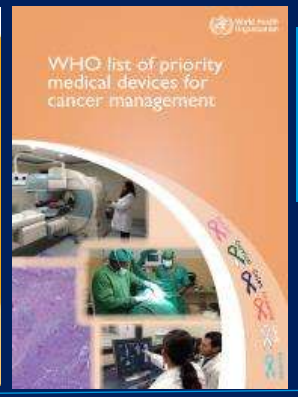
Health care providers
- Procurement, installation, training, maintenance,
- Safe use, operating costs
- Post market surveillance and adverse event report
- Decommissioning and replacement

World Health Organization

Medical devices can save lives and increase quality of life

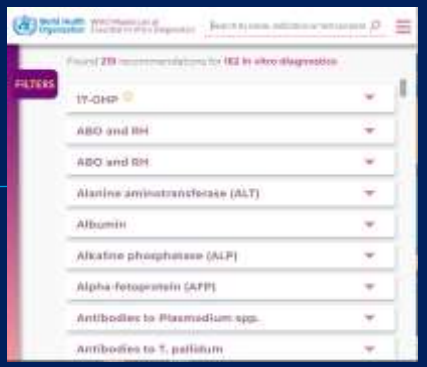
WHO selects Priority medical devices for MS to include in the national list.

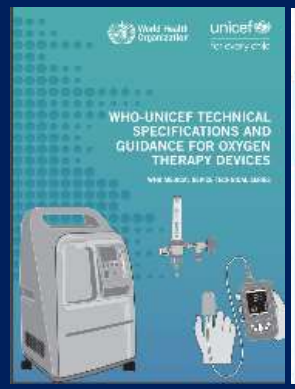


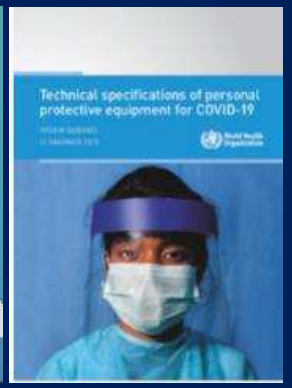


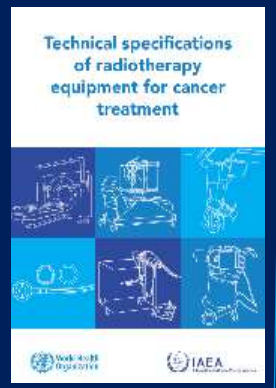
Oxygen related med devices are described in all of them!

List of essential/ priority

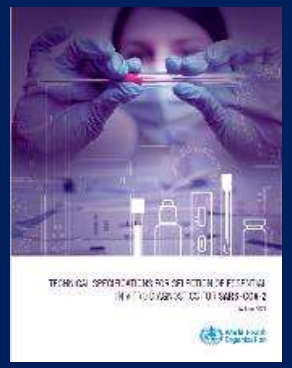








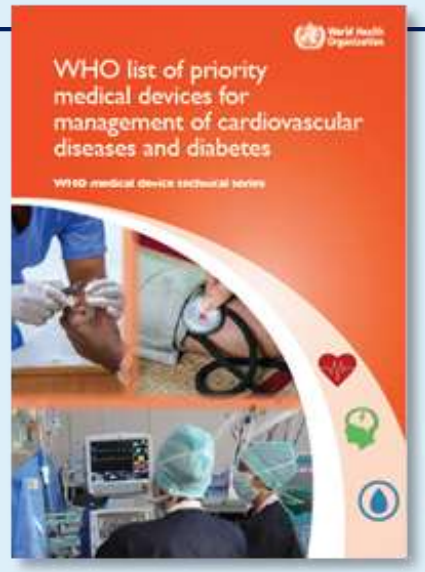
Technical specifications

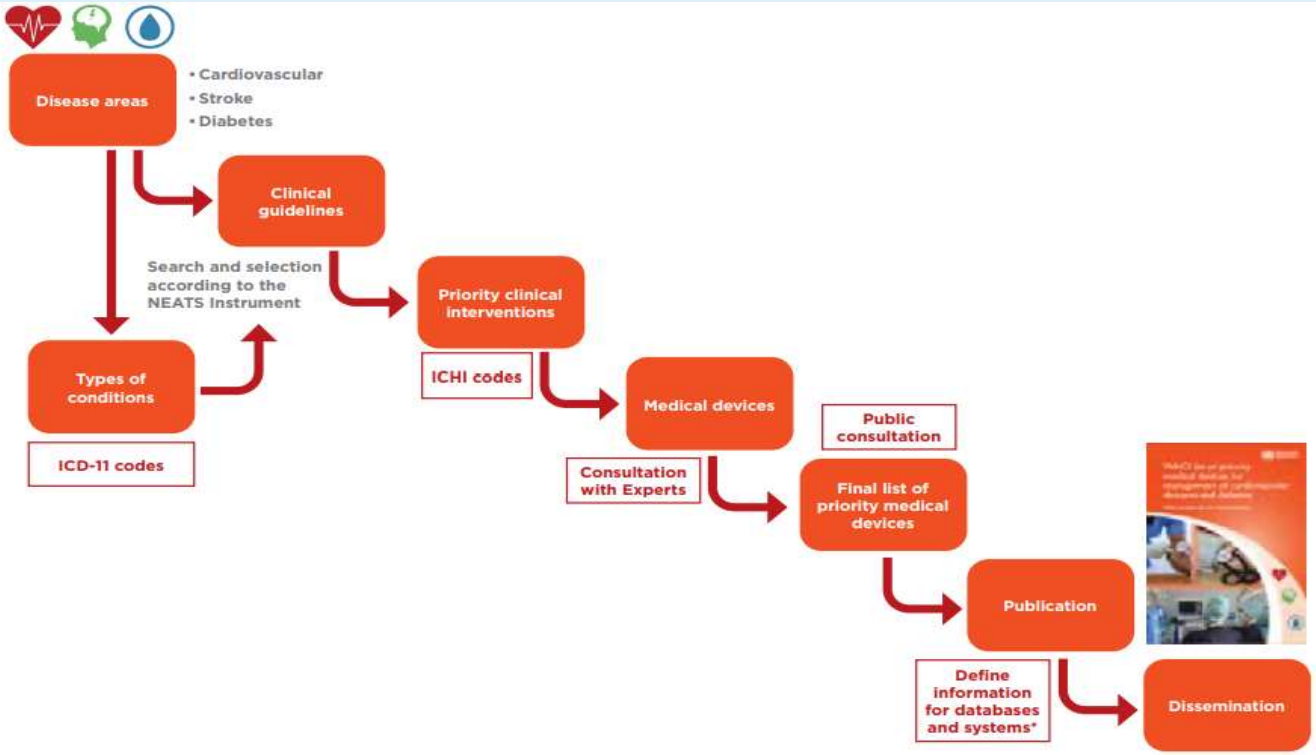


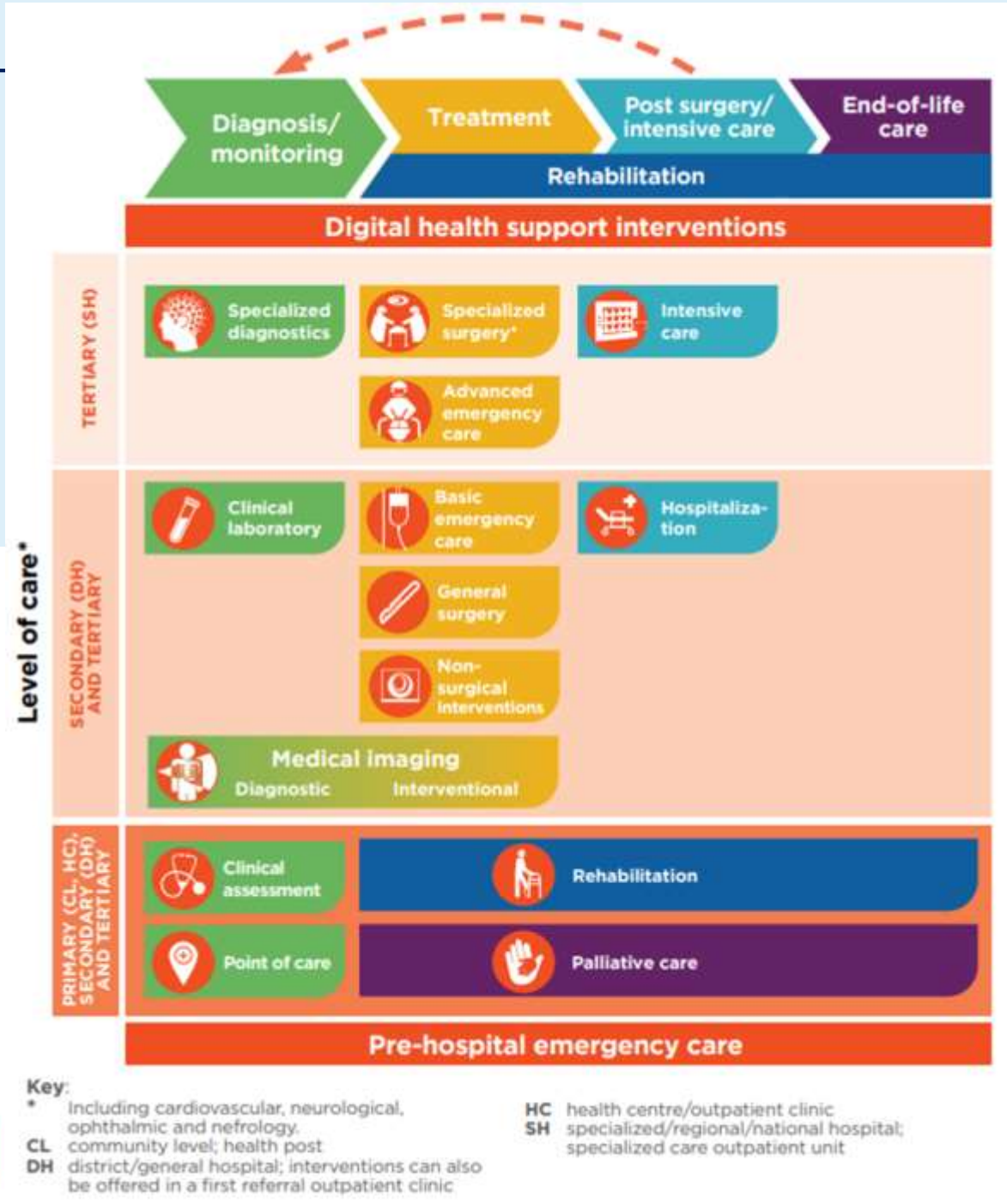
2015 2017 2020 2021 2018-2019-2021-2023

World Health Organization

https://www.who.int/health-topics/medical-devices
https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1
https://medevis.who-healthtechnologies.org/


WHO list of priority medical devices for management of cardiovascular diseases and diabetes


Disease areas
• Cardiovascular
• Stroke
• Diabetes
Clinical guidelines
Search and selection according to the NEATS instrument
Types of conditions
ICD-11 codes
Priority clinical interventions
ICHI codes
Medical devices
Consultation with Experts
Public consultation
Final list of priority medical devices
Publication
Define information for databases and systems*
Dissemination


Diagnosis/ monitoring
Treatment
Post surgery/ intensive care
End-of-life care
Rehabilitation
Digital health support interventions
Level of care*
TERTIARY (SH)
Specialized diagnostics
Specialized surgery*
Intensive care
Advanced emergency care
SECONDARY (DH) AND TERTIARY
Clinical laboratory
Basic emergency care
Hospitaliza-tion
General surgery
Non-surgical interventions
Medical imaging
Diagnostic
Interventional
PRIMARY (CL, HC), SECONDARY (DH) AND TERTIARY
Clinical assessment
Rehabilitation
Point of care
Palliative care
Pre-hospital emergency care
Key:
* Including cardiovascular, neurological, ophthalmic and nefrology.
CL community level; health post
DH district/general hospital; interventions can also be offered in a first referral outpatient clinic
HC health centre/outpatient clinic
SH specialized/regional/national hospital; specialized care outpatient unit

The Priority medical devices lists (MDL), and the WHO model list of Essential in vitro diagnostics (EDL) can be used as a reference to Member States to develop or update medical devices national lists

- WHO

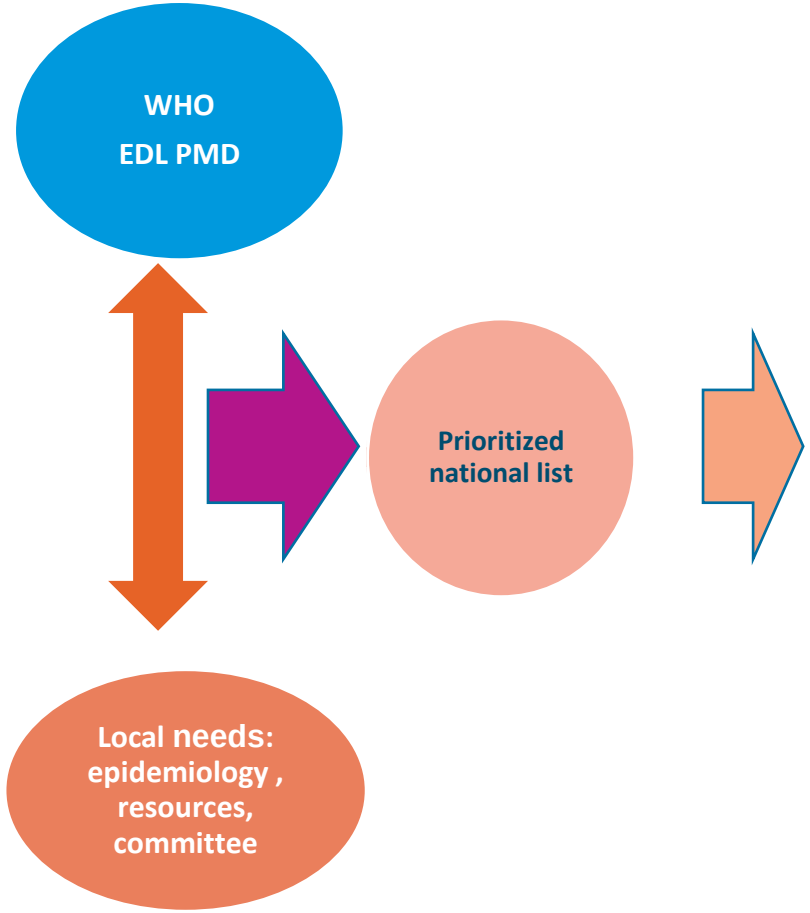
Review of evidence, guidelines, types of medical devices for interventions

Expert input, Public consultation

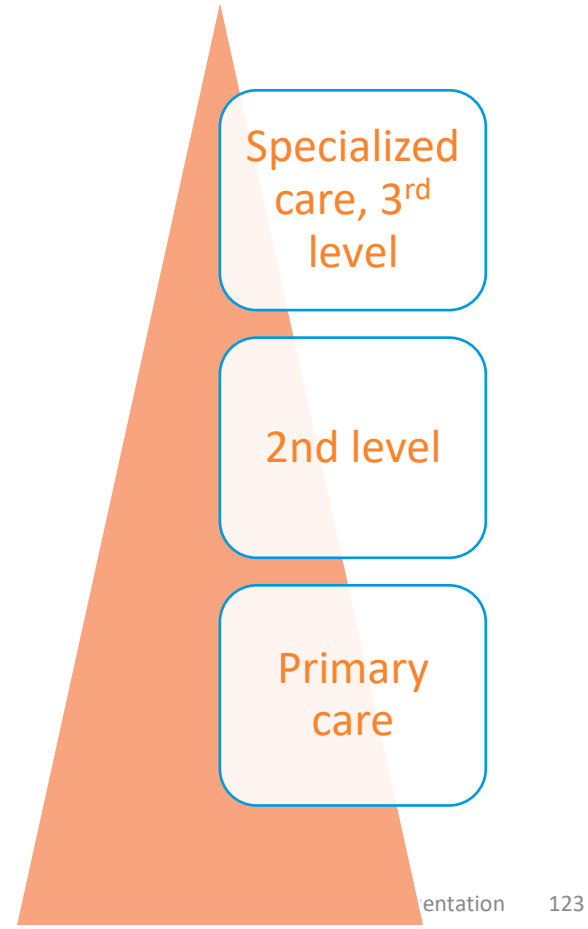
Recommendations by SAGE IVD / STAG MEDEV

Publication of list and update e-EDL, MEDEVIS, UHCC, ICD

- Country: Selection by National committee

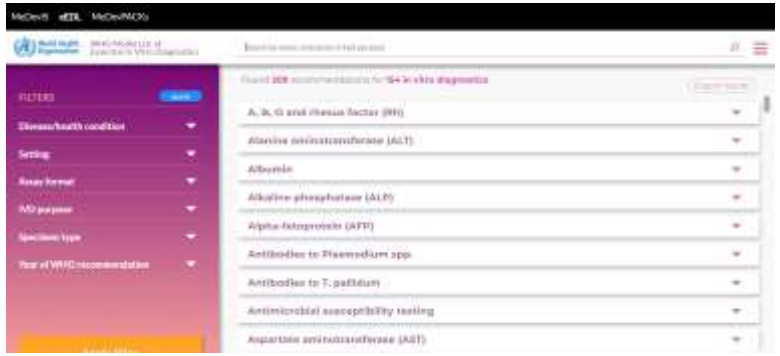


- Health facilities. Final users



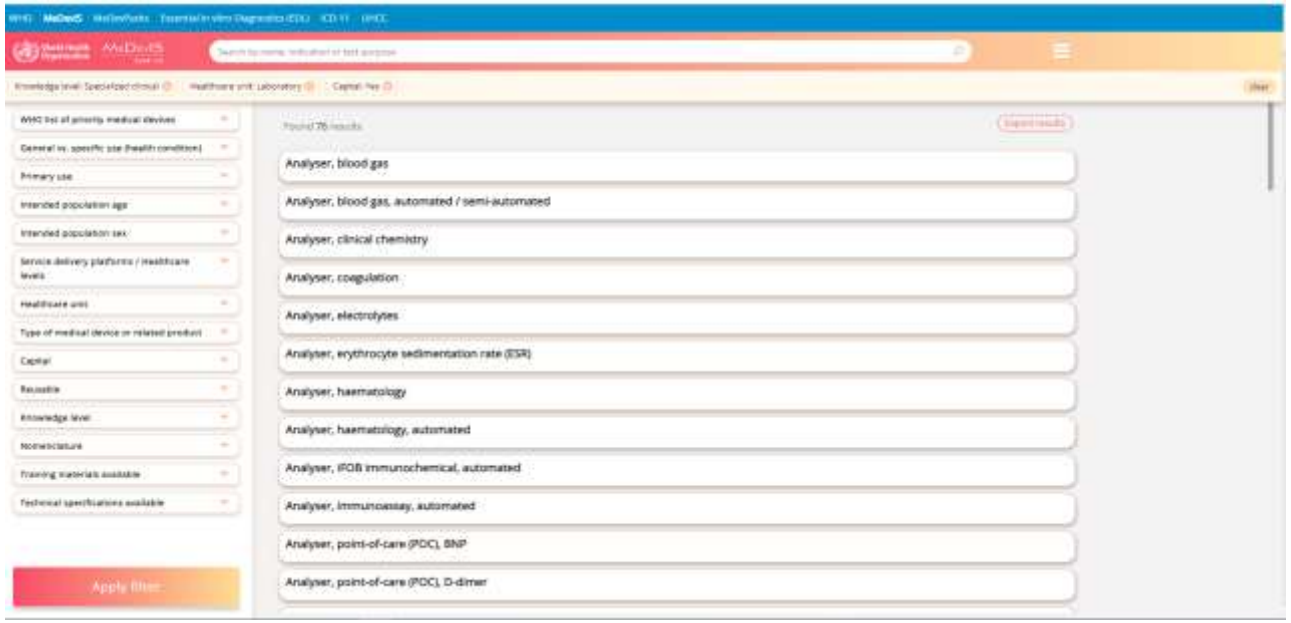
WHO digital platforms

WHO model list of Essential in vitro diagnostics (type of tests)
Updates every 2 years (@200 tests)



WHO list of Priority Medical Devices (technologies)
Updates every 3 months, (@2,500 devices)

Universal Health Coverage compendium.
(Retrieves information from eEDL and MeDevIS, same case would be for ICD 11)



World Health Organization

https://medevis.who-healthtechnologies.org/

WHO Health products Lists, a reference for national lists

Since 1975 — Since 2005 — 2010 — Since 2015 — Since 2016 — Since 2018

WHO Essential medicines list & Essential medicine list for children

ATC code, INN name


1.1 General anaesthetics and oxygen
1.1.1 Inhalational medicines
Sevoflurane - addition - EML & EMLc
Sevoflurane — ATC code: N01AB08
Proposal
Addition of sevoflurane to the core list of the EML and EMLc as an inhalational gas for general anaesthesia.

World Health Organization

WHO Priority medical devices list

WHO Priority assistive products list

WHO model list of essential in vitro diagnostics

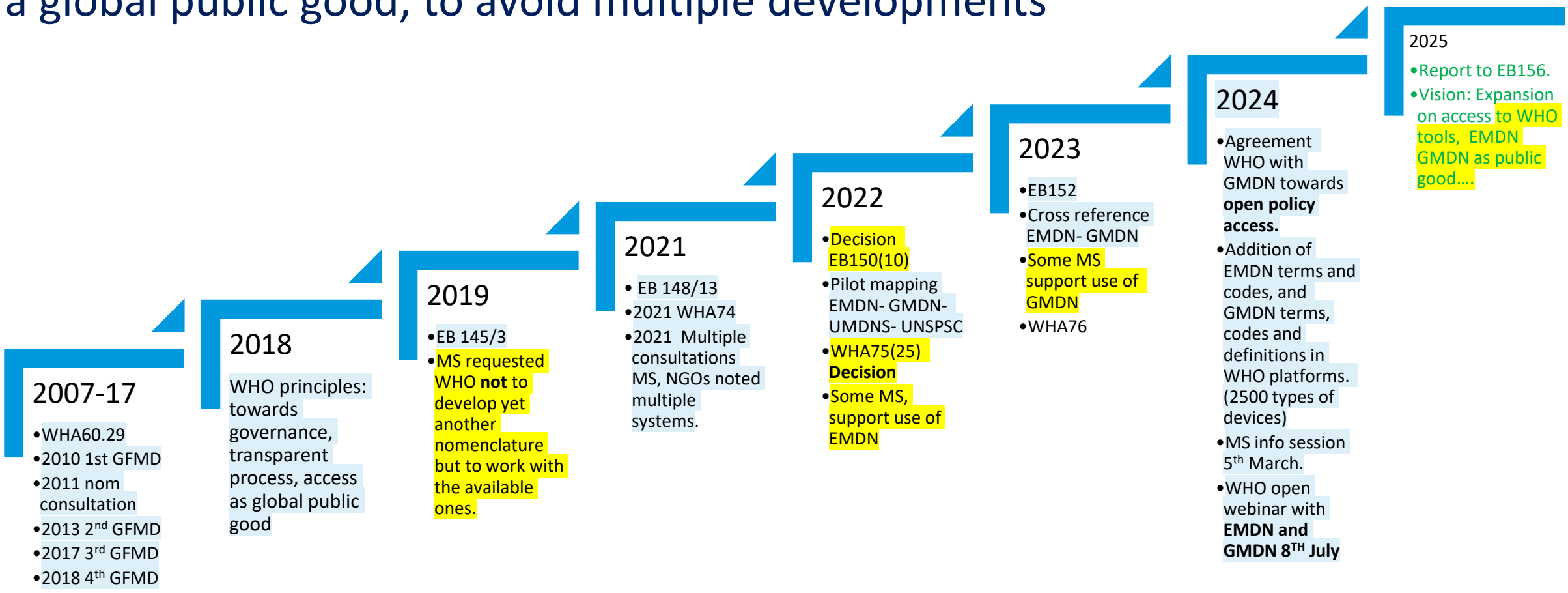
Lack of a single nomenclature

There are three key areas where a lack of standardization negatively affects the rational choice of medical device procurement—regulation, standards, and nomenclature. Harmonization towards regulation and standards are briefly mentioned in Chapter 5.1.2. However, as something so basic poses such problems for appropriately choosing medical devices, lack of a single nomenclature is discussed in detail here.

Did not have code or harmonized name

We have come a long way, uphill, approaching, but still not there…

need to ensure everyone has access to naming system for medical devices as a global public good, to avoid multiple developments



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Decision approved **28 May 2022** in WHA 75 on Standardization of medical devices nomenclature: **WHA75(25)**

- Member States request to the Director General:
- to integrate **available** information related to medical devices, including **terms, codes, and definitions**, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and now available as the Medical Devices Information System (MEDEVIS); and to **link this to other WHO platforms**, such as the International Classification of Diseases, (ICD-11) to serve as a reference to stakeholders and Member States;
- (2) to submit a substantive report on progress made in implementing this decision to the Executive Board at its 152nd session in January 2023, and **its 156th session in January 2025**

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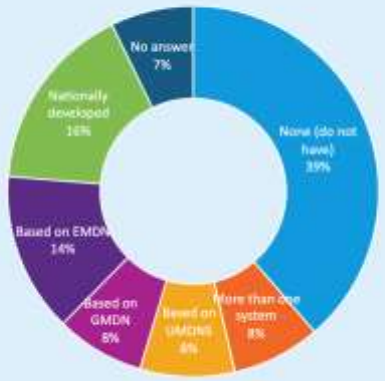
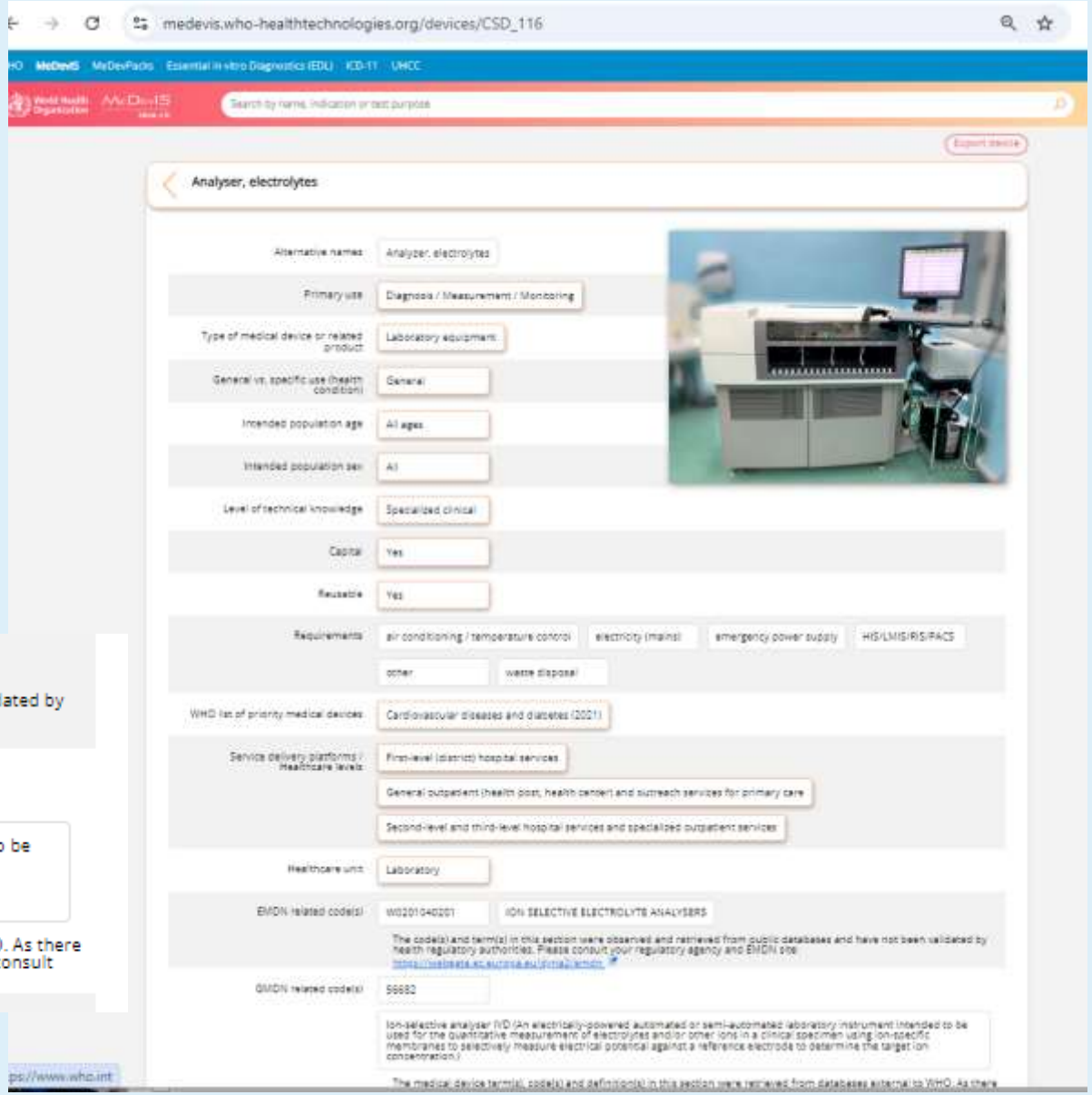
Existence and type of official nomenclature system for medical devices



N= 194

MeDevIS now includes **EMDN and GMDN nomenclature codes,** terms, disclaimer, link to their website.

Access the MeDevIS



EMDN related code(s) W0201040201 ION SELECTIVE ELECTROLYTE ANALYSERS

The code(s) and term(s) in this section were observed and retrieved from public databases and have not been validated by health regulatory authorities. Please consult your regulatory agency and EMDN site: https://webgate.ec.europa.eu/dyna2/emdn

GMDN related code(s) 56682

Ion-selective analyser IVD (An electrically-powered automated or semi-automated laboratory instrument intended to be used for the quantitative measurement of electrolytes and/or other ions in a clinical specimen using ion-specific membranes to selectively measure electrical potential against a reference electrode to determine the target ion concentration.)

The medical device term(s), code(s) and definition(s) in this section were retrieved from databases external to WHO. As there might be more than one name, definition and "Nomenclature Code" related to the specific medical device, please consult https://gmdnagency.org GMDN ®. ® GMDN Agency 2005-2024

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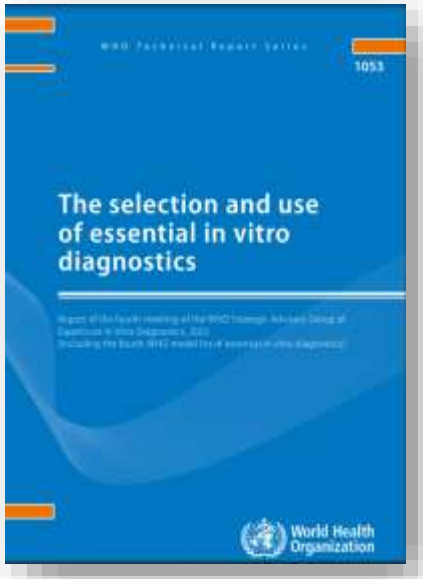
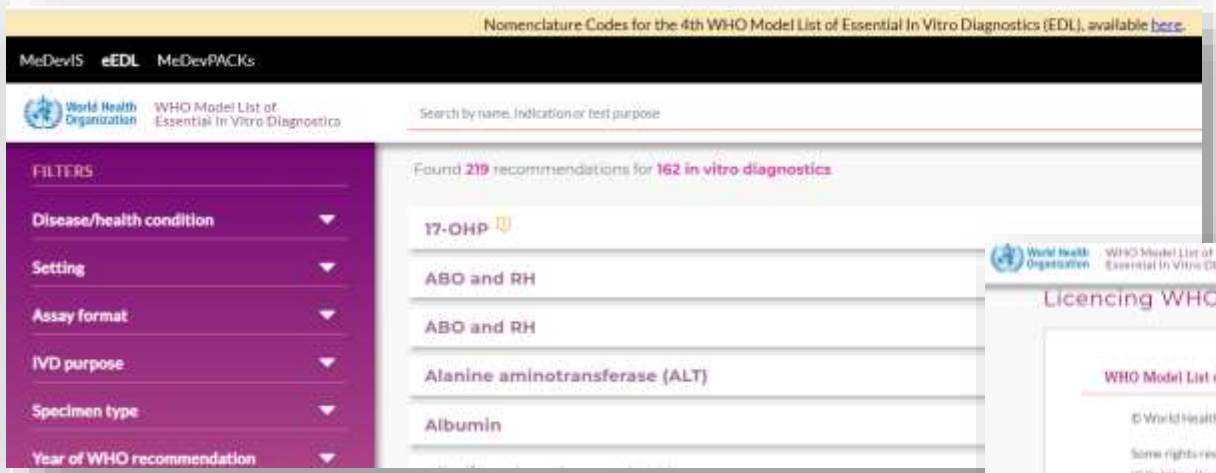
eEDL 2024, v 1.0 includes 4th WHO model list of Essential in vitro diagnostic (EDL) and reference table with GMDN naming (July 2024) EMDN will be added





DIAGNOSTIC TEST	TEST PURPOSE	ASSAY FORMAT	GMDN CT	GMDN CT NAME	GMDN CODE	GMDN TERM NAME	GMDN TERM DEFINITION
17-Hydroxyprogesterone (17-OHP)	To diagnose and monitor congenital adrenal hyperplasia (CAH) outside of the neonatal period (Not appropriate for screening)	Immunoassay	CT850	Clinical chemistry hormone IVDs	63577	17-Hydroxyprogesterone IVD, kit, enzyme immunoassay (EIA)	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of 17-hydroxyprogesterone in a clinical specimen, using an enzyme immunoassay (EIA) method. It is typically used to aid in the diagnosis of congenital adrenal hyperplasia (CAH).
ABO blood groups and Rhesus (Rh) factor typing	To determine ABO groups and Rh factor	Point-of-care test	CT753	Multiple blood grouping and typing IVDs	67265	ABO/Rh multiple blood grouping IVD, kit, rapid agglutination, clinical	A collection of immunoglobulins capable of binding to specific antigenic determinants and intended to be used together in testing a clinical specimen for a combination of multiple ABO system and Rh group red blood cell antigens within a short period, relative to standard laboratory testing procedures, using a rapid agglutination method. This is a rapid test commonly used in the laboratory or in point-of-care analyses. It is not intended to be used for self-testing.
ABO blood groups and Rhesus factor typing	To determine ABO groups and Rh factor	Slide agglutination test	CT753	Multiple blood grouping and typing IVDs	45308	ABO/Rh multiple blood grouping IVD, kit, agglutination	A collection of immunoglobulins capable of binding to specific antigenic determinants and intended to be used together in testing a clinical specimen for a combination of multiple ABO system and Rh group red blood cell antigens, using an agglutination method.

Access the eEDL

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https://www.who.int/publications/i/item/9789240081093

WHA76.3 Increasing access to medical oxygen Resolution and WHA76.5 Strengthening Diagnostics capacity

2022-2023

3 mandates from the World Health Assembly related to medical devices

WHA76.3

Access to medical oxygen

1.15 MS : to provide transparent procurement of medical oxygen

and related diagnostic tools and therapies

WHA76.5

Increase diagnostics capacity

MS 1.4. to make essential

diagnostics available, accessible and affordable at the primary health care level

WHA75.25

Standardization of medical device nomenclature

In MeDevIS

Adding MD nomenclatures:

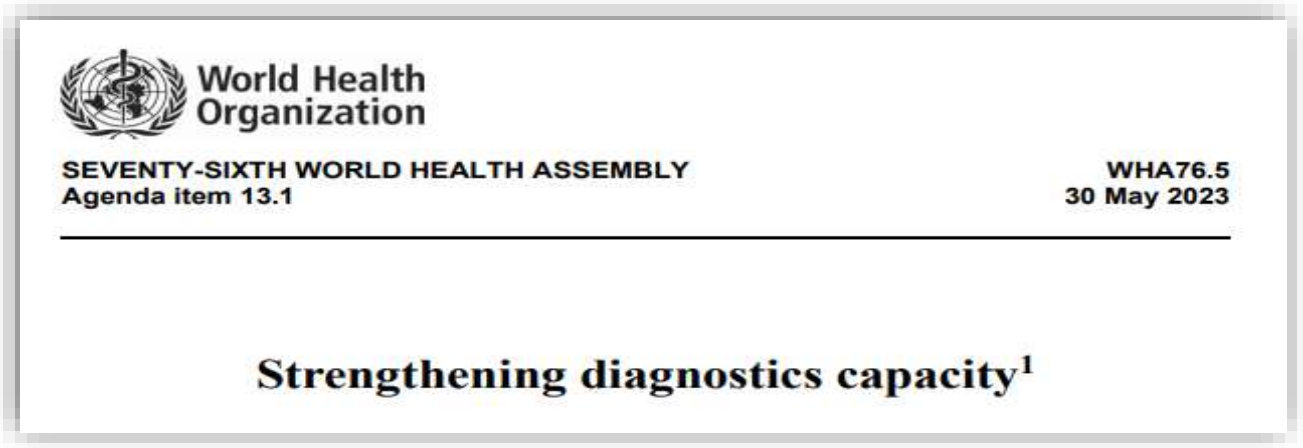
EMDN codes and terms

GMDN codes terms and definitions

Therefore, WHO looks forward to working with you on the 3 topics above!

https://www.who.int/about/governance/world-health-assembly/seventy-sixth-world-health-assembly

WHA 76.5 Strengthening Diagnostics capacity.



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SEVENTY-SIXTH WORLD HEALTH ASSEMBLY
Agenda item 13.1

WHA76.5
30 May 2023

Strengthening diagnostics capacity[1]

"For the purpose of this resolution, the term "diagnostics" includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types"

World Health Organization

https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R5-en.pdf

WHA76.5 Urges Member States to consider:
(1) National Diagnostics strategies, regulation, assessment and management, integrated networks, avoiding silos
(2) HTA for the systematic evaluation cost effectiveness for selection of diagnostics
(3) Development of national diagnostics list considering WHO Essential in vitro diagnostic List and WHO Priority medical devices
(4) Diagnostics available, accessible and affordable for primary health care
(5) Investing in health care workforce for diagnostics
(6) Safe use of diagnostics imaging for protection of patients, staff and public.
(7) Investment in R & D, promote local production
(8) Funding agreements for R & D
(9) Policy measures for equitable and timely access for all diagnostics, including transfer of technology
(10) TRIPS agreements and DOHA declaration to promote access to diagnostics for all
(11) Prevent anti-competitive practices that hinder access to diagnostics
(12) Collaboration, harmonization and reliance for regulations, manufacturing and supply of diagnostics
(13) Data collection systems
(14)Diagnostic services (15) International collaboration during epidemics and pandemics

WHA76.5 Strengthening Diagnostics capacity

On going
Urgent consultation
Require input

WHA76.5 Requests to DG	WHO staff / unit
(1) to collect data on affordability, availability	
(2) technical advice for procurement	RI, AS, C
(3) cross-references between EDL and PMD,	AA, AV / MDD
(4) to update WHO Model Lists EDL and PMD	AA, FM, AV / MDD
(5) health technology management of diagnostics	
(6) local production of diagnostics	LPA
(7) regulatory system	RSS
(8) Member States national lists	MDD
(9) interagency emergency health kits	WHE MDD
(10) MeDevIS and "e-EDL"	MDD
(11) Laboratory networks	Various
(12) definitions of Dx	MDD and various
(13) horizontal health program approach not silos	
(14) integrated diagnostic networks	

World Health Organization

Diagnostics

Contact us

The WHO Diagnostic Task Force includes senior management, a coordination group and 5 working groups: advocacy; country strategy and support; technical issues; resource mobilization and; resolution implementation workplan.

If you are a stakeholders working with countries on strengthening diagnostics capacity contact us using the email below.

diagnostics-taskforce@who.int

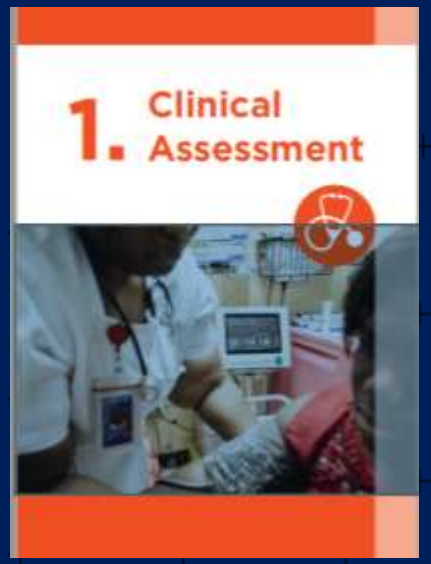
Strengthening diagnostics capacity

World Health Organization

WHO Diagnostics Taskforce was created in July 2023

1. Workplan
2. Country Strategy and Support
3. Technical issues
4. Advocacy
5. Resource mobilization

To align all WHO staff members dealing with all types of diagnostics, to work together towards the implementation of the resolution WHA76.5 in a harmonized integrated way.



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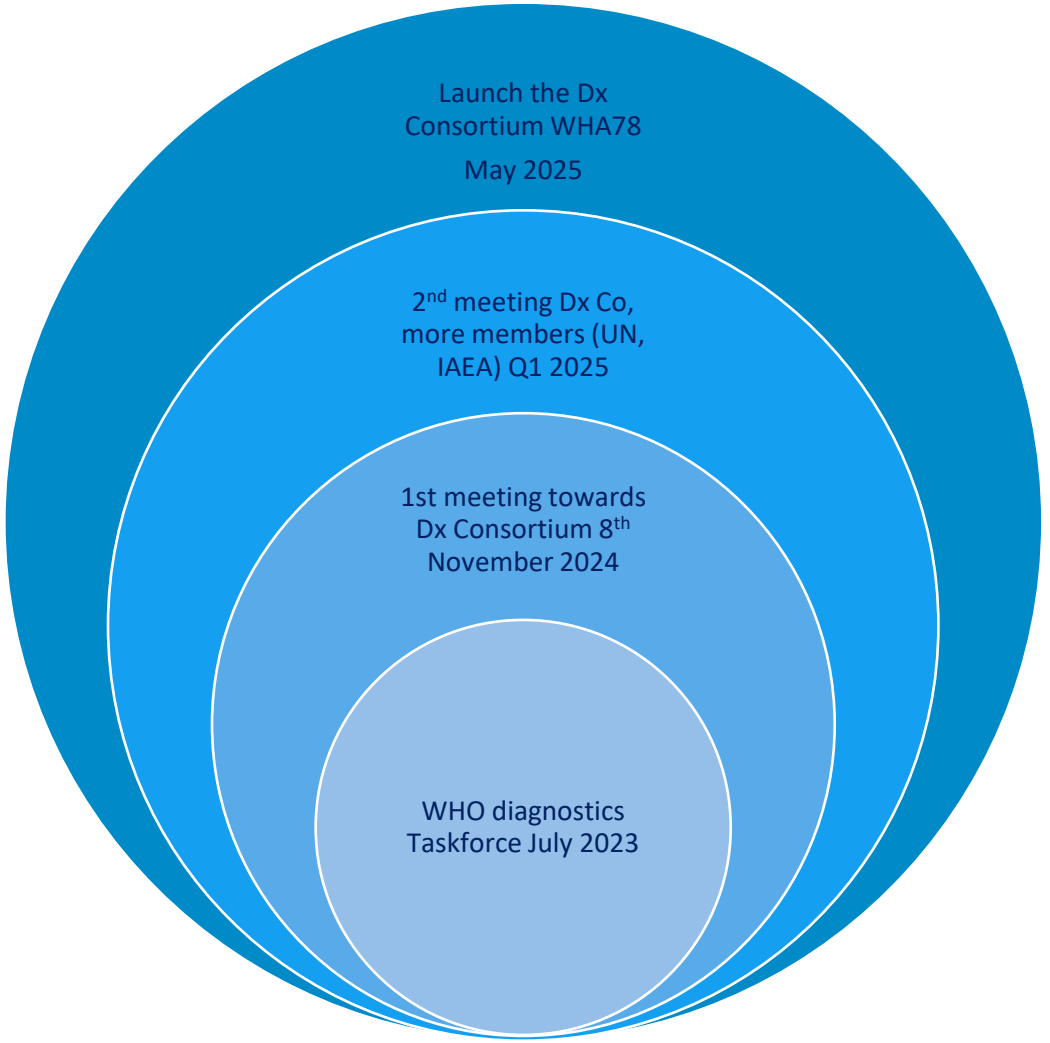
Proposed Dx Consortium!

General Objective of the Consortium

To increase diagnostics capacity by supporting: advocacy, implementation in countries, monitoring impact, and resource mobilization.



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Future: Towards interconnected, WHO information on medical devices in **open** platforms, for Member States reference.

Using Naming EMDN and GMDN

World Health Organization

5TH GFMD - 2 to 4th June 2025 WHO HQ

- Setting organizing committee with:
  - WHO staff (HQ, regional and country)
  - UN agencies
  - Member States
  - NGOs

Define agenda to present all new publications and response to WHA resolutions:

  - HTA
  - Policies
  - CMMS
  - MeDevIS
  - Diagnostics work

Fifth WHO Global Forum on Medical Devices

10 - 12 June 2025 | Geneva, Switzerland

June 2025, Geneva, Switzerland

Save the date: WHO cordially invites you to the **5th WHO Global Forum on Medical Devices** which will take place in Geneva, in June 2025, in a hybrid format, both in person and online, to ensure increased participation.

Medical devices include technologies to screen, diagnose, treat, palliate, assist and are used in all health care levels, yet many of them are not available, not accessible, not safe or not affordable to all the patients that need them. Much has been done but much remains to be done! So, the Forum will bring together multiple stakeholders to share information and discuss the best way forward to ensure med tech for better patient care.

The changing world presents new challenges, for medical devices to address: the Sustainable Development Goals, the climate change, scientific and technological advances, as well as increasing events of crisis and emergencies, as indicated in the WHO 14th Global Program of work.

WHO has convened 4 Fora: the 1st Global Forum in Bangkok in 2010, the 2nd in Geneva in 2013, and the 3rd also in Geneva in 2017. The 4th Global Forum was held in Visakhapatnam, India, in 2018. Fora have been attended by participants from over 90 Member States. These events serve to share information on medical devices for global health priorities.

Since the 4th Global Forum, World Health Assembly mandates related to medical devices had been approved and need to be implemented, ie: Increasing access to medical oxygen, Strengthening diagnostics capacity and Standardization of medical devices nomenclature.

The programme of the 5th GFMD will consider sessions on: Selection of Priority Medical Devices, Medical Devices information system, Essential in vitro diagnostics, innovation, regulation, health technology assessment for medical devices, health technology management (needs assessment, procurement, technical specifications, donations, maintenance and appropriate safe use), local production and technology transfer of medical devices, sustainability, development of national lists, human resources for medical devices, primary health care and the relation with the disease areas: communicable, emergencies and non-communicable.

- information on Registration and program will be announced in 2025.

Related

Full programme coming soon!

Events

First WHO Global Forum on Medical Devices
9 – 11 September 2010

Second WHO Global Forum on Medical Devices
22 – 24 November 2013

Third WHO Global Forum on Medical Devices
10 May – 12 June 2017

Fourth WHO Global Forum on Medical Devices
13 – 15 December 2018

More

World Health Organization

https://www.who.int/news-room/events/detail/2025/06/10/default-calendar/fifth-who-global-forum-on-medical-devices

Conclusion:

On in vitro diagnostics and other diagnostics:

1. EDL 5 will provide information to multiple other WHO databases for MS and stakeholders as reference.

2. We must collaborate, for the well being of patients globally.

3. We have a responsibility for the future generations.

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Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

WHO

20, Avenue Appia
1211 Geneva

Switzerland

medicaldevices@who.int

Subscribe to our Medical device monthly newsletter

Visit WHO Medical devices website

Q&A session

World Health Organization

Thank you

For more information on the EDL, please contact us at
EDLsecretariat@who.int

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