

# AMR Diagnostic Initiative

## Strengthening global capacity for bacteriology and mycology laboratory services and diagnostics

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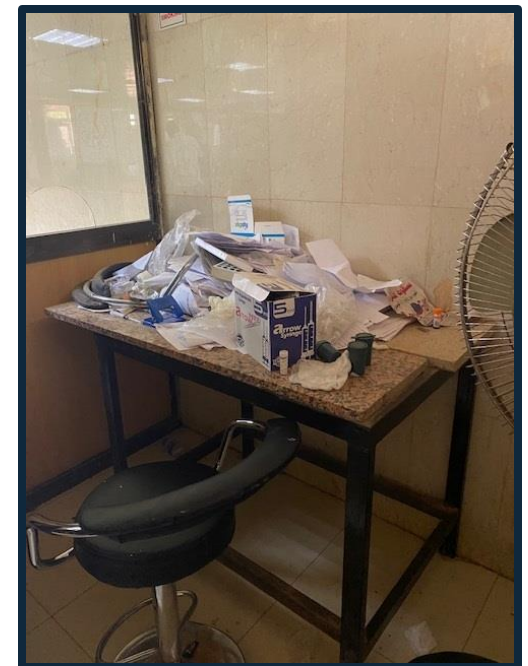
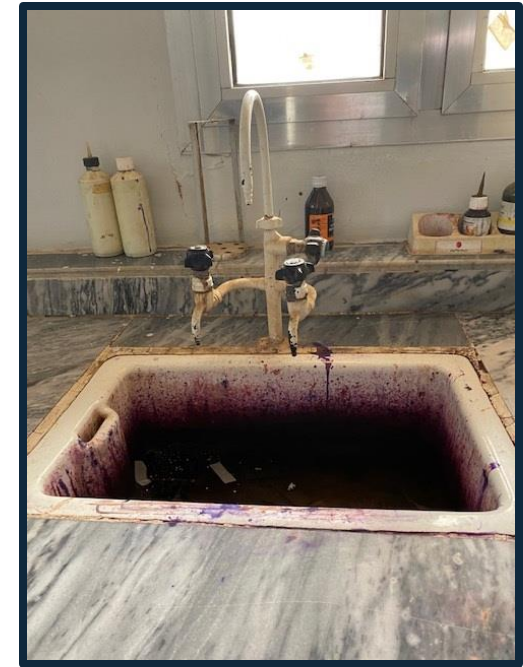
Surveillance, Prevention and Control

AMR Division, World Health Organization



Half the global population has little or no access to diagnostics\*

1.3% of labs in 14 African countries have bacteriology lab capacity\*\*

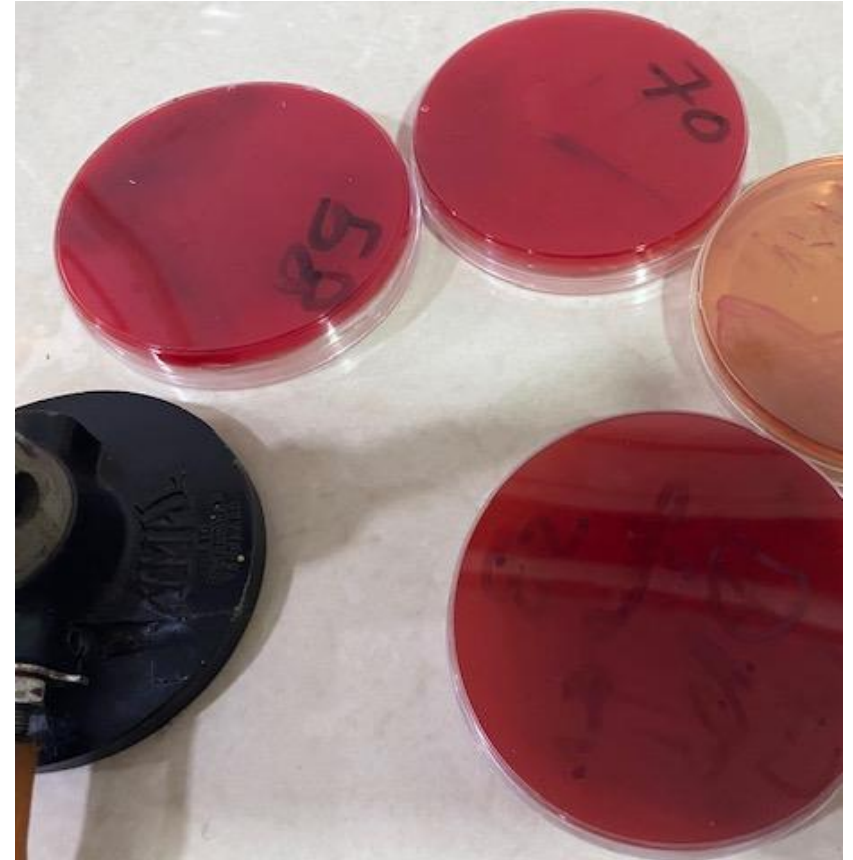


\*The Lancet Commission on diagnostics, 2021;

\*\* MAAP, ASLM, 2022

# We need to strengthen bacteriology & mycology diagnostics to...

- **Meet the need of people in low resource settings who face the greatest burden of AMR** – particularly women, neonates and vulnerable groups
- **Implement the Global Action Plan on AMR:** patient management, AMS, IPC, outbreak investigation, surveillance
- **Achieve the 2030 global targets for HIV, tuberculosis and malaria**





# The challenges

- **Weak diagnostic systems**
  - Diagnostics underfunded
  - Poor planning and prioritization
  - Procurement and maintenance challenges
- **Limited workforce** with required competencies, resulting in low access to quality laboratory diagnosis.
- **Limited standardization & quality assurance**
- **Even when there is diagnostic capacity, low testing demand & under-utilization:**
  - unaffordable costs for the patients
  - suboptimal lab-clinical engagement
  - lack of trust of lab results
  - lack of knowledge of appropriate use of lab results



# Political momentum

## WHA member states vote to adopt 'Resolution on strengthening diagnostics capacity'

### It urges Member States:

....to consider the establishment of **national diagnostics strategies**, as part of their national health plans, ....

....to take policy measures for **equitable and timely access for all to diagnostics technologies and products**

### It urges WHO ....

....to develop or strengthen **national, regional and global laboratory networks and diagnostics initiatives**

....to **support Member States** in developing and implementing quality management systems for ensuring safe, affordable, accessible diagnostic services and quality assured diagnostics

30 May 2023



World Health  
Organization

SEVENTY-SIXTH WORLD HEALTH ASSEMBLY  
Agenda item 13.1

WHA76.5  
30 May 2023

### Strengthening diagnostics capacity<sup>1</sup>

The Seventy-sixth World Health Assembly,

Having considered the consolidated report by the Director-General;<sup>2</sup>

Recognizing the Declaration of Alma-Ata (1978), which identified primary health care as “essential health care based on practical, scientifically sound and socially acceptable methods and technology [...] at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination”, and the Declaration of Astana (2018) on building sustainable primary health care in accordance with the call of the 2030 Agenda for Sustainable Development to achieve universal health coverage and the health-related Sustainable



# The AMR Diagnostic Initiative

## 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

1



### Strategic and Operational Framework

Strengthen diagnostic capacity, laboratory systems and service delivery for AMR

2



### Laboratory Assessment Framework

Evaluate and monitor global AMR laboratory capacity

3



### Global AMR Laboratory Network

Establish a global network of laboratories to enhance diagnostic capacities

4



### Research and Innovation

Promote research and diagnostic innovation to inform policy and clinical care

1



# Building block 1: Strategic and Operational Framework

**Aim:** support Member States by setting out **strategic goals**, accompanied by **achievable objectives** and **key activities** required to establish a well-functioning country-wide system of clinical bacteriology and mycology laboratories.

Strategic and  
Operational  
Framework



## Strategic Goal 1

Strengthen **governance, financing and enabling factors**



## Strategic Goal 2

Establish capacity and capabilities to support **equitable access of diagnostic services** across the health system



## Strategic Goal 3

**Ensure quality** of bacteriology and mycology diagnostic services



## Strategic Goal 4

Enable **optimal utilization of laboratory tests**



1



# Building block 1: Strategic and Operational Framework

**Aim:** support Member States by setting out strategic goals of a well-functioning country-wide system of clinical bacteriology and mycology laboratories.



Expected to support Member States to set up, reinforce, identify gaps and plans for remedial action, and monitor progress.

Strategic and  
Operational  
Framework

	Goals	Objectives	Activities ("what")	Implementation consideration ("how")	Outcomes
	1. <b>Strengthen governance</b> and resource allocation	✓	✓	✓	✓
	2. Establish capacity and capabilities for <b>equitable access</b> of diagnostic services across the health system	✓	✓	✓	✓
	3. <b>Ensure quality</b> of bacteriology and mycology diagnostic services	✓	✓	✓	✓
	4. <b>Enable optimal use of laboratory results</b> and data.	✓	✓	✓	✓

**Monitoring and evaluation**

# Strategic and Operational Framework

## Purpose

01

Provide guidance for Member States to strengthen bacteriology and mycology diagnostic services across their health systems.



02

Provide actions to promote equitable access to quality diagnostics and optimal use of lab results for patient care, IPC, AMS, and surveillance.



03

Proposes toolkit/package of resources to support operationalization of the Strategic Framework



04

Provides regional and global partners with a roadmap to align financial and technical support for strengthening bacteriology and mycology diagnostic capacity and services



05

Serve as a reference document to mobilize national funding and catalyze partnerships




# Building block 1: Strategic and Operational Framework

## Four strategic goals




Improve  
Governance



Increase  
Access




Ensure  
Quality



Optimize  
Use

# DRAFT Strategic Goal 1: Strengthen governance, financing and enabling factors



Improve  
Governance

**Objective 1:** Strengthen the **representation** of microbiology diagnostic services in existing national laboratory systems and governance structures.

**Objective 2:** Ensure the **inclusion** of bacteriology and mycology diagnostic services into national laboratory strategic plans, and ensure an operational plan is endorsed.

**Objective 3:** Ensure sustainable bacteriology and mycology diagnostic services through **adequate resource allocation**.

**Objective 4:** Develop human resource plans and policies facilitating **rational and equitable distribution and retention** of microbiology laboratory workforce.

**Objective 5:** Develop **resilient mechanisms** to sustain **supply chains**, procurement and maintenance processes of equipment.

**Objective 6:** Establish an **oversight mechanism to monitor and evaluate** performance of bacteriology and mycology diagnostic services.



## DRAFT Strategic Goal 2: Strengthen capacity to support equitable access to bacteriology and mycology diagnostic services across the health system



Increase  
Access

**Objective 1: Develop an operational plan** to increase access to bacteriology and mycology diagnostic services at each level of the health system.

**Objective 2: Implement the operational plan** to increase capacity and capabilities.

**Objective 3: Develop or leverage existing specimen referral systems** to improve access to quality diagnostic services.

**Objective 4:** Foster collaborations between **public and private sector** to expand access to laboratory services.

**Objective 5: Contain** the cost of testing and out-of-pocket expenditures by patients.

## DRAFT Strategic Goal 3: Ensure quality bacteriology and mycology diagnostic services



Ensure  
Quality

**Objective 1:** Establish a **national reference laboratory** for bacteriology and mycology.

**Objective 2: Standardize** laboratory testing procedures.

**Objective 3:** Implement or strengthen **laboratory quality management systems** at bacteriology and mycology laboratories.

**Objective 4:** Implement an **external quality assurance (EQA) programme** as part of continuous quality improvement.

**Objective 5:** Ensure **safe and secure working environment**.

**Objective 6:** Maintain and monitor **competencies of microbiology** in the laboratory workforce.

## DRAFT Strategic Goal 4: Ensure optimal utilization of the bacteriology and mycology diagnostic tests

Optimize  
Use

**Objective 1:** Improve the utilization of the bacteriology and mycology diagnostics for patient management

**Objective 2:** Strengthen the utilization of local AMR data to facilitate targeted interventions **at facility level.**

**Objective 3:** Strengthen the collection and use of AMR surveillance data **at national level**







1



# Building block 1: Strategic and Operational Framework

## Toolkit/package of norms & standards

Technical briefs, guidance, protocols, SOP to support access to and use of quality assured tests for bacterial and fungal infections and resistant pathogens, including:

Strategic and  
Operational  
Framework

- ◆ **pre-analytical procedures**  
(collection, handling, transportation, storage)
- ◆ **analytical**  
(preparation, detection, ID/AST, interpretation)
- ◆ **post-analytical**  
(reporting of results)
- ◆ **syndromic diagnostic stewardship**  
(what test, to whom, when and how)



# WHO Essential Diagnostic List

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

Discipline	Diagnostic test	Test purpose	Assay format	Specimen type
Bacteriology, mycology and parasitology	Urinalysis test strips	Detection of urinary tract infections (UTIs)	Multi-parameter strips including nitrite test	Urine
	Microscopy	Microbial morphology, presence or absence of white blood cells, red blood cells versus squamous epithelial cells for presumptive identification; presence of casts and crystals in urine	Microscopic examination of slides as wet preparations or treated with organism-specific chemical stains (e.g. Gram stain, Giemsa stain, modified Ziehl-Nielsen stain, stains for fungi)	Disease-appropriate specimens (e.g. venous whole blood, urine, stool, cerebrospinal fluid) or cultures
	Culture	Initial step in detection and identification of bacterial and fungal species for selection of appropriate antibiotic 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, cerebrospinal fluid, etc.)
	Blood culture	For the detection of 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	For the identification of the genus or species of bacteria or fungi from cultured isolates	A range of biochemical tests that may be performed manually or on automated equipment.	Isolates from bacterial or fungal cultures
	Antimicrobial susceptibility testing (AST)	Final step in selection of appropriate antibiotics after species identification and interpretation by EUCAST <sup>1</sup> and CLSI guidelines <sup>2</sup>  Note: WHO regards the development of antimicrobial resistance (AMR) a high-priority global health issue. See WHO Global Antimicrobial Resistance Surveillance (GLASS)	Antimicrobial susceptibility testing of isolates May be done manually by disc diffusion, gradient tests, broth microdilution or automated platforms	Microbial isolates

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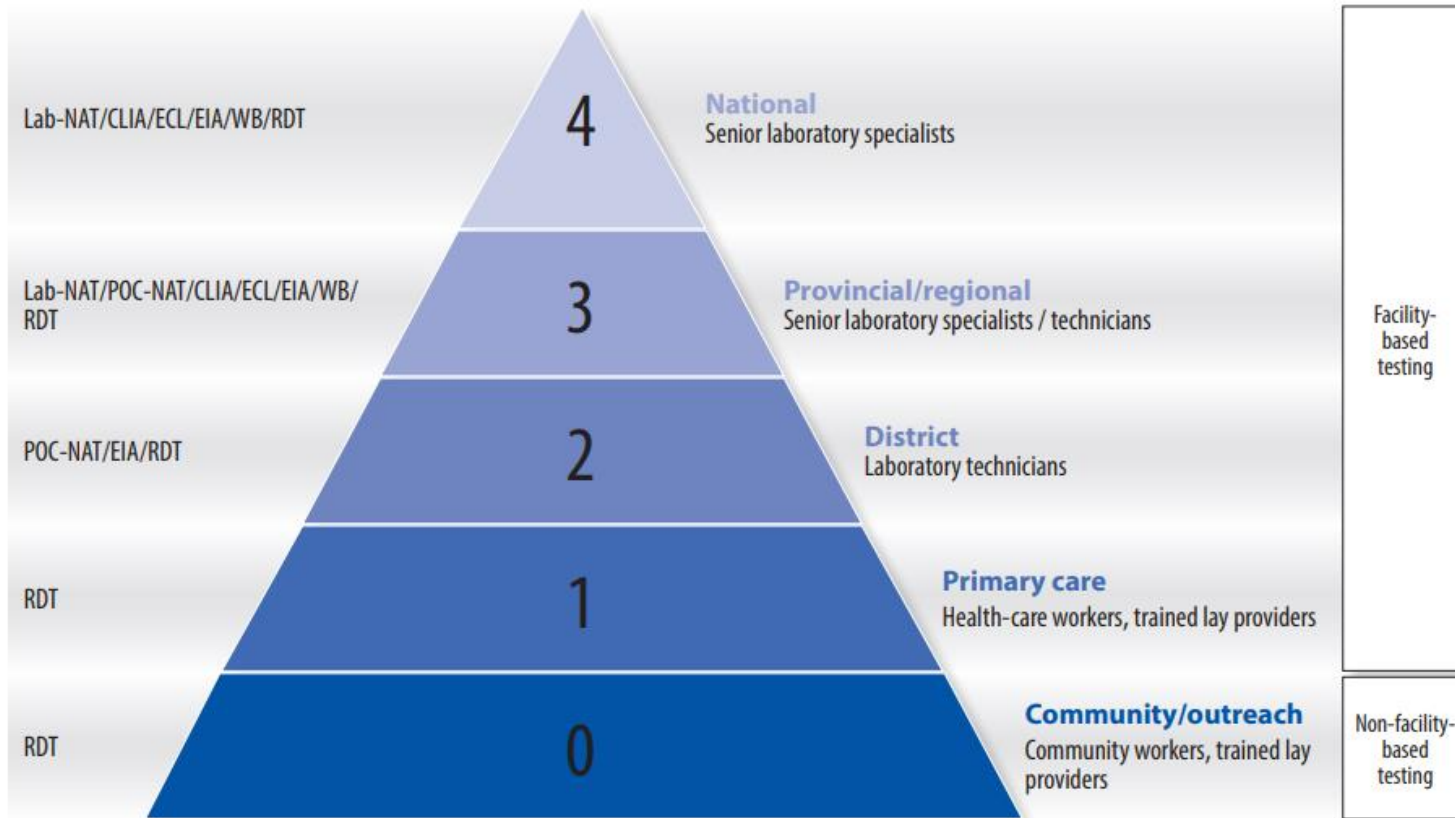


Strategic and Operational Framework

# Ensuring access to quality diagnostics

**Key need:** national essential diagnostic list plus appropriate allocation of bacteriology and mycology capacity to respond to health needs at different levels of health systems

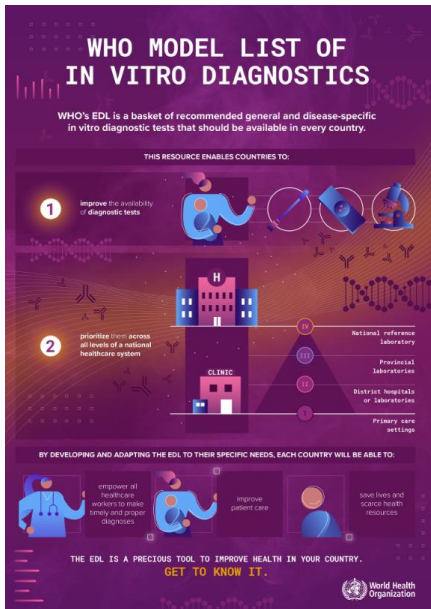
Figure 1. Illustrative example of the tiered testing network



Strategic & Operational Framework

i.e. define minimum package of diagnostic tests (bacteriology + mycology) across the different tiers of the health system;

highlight required capacity and competencies of the workforce;

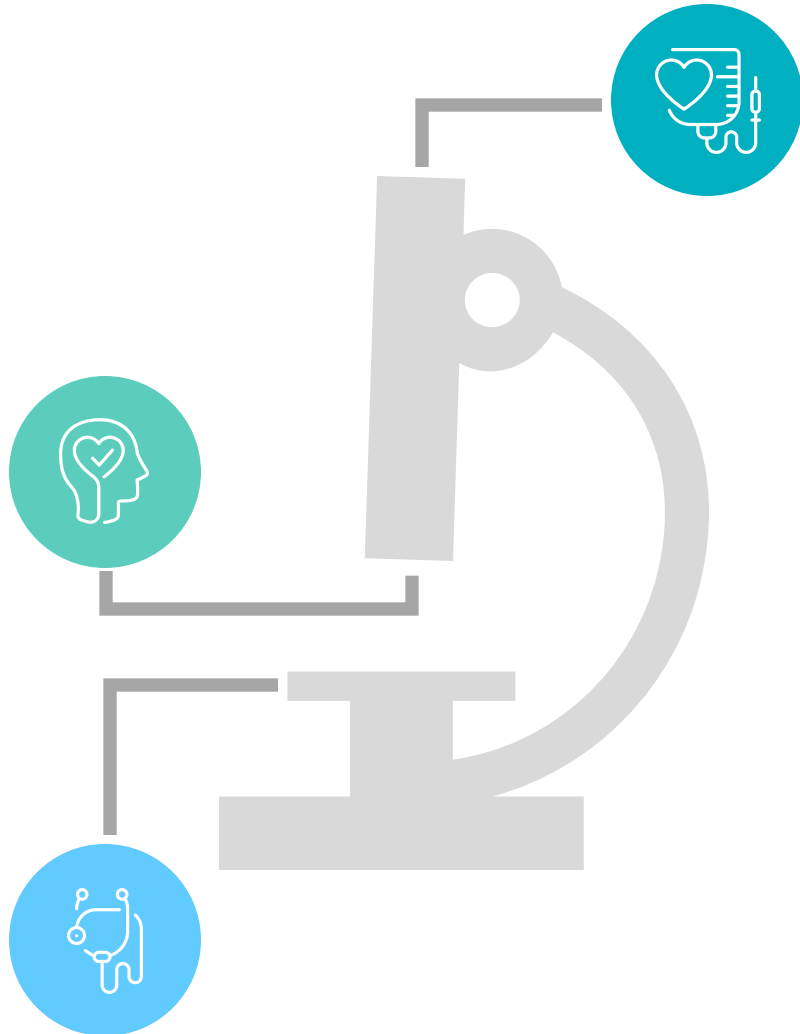


Source: Short, medium, long term product development priorities in HIV-related diagnostics. WHO expert meeting report. Geneva: World Health Organization; 2012  
Note: with evolving technology development, POC-NAT may soon be possible at Level 1 health facilities.

2

# Assessment Framework

Assessment  
Framework



**Aim:** provide Member States with **standardized tools** to monitor and report at national and global on:

1. National Reference Bacteriology Laboratory capacity
2. National health system capacity on bacteriology and mycology diagnostics and laboratory services

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**Conduct regular national and global surveys**, and develop reports to guide Member States, WHO and stakeholders on areas for improvement, funding requirements and technical assistance needs.



3



# Global AMR Laboratory Network

Laboratories **designated by WHO** at national, supranational, and specialized levels through a thorough and standardized process.

## AIMS

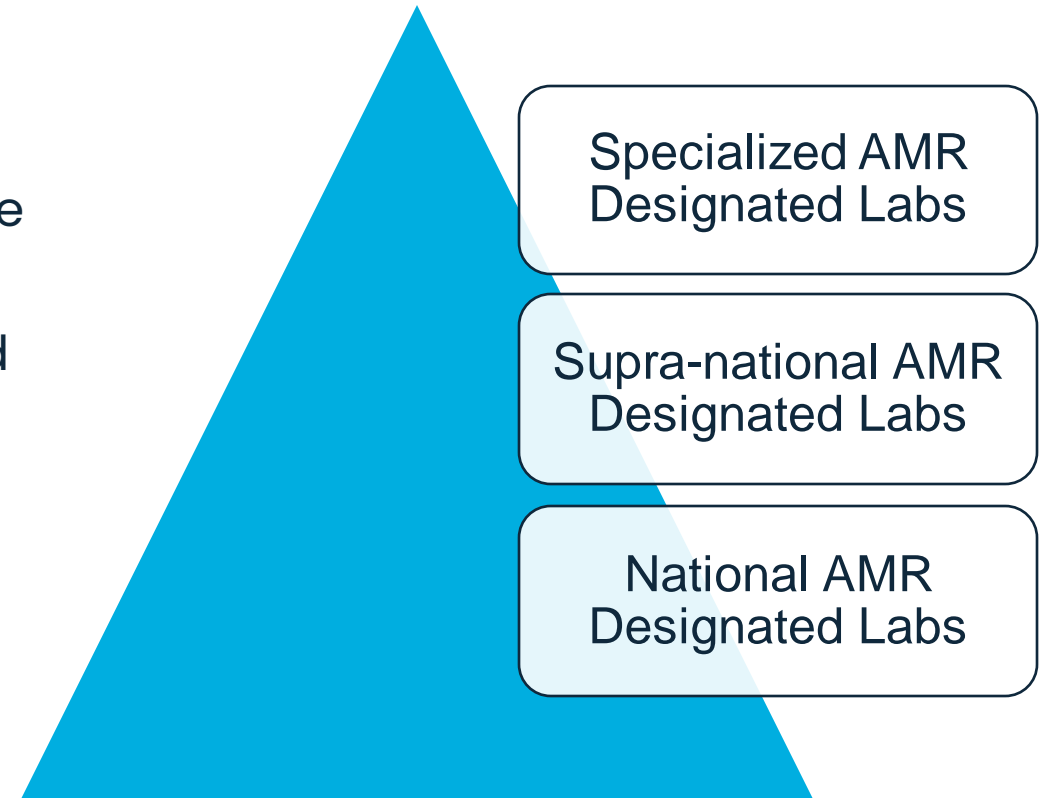
### Strengthen national and global laboratory capacity

to routinely identify and characterize bacteria and fungi and associated susceptibility to antimicrobials for improved clinical management and expanded routine AMR surveillance.

### Support the standardization and quality

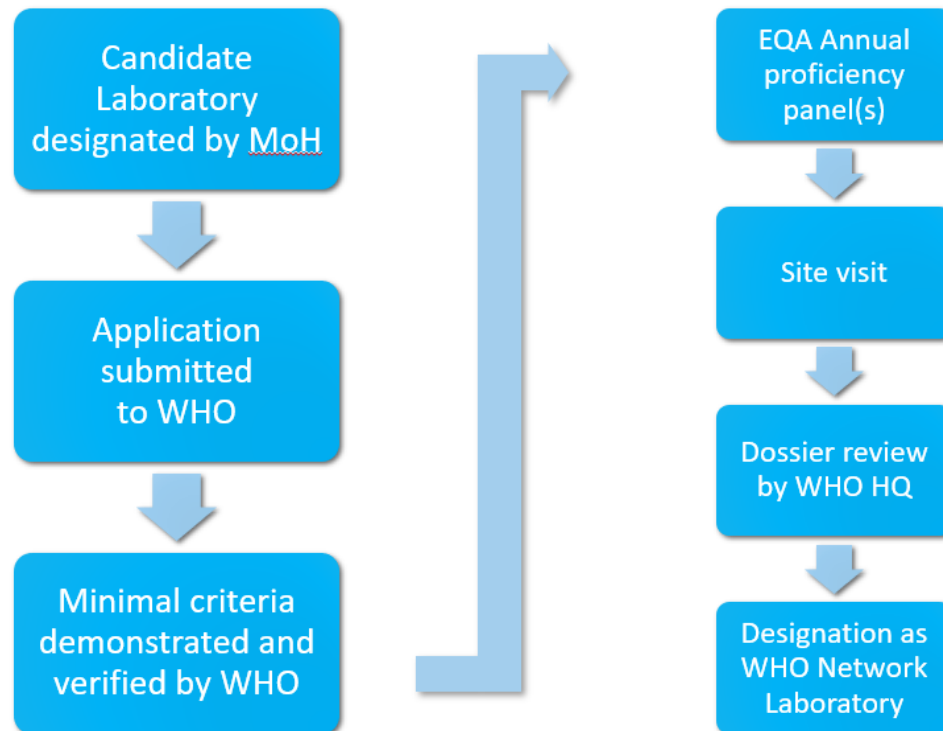
of laboratory testing procedures for bacterial and fungal infections and resistant pathogens across settings and WHO regions.

Global AMR  
Laboratory  
Network



# Global AMR Laboratory Network (cont...)

- The Network will include specialized, supra-national and national AMR laboratories equipped to deliver specific tasks and responsibilities.
- The Network laboratories will be identified by the MoH and designated by WHO based on a standardized designation process using agreed performance criteria and network needs.



4



Research  
and  
Innovation

## Promoting research and innovation in AMR diagnostics

- ❖ **Identify and advocate for implementation of research priorities in AMR diagnostics**
- ❖ **Promote digital health solutions**, including digitalization of susceptibility testing expert rules and breakpoints
- ❖ **Establish an AMR catalogue of genetic markers** for drug resistance prediction in priority pathogens.
- ❖ Develop **target product profiles** for diagnostics of bacterial and fungal pathogens, and for using and interpreting susceptibility resistance methods
- ❖ **Landscape analysis** of current diagnostics and those in the development pipeline
- ❖ Support **validation** of diagnostic tests



# Promoting research and innovation in AMR diagnostics

- ❖ Advocate for implementation of **research priorities in AMR diagnostics identified through the AMR research agenda prioritization** (published 22 June 2023)

## Research and Innovation

### Global research agenda for antimicrobial resistance in human health

Policy brief

June 2023



#### Prevention

- Investigate the impact and contribution of community WASH and waste management interventions on the burden and drivers of antimicrobial resistance
- Investigate implementation strategies and the impact of WASH-related interventions in health-care settings on the burden of health care-associated infections and antimicrobial medicine prescribing
- Identify (cost-) effective, acceptable and feasible multimodal infection prevention and control strategies and the relative effect of their components on reducing health care-associated infections
- Assess the impact of vaccines on colonization and infection by resistant pathogens, and on reducing the use of antimicrobial medicines, health-care encounters and health system costs

#### Diagnosis

- Investigate and evaluate rapid point-of-care tests to discriminate bacterial versus non-bacterial infections
- Investigate and evaluate rapid antimicrobial susceptibility testing methods from blood cultures
- Investigate and evaluate diagnostic tests for detecting pathogens and antimicrobial susceptibility testing
- Investigate and evaluate diagnostic tests for detecting fungal pathogens
- Investigate the clinical and diagnostic value of phenotypic antifungal susceptibility testing
- Investigate, assess and evaluate the implementation of novel rapid point-of-care assays and optimal testing approaches for (resistant) *Neisseria gonorrhoeae*

#### Treatment and Care

- Investigate antimicrobial stewardship interventions that are context specific, feasible, sustainable, effective and cost-effective in outpatient and inpatient settings
- Identify feasible, effective and scalable pharmacist antimicrobial medicines dispensing practices and related regulatory frameworks to improve antimicrobial stewardship in the community, especially in low- and middle-income countries
- Investigate criteria and strategies to optimize empirical antimicrobial therapy for main infectious syndromes, especially in settings with limited medicine availability, diagnostic capacity and access to health care services
- Determine optimal methods, metrics and targets to monitor antimicrobial use and consumption
- Determine the patterns and drivers of appropriate and inappropriate prescribing, use and consumption of antibiotics

- Investigate approaches to effectively use antimicrobial consumption and antimicrobial resistance surveillance data to inform stewardship and guidelines
- Investigate antibiotic treatment regimens for infections, especially for extended-spectrum beta-lactamase-producing and carbapenem-resistant Enterobacterales
- Investigate antibiotic treatment regimens for infections by drug-resistant typhoid and non-typhoidal salmonellae
- Investigate empirical antibiotic treatments for gram-negative bacteria causing bloodstream infections among neonates and young children in settings with high antimicrobial resistance prevalence
- Investigate antifungal regimens for infections caused by WHO fungal priority pathogens with critical importance for antimicrobial resistance
- Investigate regimens for urogenital and extragenital sexually transmitted infections in the context of increasing antimicrobial resistance levels

#### Cross-cutting

- Investigate the epidemiology, mortality, morbidity and impact of infections by resistant WHO bacterial priority pathogens
- Investigate the epidemiology, morbidity, mortality and impact of infections by resistant WHO fungal priority pathogens with critical importance for antimicrobial resistance
- Investigate factors driving colonization and infection by resistant WHO bacterial priority and fungal pathogens

- Identify optimal surveillance methods to generate accurate and reliable data on the epidemiology and burden of antimicrobial resistance
- Assess the impact of mass administration of antimicrobial medicines on antimicrobial resistance
- Evaluate how currently recommended syndromic sexually transmitted infection management and treatment of people with asymptomatic sexually transmitted infections affect antibiotic prescribing and antimicrobial resistance

- Determine the most (cost-) effective behavioural change interventions to mitigate antimicrobial resistance emergence and spread
- Evaluate the implementation of antimicrobial resistance-related policies and regulations and their effectiveness in mitigating antimicrobial resistance and improving health outcomes
- Investigate implementation strategies for national policies, legislation and regulations to improve infection prevention, patient care and the use of antimicrobial medicines

- Identify the most (cost-) effective interventions and an investment case to mitigate antimicrobial resistance globally and across countries
- Investigate strategies to integrate antimicrobial resistance interventions into broader health, health financing, development and welfare structures and evaluate their impact
- Investigate how regulatory frameworks, marketing incentives and financing models affect the sustainable development, availability, equitable access and use of new antimicrobial medicines

#### Drug-resistant TB

- Investigate effective preventive TB vaccines that meet WHO preferred product characteristics criteria and demonstrate impact on prevention of infection, disease and recurrence
- Investigate how the diagnostic performance of molecular assays can be improved to detect drug resistance among people with extrapulmonary and pulmonary TB
- Determine optimal diagnostic and treatment delivery models to improve the access, effectiveness, cost-effectiveness, feasibility and acceptability of drug-resistant TB treatment
- Investigate better tolerated, optimally dosed, more effective and shorter combination regimens for treating all forms of drug-resistant TB
- Determine the optimal, (cost-) effective, shortest duration and safest TB preventive treatment for the contacts of people with drug-resistant TB
- Investigate strategies for improving treatment outcomes among people with drug-resistant TB who have known risk factors and conditions and among populations experiencing vulnerability
- Investigate the programmatic effectiveness, safety and tolerability of currently used WHO-recommended treatment regimens for drug-resistant TB

Antimicrobial-resistant bacterial and fungal infections



4



Research  
and  
Innovation

## Example (1): Digitalization of expert rules and breakpoints

- Access to *current* CLSI and EUCAST AST breakpoints and expert rules is required for correct AST interpretation and reporting

### Challenges of current system

- CLSI and EUCAST **breakpoints data tables and expert rules not** available in a format that is “**machine readable**” by software
- Manual implementation is complex and time consuming (i.e. manual coding into software platform)

**Solution: WHO is convening CLSI/EUCAST/stakeholders to develop and maintain AST breakpoint and expert rules tables, freely accessible in a machine-readable, open-source format.**



4



Research  
and  
Innovation

## Example (2): WHO AMR Catalogue

### The need:

A common, standardized reference for the interpretation of genetic and genomic data for predicting antimicrobial drug resistance in priority pathogens.

### WHO AMR catalogue

- Develop a WHO endorsed, standardized, comprehensive reference catalogue of genetic variants predictive of AMR in WHO priority pathogens
- Develop quality, standardized, user friendly resources and bioinformatic tools to use the catalogue

i.e. a **WHO hosted global platform of matched individual-level genetic and phenotypic data**

# Conclusions

- The GAP for AMR does not provide enough emphasis on the need to strengthen bacteriology and mycology diagnostics
- Better diagnostics are key for patient management, IPC, AMS, and surveillance
- The AMR Diagnostic Initiative aims to push the diagnostic agenda, increase visibility and promote increased access and quality of testing
- Strategic Framework – a guide for MoH – is in preparation



The AMR  
Diagnostic  
Initiative



Thank you

