AMRDETECTOOL
Detection in 30 min

MARKET ANALYSIS
Low and Middle Income Countries

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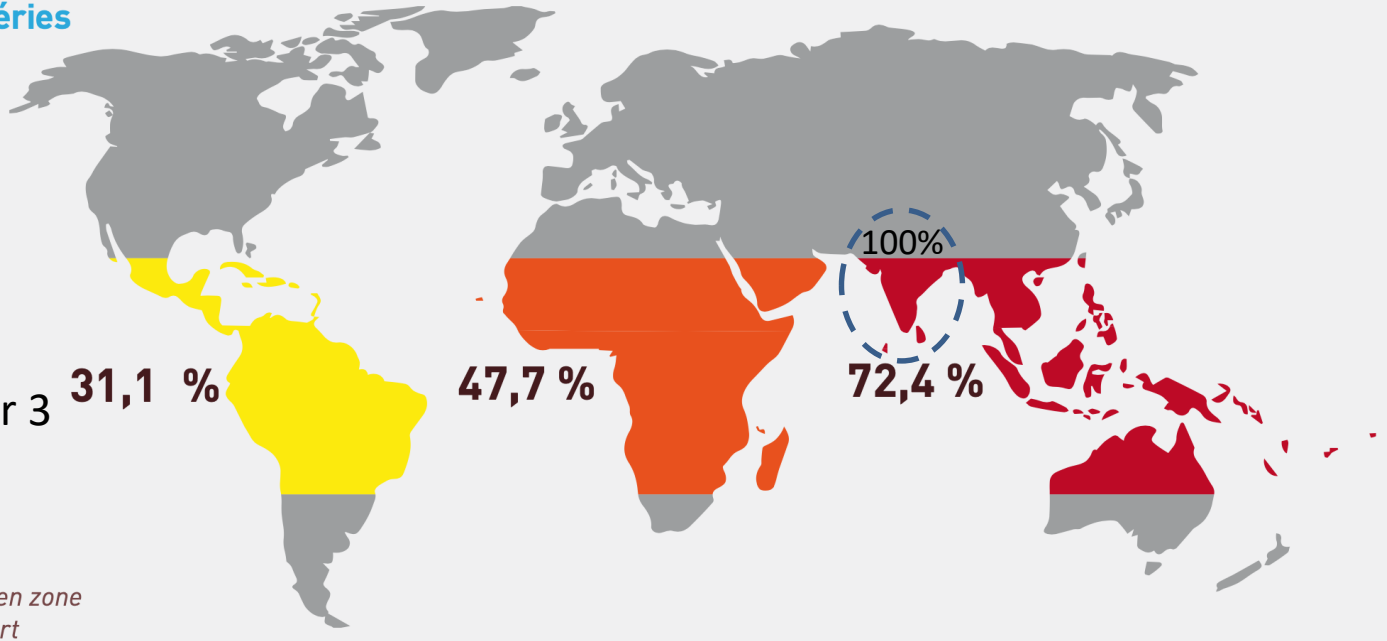
EIT Health is supported by the EIT, a body of the European Union

Global spread of resistances

Taux d'acquisition d'entérobactéries multirésistantes au cours d'un voyage en pays tropical



Who is at risk?

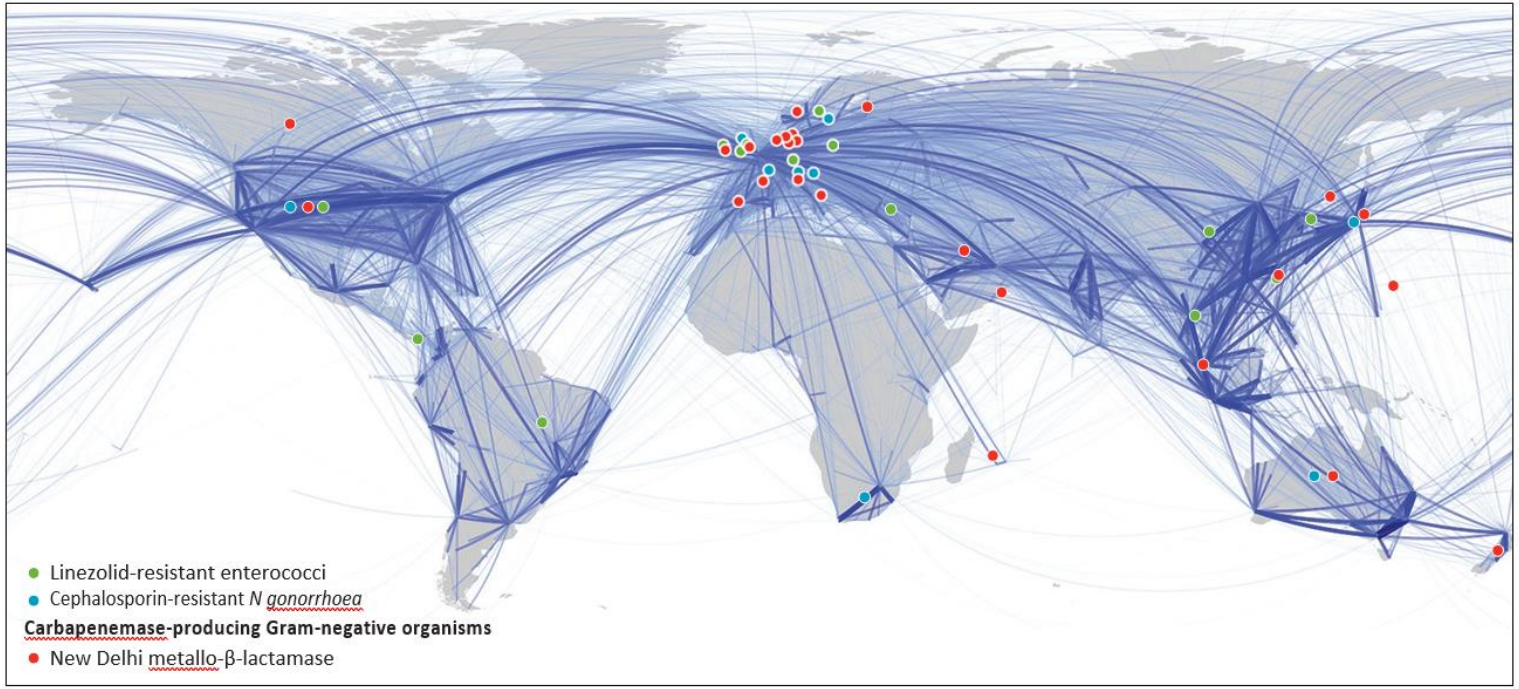
5% remained positive after 3 months

Source : Voyag-R : Étude sur 574 voyageurs en zone intertropicale dépistés négatif avant le départ

Worldwide travel routes and emergence of antimicrobial resistance

Promotes Spread –
proliferation – genes sharing

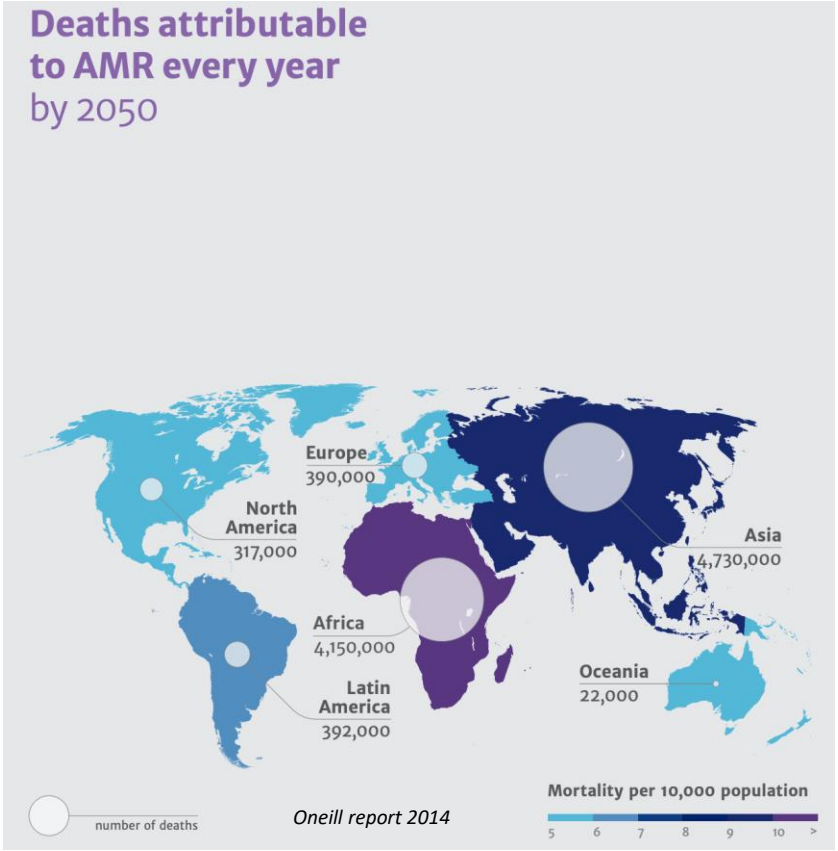
One health approach needed



Holmes et al. (2016). Understanding the mechanisms and drivers of antimicrobial resistance. The Lancet, 387

A worrisome future?

Where will the impact be greater if no action is taken?



The Needs

Gardp Report 2018: "*Low-and middle-income countries already bear significantly higher resistance rates (40-60%) compared to an average of 17% for OECD countries".*

Over the counter sales of drugs, including last resort antibiotics.
What does it lead to? → **over-use and mis-use of ABs**

Addressing AMR is key to deliver the **SDGs**, the **Sustainable Development Goals.**

Benin, West Africa

Mendelsonet al. (2016). Maximising access to achieve appropriate human antimicrobial use in low-income and middle-income countries. The Lancet, 387

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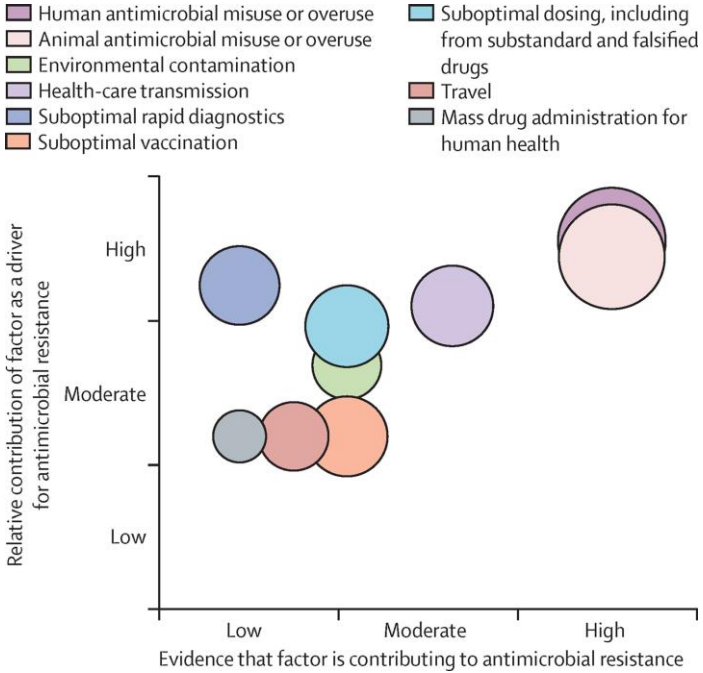
The Needs

Suboptimal rapid diagnostics
Mis-use and over-use

- **Fear** of **missing a bacterial infection**
- **Availability** of **antibiotics** over the counter
- Under-use or **Lack of Access** to diagnostics reasons:
    - Due to long **turnaround times** and poor clinical performances
    - **Affordability** issues
    - **Supply** problems
    - **Quality** assurance



Holmes et al. (2016). Understanding the mechanisms and drivers of antimicrobial resistance. The Lancet, 387

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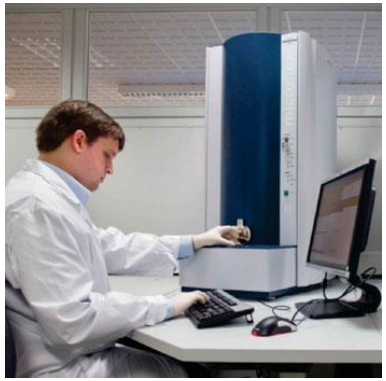
Technological needs

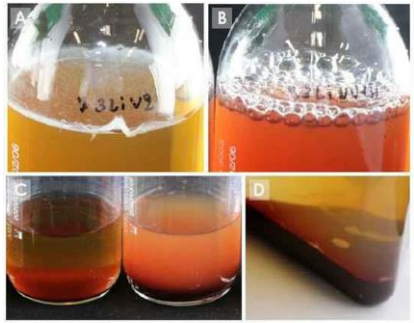
Affordability → technological gap, exacerbated by the technological improvements in HICs.

Expensive, require sophisticated laboratories with significant infrastructure, consistent electricity, climate control and refrigeration, and well-trained laboratory technicians

LMICs – equipment's and technologies that date from the late **1800s**: **traditional culture** –based techniques



MALDI-TOF



Manual blood culture

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Technological needs

	High income country	Low-income country
Culture-based growth	**Automated** blood culture systems with continuous growth monitoring and automated detection	**Manual** blood cultures. Automated equipment rarely used because of **high cost and stringent requirements for infrastructure**; service contracts are unavailable or unaffordable in many settings;
Identification	**MALDI-TOF**. Identification systems validated with bacterial collections obtained in high-resource settings	**MALDI-TOF rarely used**. Identification methods not validated with bacterial collections from low-resource settings; some tropical bacteria cannot be reliably identified with commercial identification methods
AST	Harmonised criteria by international guidelines **(CLSI, EUCAST**) integrated in automated antimicrobial susceptibility testing methods assuring correct and updated use of breakpoints and expert rules	**Guidelines** are often temporary, not well disseminated, only available in English, and **poorly followed**; expert rules are too complicated to be mastered by **staff without expertise in microbiology**

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Ombelet, et al. Clinical bacteriology in low-resource settings: today's solutions. The Lancet Infectious Diseases (2018)

Challenges to be addressed

Factors unlikely to change in short term:

- Supply problems
- Lack of microbiology experts
- Environmental conditions
- Power outages
- Low budgets

LANCET, 2018*: Need of developing rapid diagnostic devices:

- Low tech (easy to use and interpret)
- Low cost
- Low maintenance
- Little waste
- Electricity free or consume Little energy
- Specific and sensible

Does that sound familiar?

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*Ombelet, et al. Clinical bacteriology in low-resource settings: today's solutions. The Lancet Infectious Diseases (2018)

AMR DetecTool features

Inexpensive ✓
Easy to use ✓
Fast ✓
No extra equipment needed, low fingerprint ✓
Interpretability ✓
Clinically accurate ✓
Electricity free ✓

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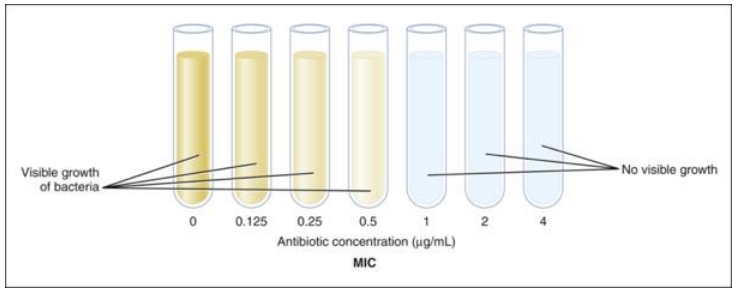
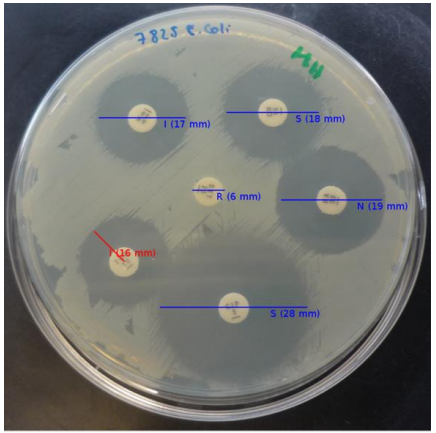
AMR tests in LMICs

- **Little active screening of resistances**, mainly for **surveillance purposes** in some **reference laboratories** → AMR DetecTool represents an extra cost
- Resistances **detected late** in the workflow, at AST (MIC or Disk diffusion)
- Implications in Market size studies



MIC



Disk diffusion

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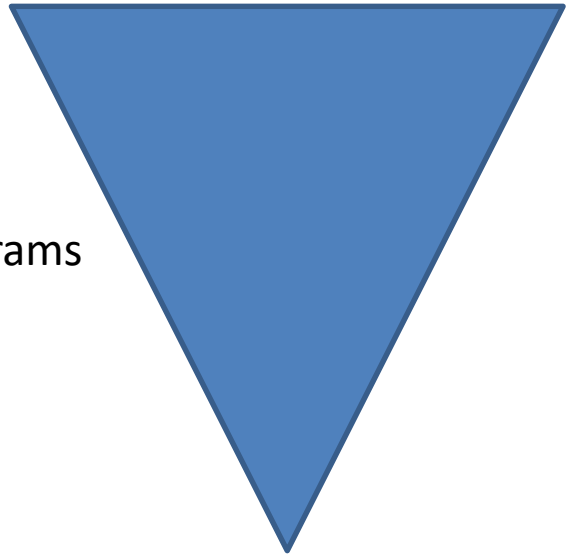
Market opportunity for AMR DetecTool

What are the **main factors?**

- Affordability
- Prevalence
- Access to antibiotics
- Fit into workflows and infrastructure
- National AMR plans and stewardship programs

Top-down approach



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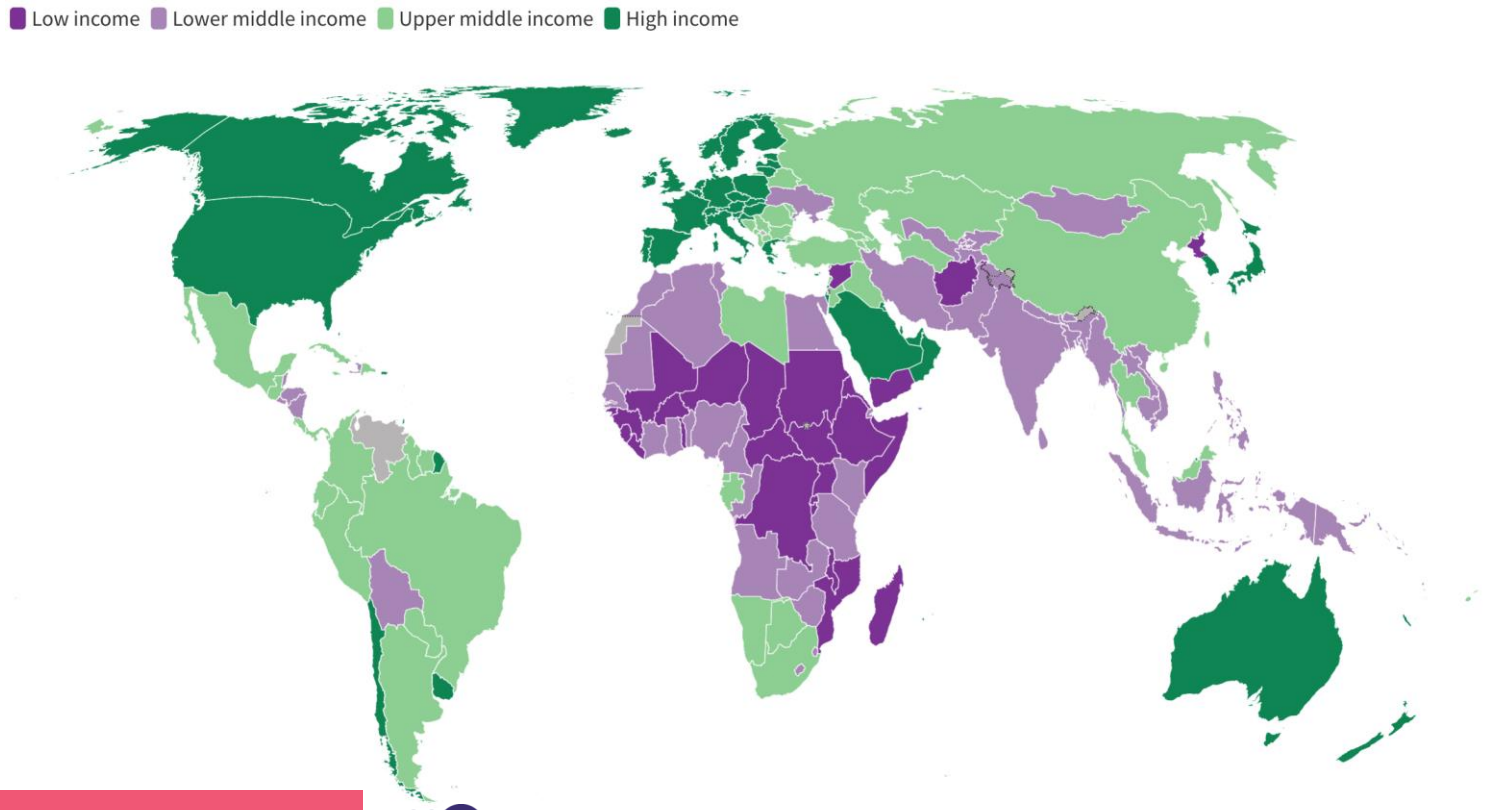
LMICs classification (World Bank)



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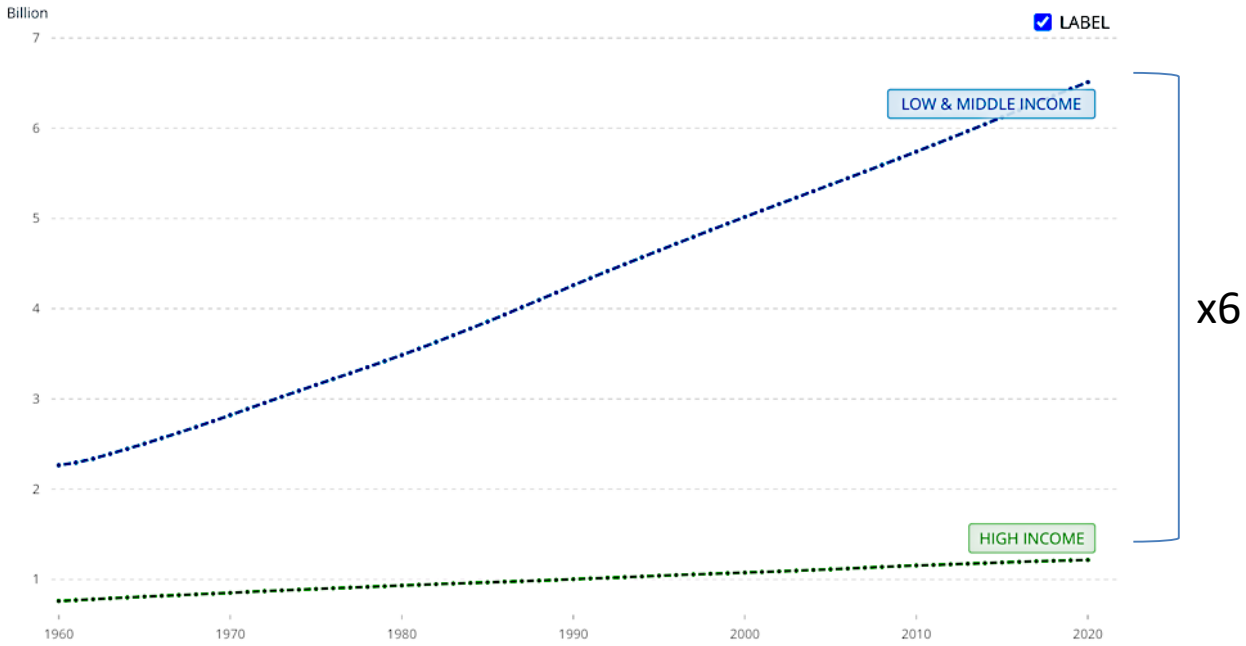
Population LMIC vs HIC (World Bank)



With **lower price**, better access (for the most needing) and **increased market**

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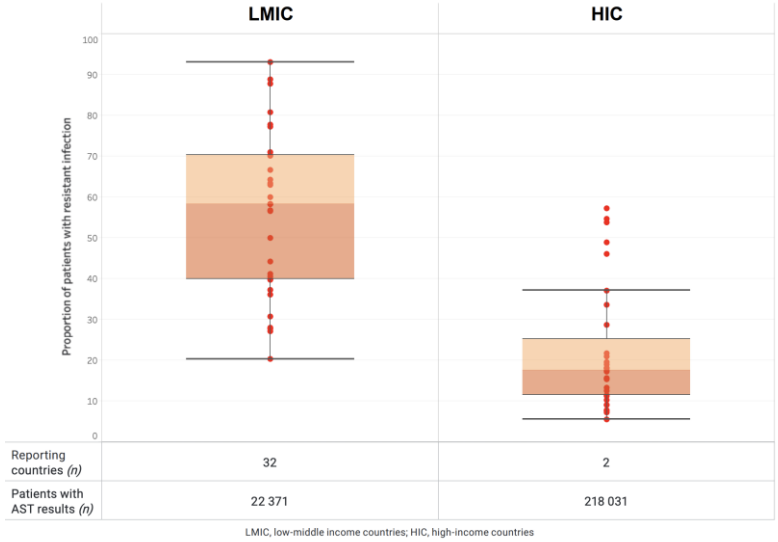
Prevalence of AMR

- **Level of AMR prevalence** – indicates the need, better knowledge of prevalence guides testing
- **Optimal prevalence** for AMR DetecTool?
  60-70% > Optimal Prev. > 10/20%
- **WHO Glass Portal**
  - **Best source of information**
  - **Data lacking** for LMICs (compared to HICs)
  - **Higher levels of resistance** in LMICs
  - Challenge for countries where data not available (other sources needed)



Proportion of patients with BSIs caused by E. coli resistant to 3rd generation cephalosporins by country income level (WHO Glass report 2021)

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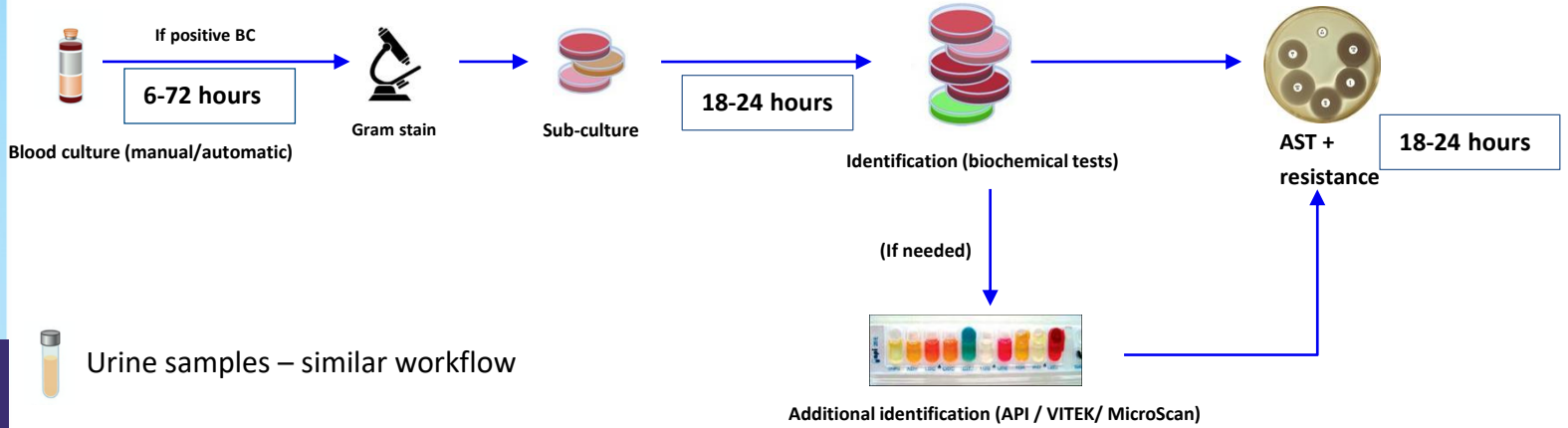
Typical workflow

Typical blood workflow in LMICs



Urine samples – similar workflow

Stool samples – **not** usually performed, no isolation wards, cultural interferences

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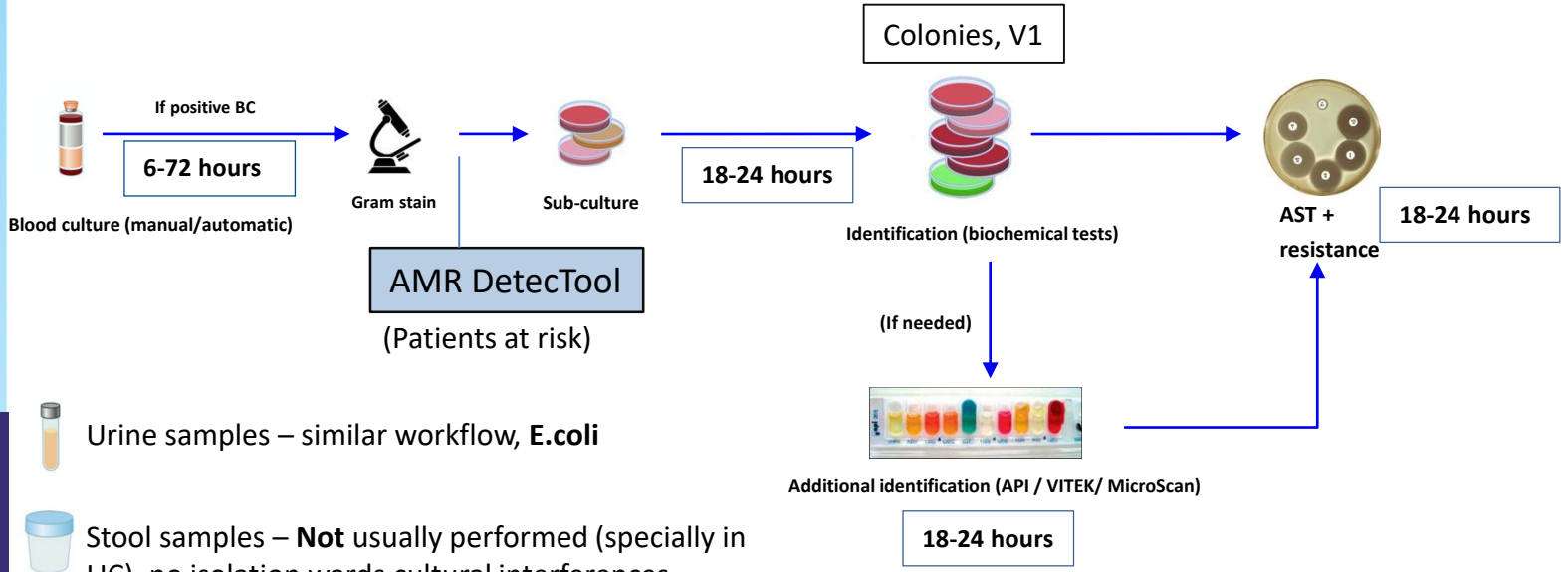
Fit into the typical workflow

Typical blood workflow in LMICs



Urine samples – similar workflow, **E.coli**

Stool samples – **Not** usually performed (specially in LIC), no isolation wards,cultural interferences

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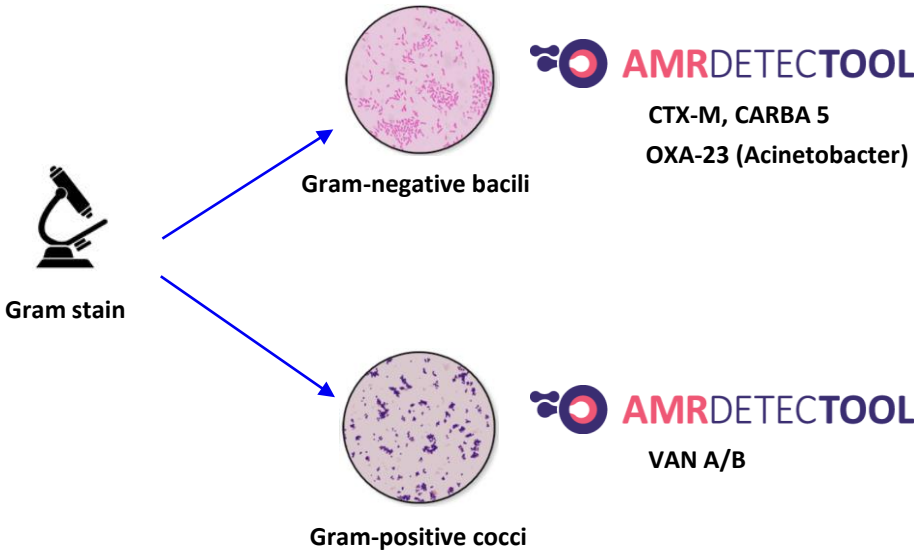
Gram stain as pre-condition of choosing the type of AMR DetecTool test



Target labs should be able to do gram-stain

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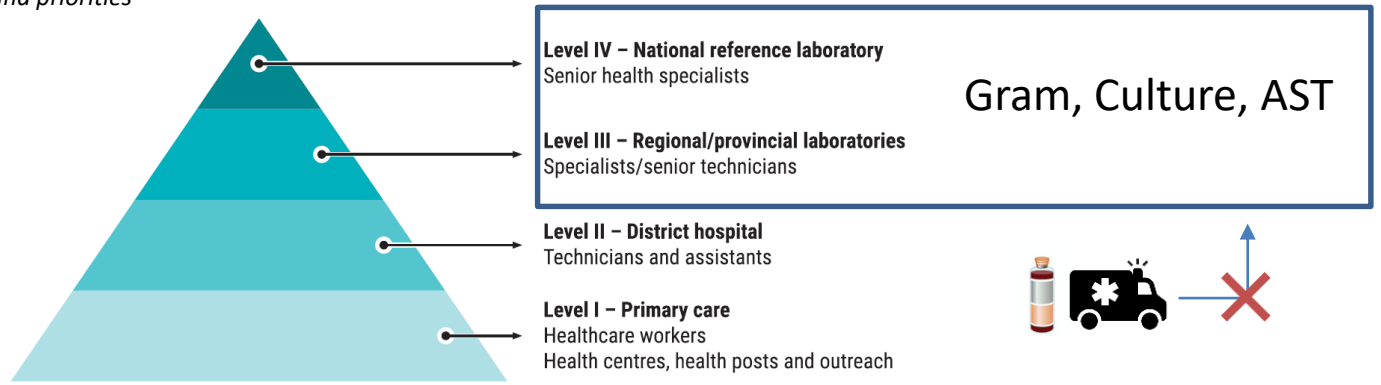
Type of lab

WHO Landscape of diagnostics against antibacterial resistance, gaps and priorities



*Some Level II hospitals in Middle-income countries have microbiology labs

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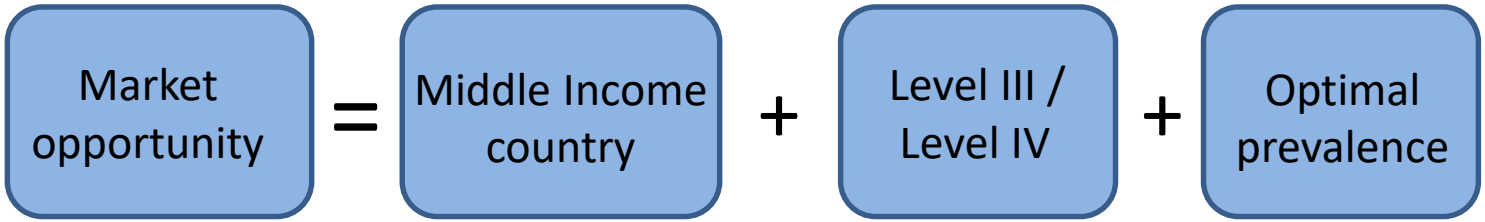
Market opportunity



- Access to antibiotics
- AMR policies
- ICUs (higher need + possibility of treatment)

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Market analysis

Microbiologist in Egypt:
"We cannot afford resistance tests. Public system does invest in detecting resistances, so we wait for Antibiogram to know the effective antibiotic. Maybe if it was very cheap (5 Euros) we would purchase it… There are no AMR policies in place. The private hospitals care more about resistance, and they might be able to pay for it"

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Market analysis

Microbiologist in Lebanon:
"If we had the test, we would use it to detect Carbapenemases. We are not very interested in ESBLs tests as we can use carbapenems. We do screen patients and the ICU and hospitalized high risk patients (mainly Carba). However, given the economic and political situation in Lebanon we cannot afford an extra cost. "

MENA region as an entry point

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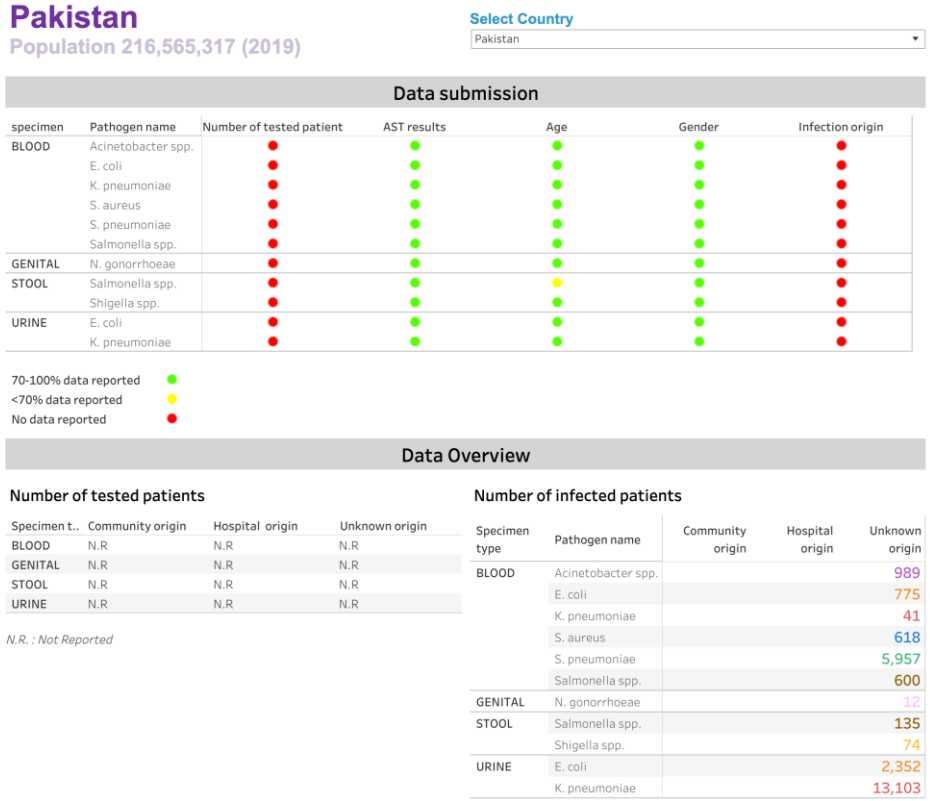
Pakistan, WHO-Glass



Pakistan

Population 216,565,317 (2019)

Select Country: Pakistan

Data submission

specimen	Pathogen name	Number of tested patient	AST results	Age	Gender	Infection origin
BLOOD	Acinetobacter spp.	🔴	🟢	🟢	🟢	🔴
	E. coli	🔴	🟢	🟢	🟢	🔴
	K. pneumoniae	🔴	🟢	🟢	🟢	🔴
	S. aureus	🔴	🟢	🟢	🟢	🔴
	S. pneumoniae	🔴	🟢	🟢	🟢	🔴
	Salmonella spp.	🔴	🟢	🟢	🟢	🔴
GENITAL	N. gonorrhoeae	🔴	🟢	🟢	🟢	🔴
STOOL	Salmonella spp.	🔴	🟢	🟡	🟢	🔴
	Shigella spp.	🔴	🟢	🟢	🟢	🔴
URINE	E. coli	🔴	🟢	🟢	🟢	🔴
	K. pneumoniae	🔴	🟢	🟢	🟢	🔴

70-100% data reported 🟢
<70% data reported 🟡
No data reported 🔴

Data Overview

Number of tested patients

Specimen t..	Community origin	Hospital origin	Unknown origin
BLOOD	N.R	N.R	N.R
GENITAL	N.R	N.R	N.R
STOOL	N.R	N.R	N.R
URINE	N.R	N.R	N.R

N.R. : Not Reported

Number of infected patients

Specimen type	Pathogen name	Community origin	Hospital origin	Unknown origin
BLOOD	Acinetobacter spp.			989
	E. coli			775
	K. pneumoniae			41
	S. aureus			618
	S. pneumoniae			5,957
	Salmonella spp.			600
GENITAL	N. gonorrhoeae			12
STOOL	Salmonella spp.			135
	Shigella spp.			74
URINE	E. coli			2,352
	K. pneumoniae			13,103

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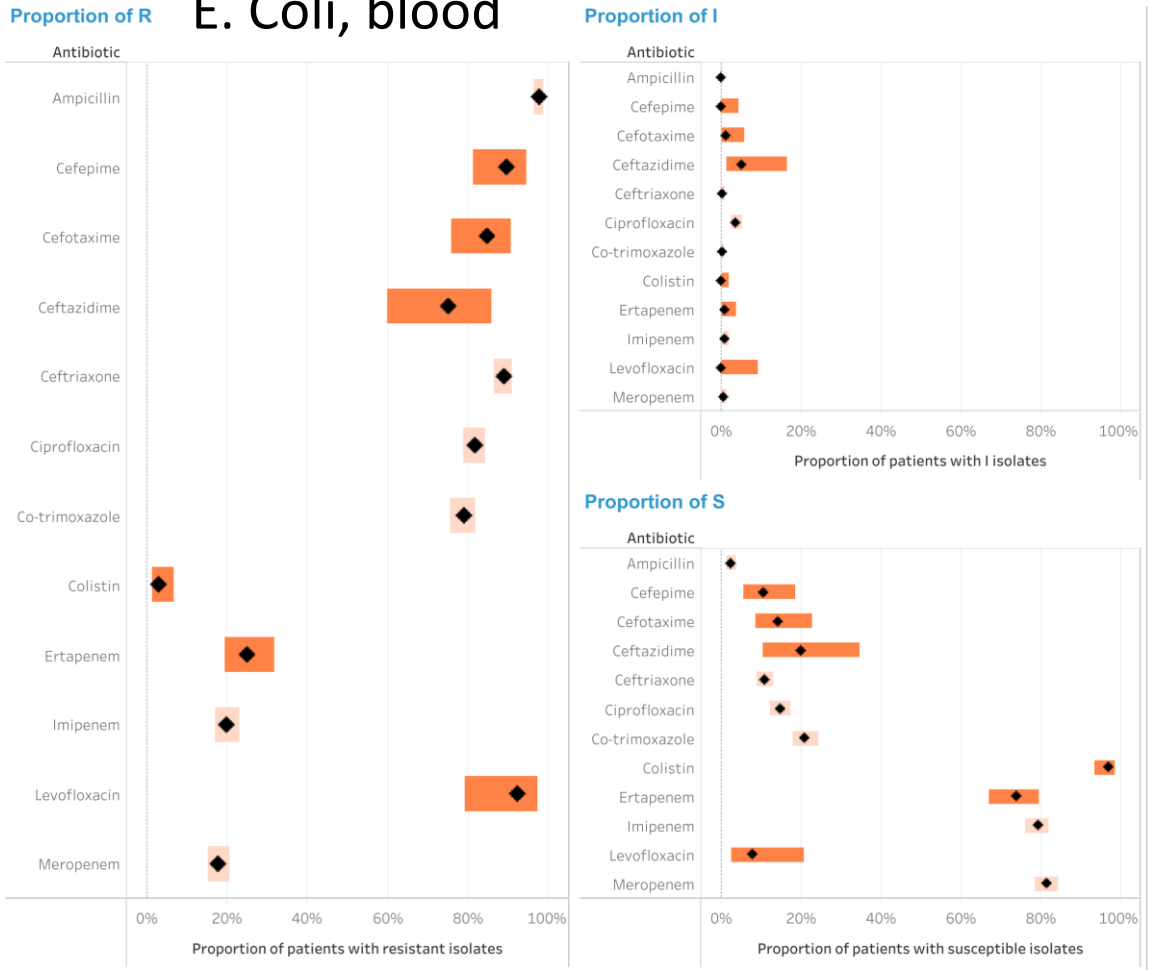
E. Coli, blood



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Event to enter the market

THIS IS YOUR PRESENTATION TITLE

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THANK YOU
FOR YOUR ATTENTION!

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