Impact and Effectiveness of POC Testing on Clinical and Public Health Outcomes

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Land Acknowledgement

We would like to acknowledge the traditional custodians of the land on which the conference is taking place, the Gadigal people of the Eora Nation, and pay our respects to their elders past, present, and emerging. We are grateful for the opportunity to gather and learn on this beautiful land

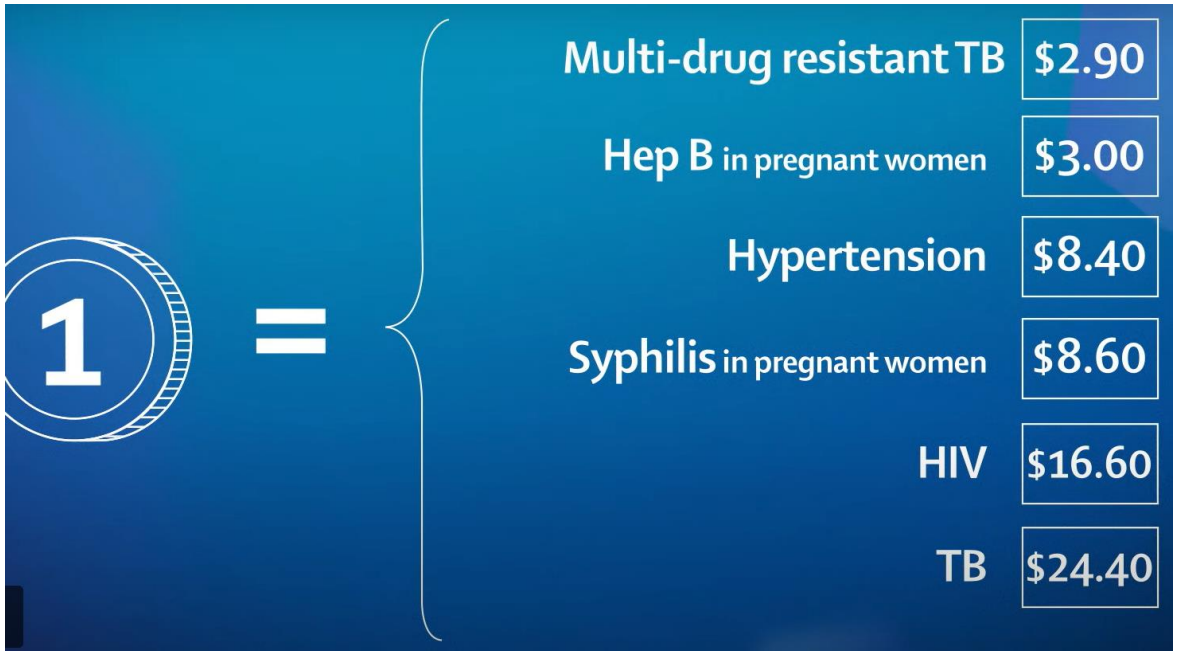
Plan of presentation

- Value of diagnostics that can be performed at the point-of-care (POC)
- POC diagnostics: defining characteristics and trade-offs
- How should countries invest in diagnostics to maximise impact on clinical and public health outcomes?

Diagnostics are under-valued and under-invested

- Diagnostics, unlike drugs and vaccines, are not considered life-saving health products
- Most governments think of diagnostics as a cost to the healthcare system and not of value
- **47% of the global population has little to no access to diagnostics, including imaging**

As an example of the potential impact, 1·1 million premature deaths in low-income and middle-income countries could be avoided annually by reducing the diagnostic gap for 6 priority conditions: diabetes, hypertension, HIV, TB, hepatitis B virus infection and syphilis for pregnant women



Fleming et al. The *Lancet* Commission on diagnostics: transforming access to diagnostics. *The Lancet*, Vol. 398, No. 10315, October 6, 2021
https://www.thelancet.com/commissions/diagnostics

WHO STI POC Test Initiative

World Health Organization

human reproduction programme hrp research for impact
UNDP-UNFPA-UNICEF-WHO-WORLD BANK

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Sexual and reproductive health

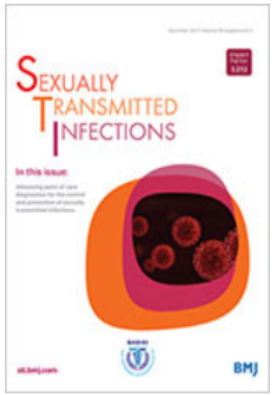
"The way forward": Quick, accurate tests to diagnose sexually transmitted infections

Greater investment needed worldwide in point-of-care tests

12 December 2017: A special supplement to the journal *Sexually Transmitted Infections* highlights the urgent importance of investing in the research, development and scaling up of the use of point-of-care tests.

– Download the supplement

Each year, there are an estimated 357 million new infections with 1 of the following 4 curable STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis. An estimated 290 million women are infected with human papillomavirus – an STI which can cause cervical cancer. Herpes simplex virus and syphilis can increase the risk of



- Target Product Profiles for POCTs
- STI POCT Landscape
- Systematics reviews
- Protocols for POCT evaluations
- Multi-country evaluations

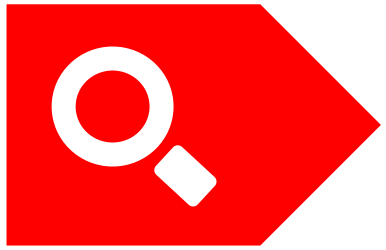
https://www.who.int/reproductivehealth/topics/rtis/pocts/en/

Toskin I et al. Advancing point of care diagnostics for the control and prevention of STIs: the way forward. Sex Transm Infect 2017;93:S81–S88.

Role of Diagnostics for Emergency Response for COVID-19

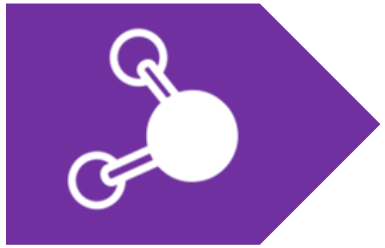
Ref: Peeling RW, Heymann DL, Teo YY, Garcia PJ. Lancet. 2022 Feb 19;399(10326):757-768.

Confirm clinical diagnosis
to guide patient management and enable implementation of public health measures



Refine clinical case definition and standardise case reporting

Enable research
to identify vulnerable populations, understand modes of transmission, facilitate modelling to estimate impact of control strategies



Facilitate data display to show extent of outbreak, hotspots and evolving trends

Enable drug and vaccine trials

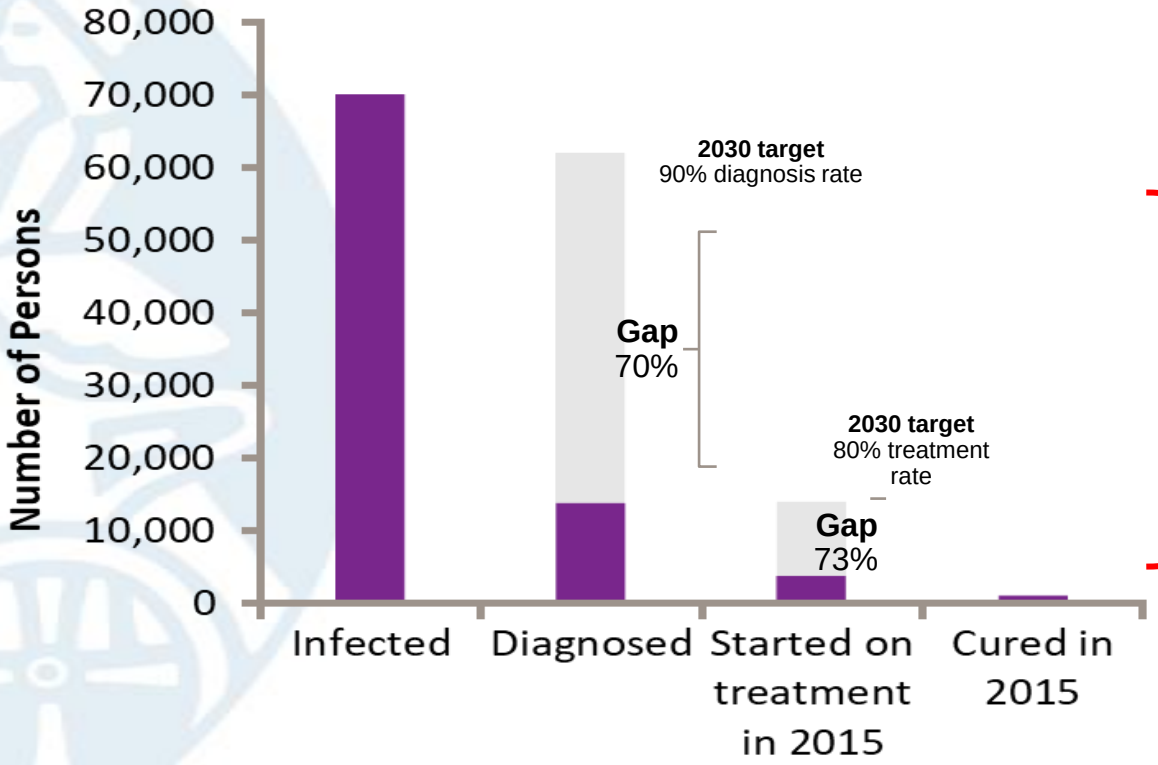
Use of diagnostics for case detection to enable the implementation of public health measures is the only means of controlling disease transmission before availability of drugs and vaccines

Advocating the Value of POC Diagnostics

Develop models of the impact of POC diagnostics in messages that resonate with government decision makers - reducing health care costs, increasing the efficiency of the healthcare system and saving lives

- Patient diagnosis and management: malaria RDTs
- Screening to avert costly disease progression: HIV, STIs, HPV, HCV
- Surveillance, outbreak alerts and containment
- Rational use of antibiotics to reduce the threat of Antimicrobial Resistance (AMR)
- Earlier and more efficient deployment of vaccines

Screening for HCV is Highly Cost-effective



WHO HCV Fact Sheet and Global Hepatitis Report, 2017.
http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf?ua=1 .

Screening for HCV and providing treatment will avert costly sequelae, reduce stress to the healthcare system and save lives

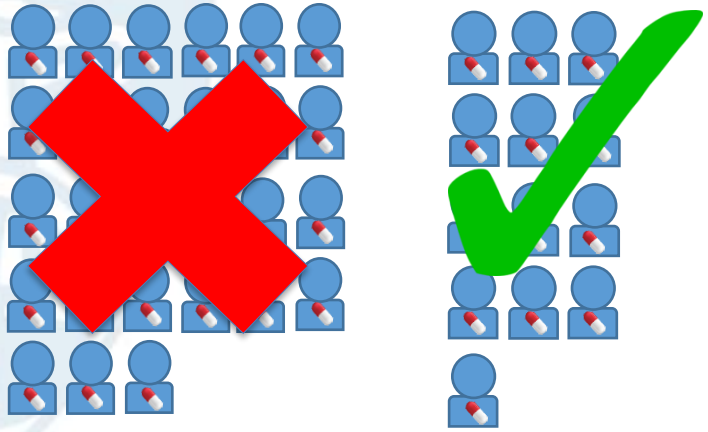
Untreated infections:
- **Cirrhosis**
- **end-stage liver disease**
- **Transplantation**
- **hepatocellular carcinoma (HCC)**

+ incalculable costs of associated mortality and economic productivity

POC Tests to Reduce Overuse of Antibiotics in Clinical Medicine

Fever and respiratory infections are among the most common reasons why people seek care. Presumptive treatment with broad spectrum antibiotics has contributed and accelerated to the emergence of antibiotic resistance

In the US each year, approx. 40 million people are given antibiotics each year for respiratory issues but 27 million were given antibiotics unnecessarily.



Ref: Shapiro et al. Antibiotic prescribing for adults in ambulatory care in the USA, 2007-9. J Antimicrobial Chemother 2013.

Host biomarkers have been used to guide appropriate use of antibiotics:

wbc, CRP, PCT, ESR

ELISA-based ImmunoExpert™ assay (MeMed Diagnostics, Israel) measures 3 different host proteins: CRP, TNF-related apoptosis-inducing ligand (TRAIL) and interferon gamma-induced protein 10 (IP-10)

FebriDx™ (RPS Diagnostics,USA), is a semi-quantitative test that combines CRP and the myxovirus resistance protein 1 (MxA), a marker for viral infection, and provides results within 15 min

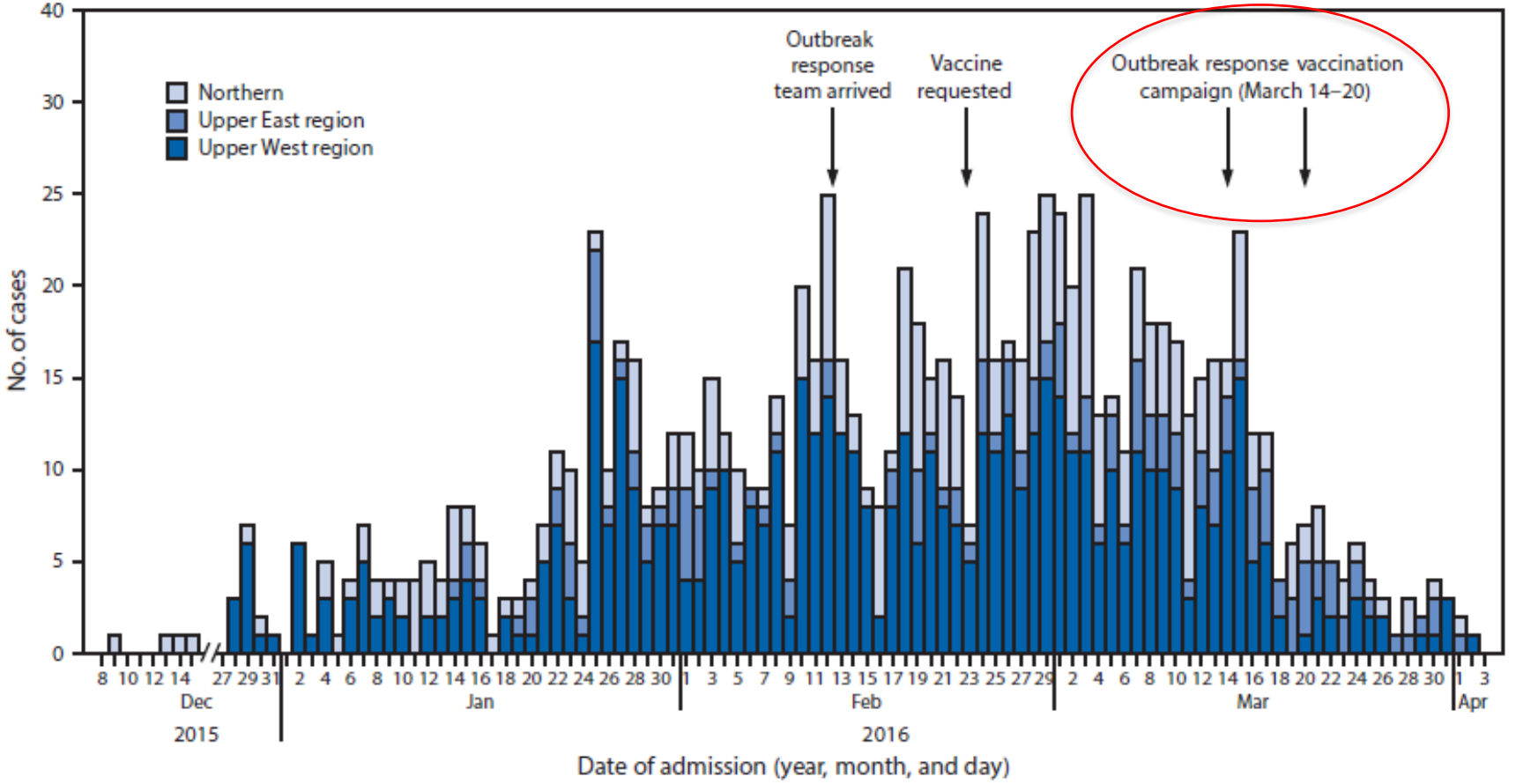
Ross MH et al. Host Based Diagnostics for Acute Respiratory Infections. Clinical Therapeutics 2019; 41: 1923-1938

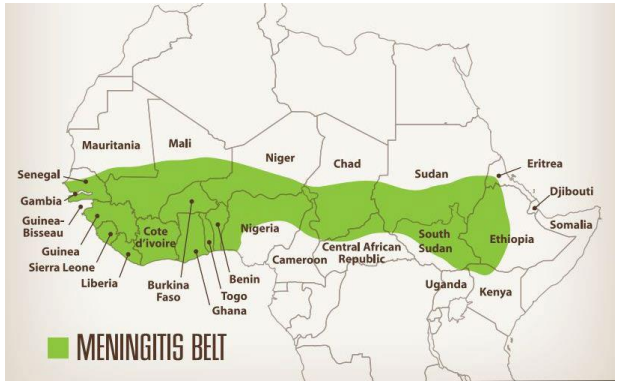
Diagnostics to make immunisation programmes more efficient, equitable, and effective

Hampton LM, et al. Lancet Microbe. 2022 Apr;3(4):e242-e243.

FIGURE 1. Suspected meningitis cases (N = 1,006), by date of admission and region and dates of vaccination campaigns with meningococcal polysaccharide ACW* vaccine — northern Ghana, December 2015–April 2016

MMWR / August 4, 2017 / Vol. 66 / No. 30





Having a rapid POC test that can use urine specimens will allow earlier detection of meningitis outbreaks and earlier vaccine deployment to save lives and avert life-long complications

ASSURED Tests to Improve Global Health

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

A = Affordable

S = Sensitive

S = Specific

U = User-friendly

R = Rapid and robust

E = Equipment-free

D = Deliverable

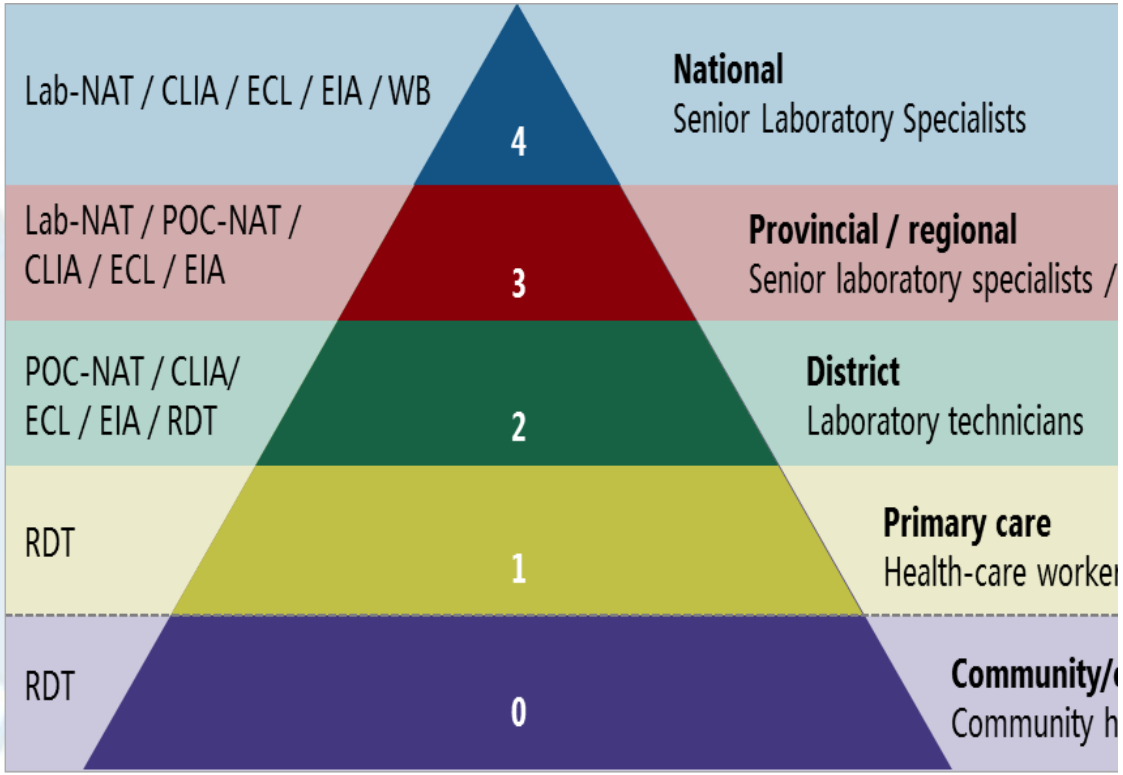
✓ Affordable

✓ Accurate

✓ Accessible

"Pick 2 of 3, you can't have them all."

Trade-off between Access vs Sensitivity



Access	Sensitivity			
	100	90	80	70
100	100	90	80	70
90	90	81	72	63
80	80	72	64	56
70	70	63	56	49
60	60	54	48	42
50	50	45	40	35
40	40	36	32	28
30	30	27	24	21
20	20	18	16	14
10	10	9	8	7

NAT: Nucleic acid tests: Lab-NAT: laboratory-based; POC-NAT: at point-of-care;
CLIA: chemiluminescence immunoassay; ECL: electrochemiluminescence immunoassay;
EIA: enzyme immunoassay; RDT: rapid diagnostic test

Rapid vs Point-of-Care (POC) Tests

Courtesy Dr. Ray Waters

Senior K. Lancet ID 9: 467 2009

The Ideal Diagnostic Test

2003

- A = Affordable
- S = Sensitive
- S = Specific
- U = User-friendly
- R = Rapid and robust
- E = Equipment-free
- D = Deliverable

2018

- R = Real time connectivity
- E = Ease of specimen collection
- A = Affordable
- S = Sensitive
- S = Specific
- U = User-friendly
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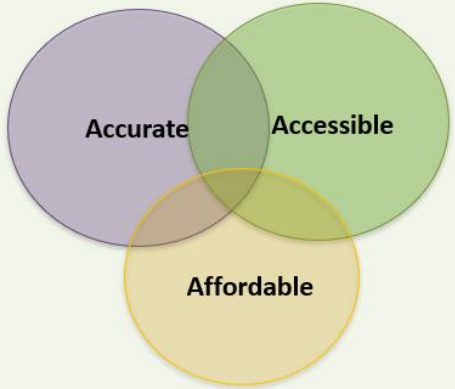
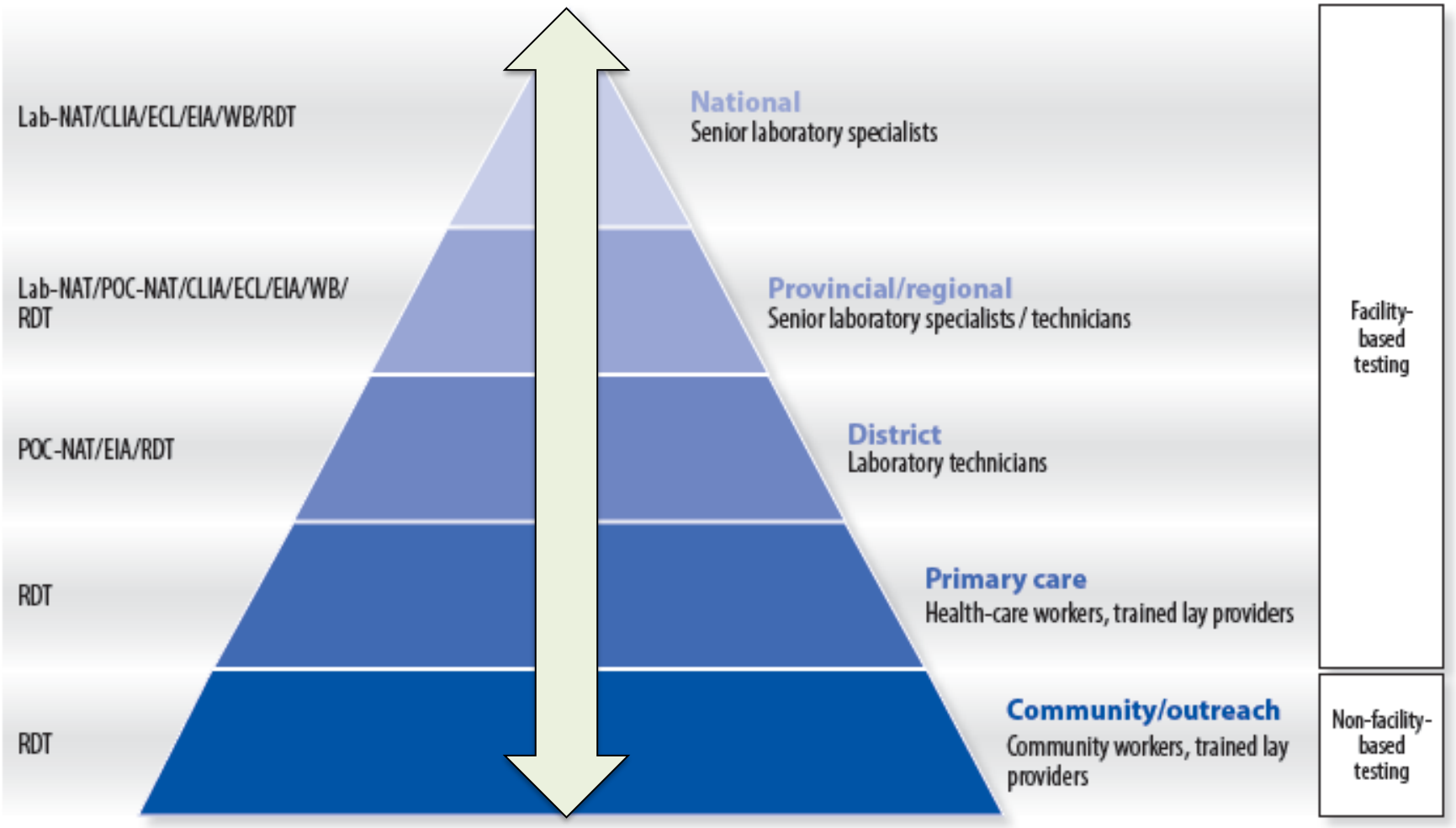


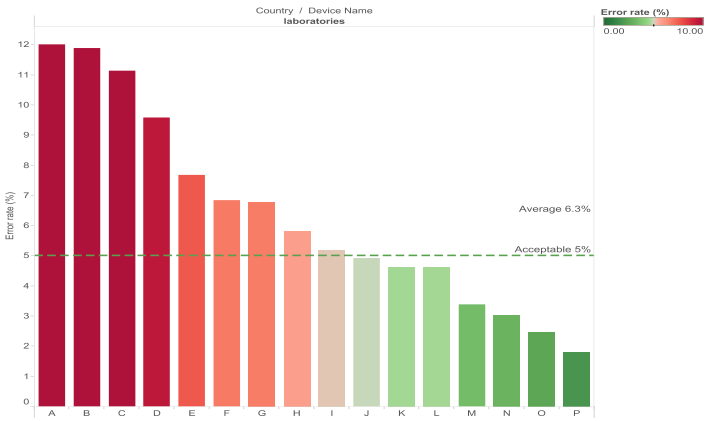
Mabey D, et al. Diagnostics for the developing world. Nature Rev Microbiol 2: 231-40, 2004.

Land KJ,et al. REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Nat Microbiol. 4(1):46-54.2019. e-pub Dec 2018.

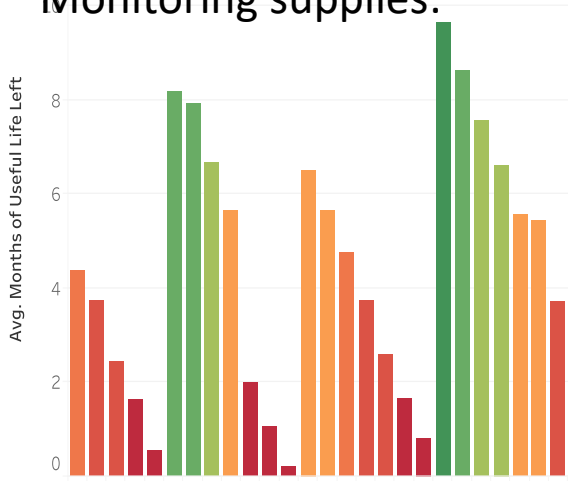
Countries should invest in a connected diagnostic system that forms the backbone of the healthcare system



Monitoring error rates:



Monitoring supplies:



Source: Adapted from WHO 2017 Guidance for procurement of *in-vitro* diagnostics and related laboratory items and equipment

Summary

- POC diagnostics have significant impact not only on clinical outcomes but can also improve access to health services and reduce stress and costs to overburdened healthcare systems
- POC testing can help address inequities by reaching remote and marginalised populations
- POC testing, including self-testing, can empower the public to act responsibly in public health emergencies
- With advances in POC testing technologies, data digitisation and connectivity, countries should invest in a connected diagnostic system, with appropriate technologies at every level of the healthcare system, detecting unusual trends and turning data into intelligence in real-time to provide early alerts of outbreaks, improve quality of services and reduce costs and stresses to the healthcare system

Thank you

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