Importance of the laboratory in the different levels of the health pyramid within WHO Essential Diagnostics List (EDL) context

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Context

- Many people cannot do laboratorial tests: luck to access to diagnostic services (***Petti et al., 2006; Sarr et al., 2016; Tinajeros et al., 2017),***
- For many others: wrong diagnosis, wrong or inappropriate treatment **(Griner *et al.*, 1982; Frank *et al.*, 2009; Kunda-Moya *et al.*, 2015).**
- WHO Estimation:

- Undiagnosed of 46% adults with type 2 diabetes worldwide increase risk serious complications and care costs
- Late diagnosis of infectious diseases HIV and tuberculosis: increase the risk of spread and difficult to treat.

Context

WHO recommendations (May 2018):

- Development of the 1st Model List of Essential In Vitro Diagnostics (EDL), to complement the WHO Model List of Essential Medicines (EML),
- Support and advise of EDL: creation of Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD), which includes 19 multidisciplinary members with global representation
- Selection based on diseases prevalence and public health relevance, evidence of efficacy and accuracy and comparative cost-effectiveness.

Context

EDL content and format

- 58 tests for detection and diagnosis, screening and management of patients with comon diseases : diabetes, cardiovascular, anaemia, liver function,
- 55 tests for detection, diagnosis and follow-up of "priority" diseases: HIV, tuberculosis, malaria, hepatitis B and C, human papillomavirus and syphilis.

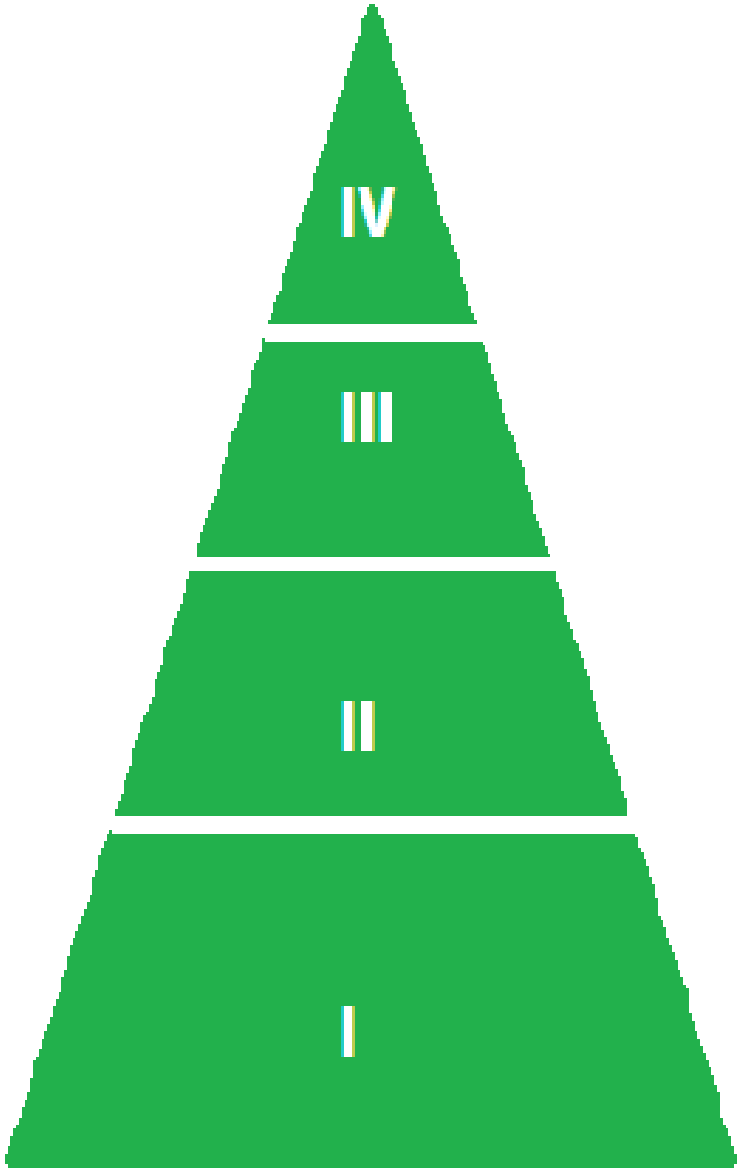
Context

- Pyramid of testing proposed by the WHO Strategic Advisor Group:

- Encompass the classification of laboratory services in 4 categories: national, reference laboratories, regional/provincial/Specialized laboratories, district/Hospital laboratories and primary care setting)
- Mirrors the modern organization of laboratory facilities with the well-known 'hub and spoke' paradigm,
- 2 grupos of tests :

i) For level I: Primary care settings - Health care professionals but not trained lab personnel, self-testing;

ii) For levels II, III and IV (figure 1),



Type of laboratories	EDL level
IV-National Reference Laboratory Senior Health Specialists	**LEVELS II, III, IV**
III-Regional/Provincial/ Specialiazed laboratories Specialists/Senior technicians	
II-Districts Hospitals/Laboratory Technicians and Assistants	
I-Primary care settings Health care professionals but not trained lab personnel, self-testing	**LEVEL 1**

Figure1: Types of testing (WHO, 2018)

Within WHO EDL, what is the importance of the laboratory in the different levels of the health pyramid?

Example: Case of Senegal

A laboratory network aligned with public health system

- The senegalese national laboratory network (RNL) is an integrated system of laboratories, organised in four (4) tiers:
  - peripheral,
  - regional,
  - national
  - central
- The RNL follows the public health delivery system (figure2).

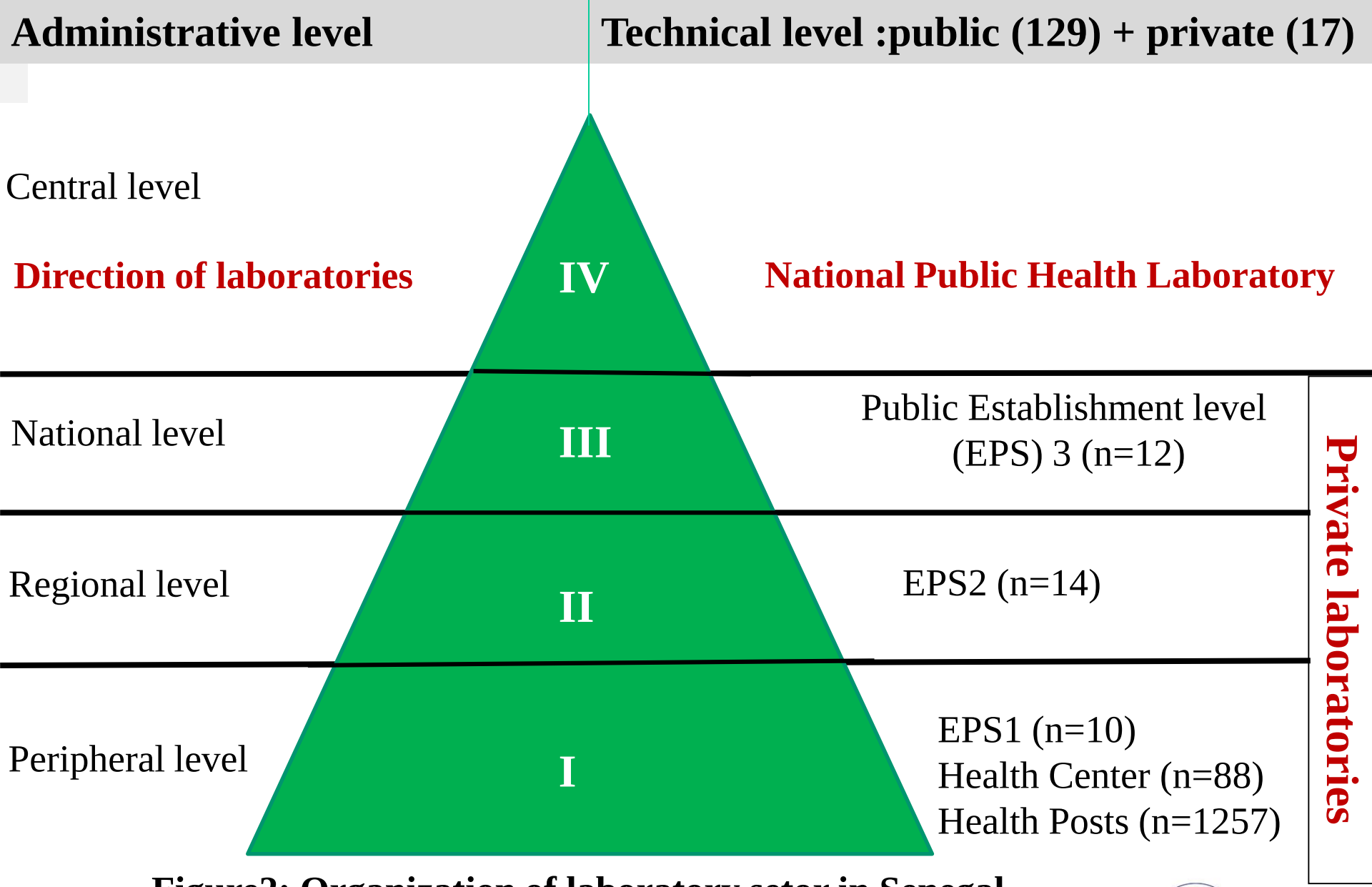


Figure2: Organization of laboratory setor in Senegal

EDL of Senegal

- MOH: has realized very early the necessity to create minimal list per level

- Evolution of EDL list with key dates and updated:

1st Edition	2nd Edition	2nd Edition (2016)
Drafted : January 2004 Reviewed: Nov. 2008 EDL + equipments *Without biochemisty*	Reviewed: Setember 2015 EDL + equipments *With biochemistry*	Completed with Human Ressources profil and infrastructures (Ministerial Order)

2004 → **2018**

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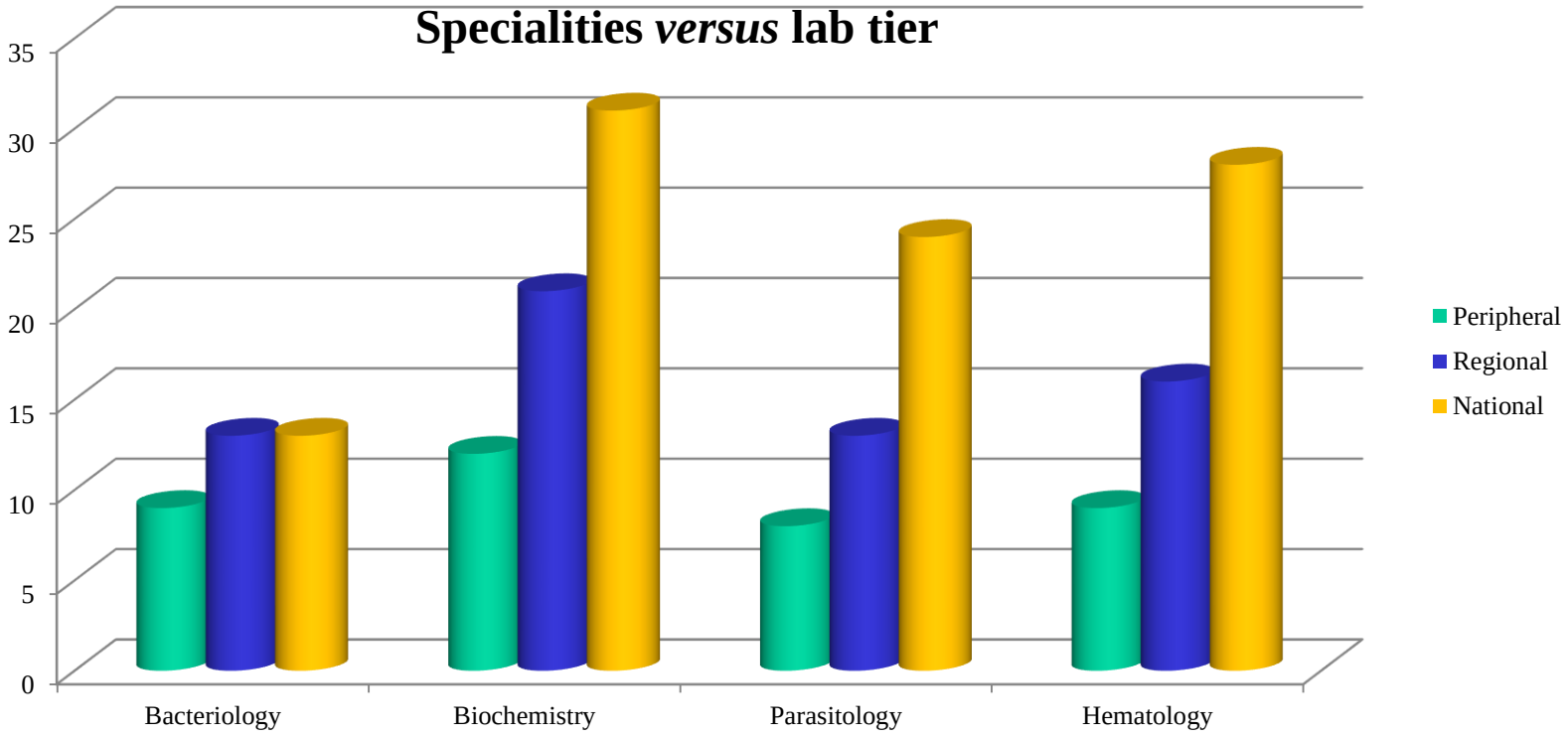
EDL of Senegal



As we go up the sanitary pyramid, more the number of tests is important, independently of the speciality

EDL of Senegal

At each level minimal, minimal conditions has been defined: i) human ressources, ii) equipements and iii) infrastructures

PROFIL	PERIPHERAL		REGIONAL	NATIONAL
	CS	EPS1	EPS2	EPS3
Biologist (Pharmacist, Medical Doctor)	-	1	2	3
Technician (university level education)	1	3	4	4
Technician	2	3	4	4
Assistant technician	1	2	3	4
Laboratory sampler (nurse or technician)	1	1	1	1
Cleaning technician	1	1	1	1
Medical Secretary	1	1	1	1

EDL of Senegal

Quality of tests

- ❑ Reglementation of IVD and reagentes: process is on going
- ❑ Availability and distributio follow 2 circuits:
  - National Pharmacy Supply (vertical programs as HIV, TB and malaria) by tender procedures,
  - National companies approved and knowned by lab practitioner (n=23), with MOH agreement, renewable
- ❑ Regular Inspection of national compagnies (once a year)

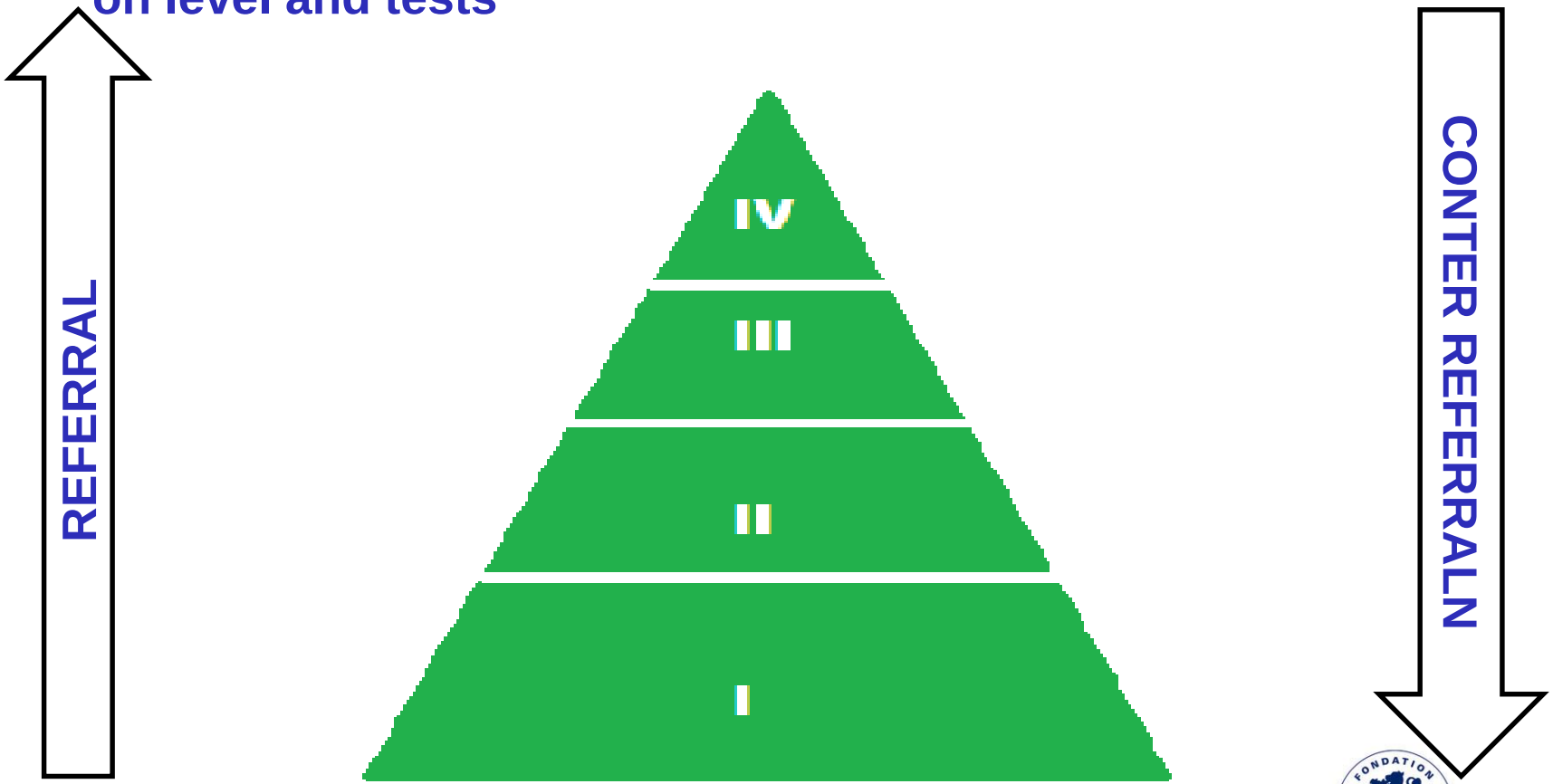
EDL of Senegal

Quality of tests

- Implementation of a National quality system across the laboratories network
- An external quality assurance (EQA), and continuous quality improvement (CQI),
- Establishing a QA system reduces the chances of variability in the laboratory processes, testing and reporting,
- Coaching program with SLIPTA tool: opportunity to strengthen laboratories performance with mentorship system (including private setor)

EDL of Senegal

Referral and Conter Referral accros lab network: depending on level and tests



WHO EDL *versus* Senegalese EDL

Similar but some relevant differences…

Level 1 of WHO EDL similar to Senegalese EDL, but some relevant differences noted:

- ❑ Levels II, III and IV not clearly specified
- ❑ EDL for two tiers while it exists 4 tiers
- ❑ Some tests are lacking at level I:

- Hematology: Sickling test (Emmel test), Fibrinogen essay, Sedimentation rate
- Blood and fecal microscopy
- Biochemistry blood: Creatinaemia, transaminases (ASAT, ALAT), electrolytes

Among others …

Similar but some relevant differences…

Test	Test purpose
Fibrinogen	Inherited and acquired bleeding disorders
D-dimer	Diagnostics of venous thromboembolism
Lactate dehydrogenase (LDH)	Cell injury, hemolysis
Creatine kinase (CK)	Muscular injuries
Uric acid	Hyperuricaemia
Prostate Specific Antigen (PSA)	Screening od prostate cancer
Thyroid - stimulating hormone (TSH)	Screening of thyroid disorders
Antimicrobial susceptibility testing	Antimicrobial Resistance

Challenges

- The term *essential* referred to either country Medecine or Diagnostic list,
- List related to local organization of the healthcare systems in term of: number and quality of services provided, access to care and treatment pathways, public or private funding, refunding policies, epidemiology and local regulations for quality
- The capacity of resource-limited countries to deliver the same level of diagnostic testing as developped countries is questionable,
- Although creating separate lists based on economics has ethical implications,

Some advantages of EDL

- Ensure safe and rational use of medicines in LMEs
- Help countries better prioritize their laboratory and infrastructure testing needs
- Increase affordability by facilitating large-scale procurement (eg through the WHO bulk purchase mechanism) and in advance
- Contribute to reducing antimicrobial resistance by facilitating the appropriate use of antimicrobial agents through improved access and use of relevant IVDs

Some advantages of EDL

- Help countries to better prepare for future epidemics by increasing the capacity of laboratories at all levels of the health system
- Facilitate the development of new diagnostic tests through the identification of priority needs to guide diagnostic developers, industry and funders
- Assist national regulatory bodies in defining their priorities for the evaluation of diagnostic tests (especially in countries with limited resources)

Recommendations

- Adoption and adaption of the EDL by countries to develop their own national EDLs,
- Implementation of national EDLs national to ensure impact,
- Integrated, connected, tiered laboratory systems, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems

Conclusion

- A revolutionary step in strengthening health laboratories at all levels of healthcare,
- Like the WHO Model List of Essential Medicines, which has been in use for more than four decades, the Essential Diagnostic Test List is intended to serve as a reference for countries to update or develop their own list of essential diagnostic tests,
- Hope IDE will promote greater access to quality and affordable IVDs at all levels.


THANK YOU

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