Role of clinical laboratories in Non communicable diseases (NCDs)

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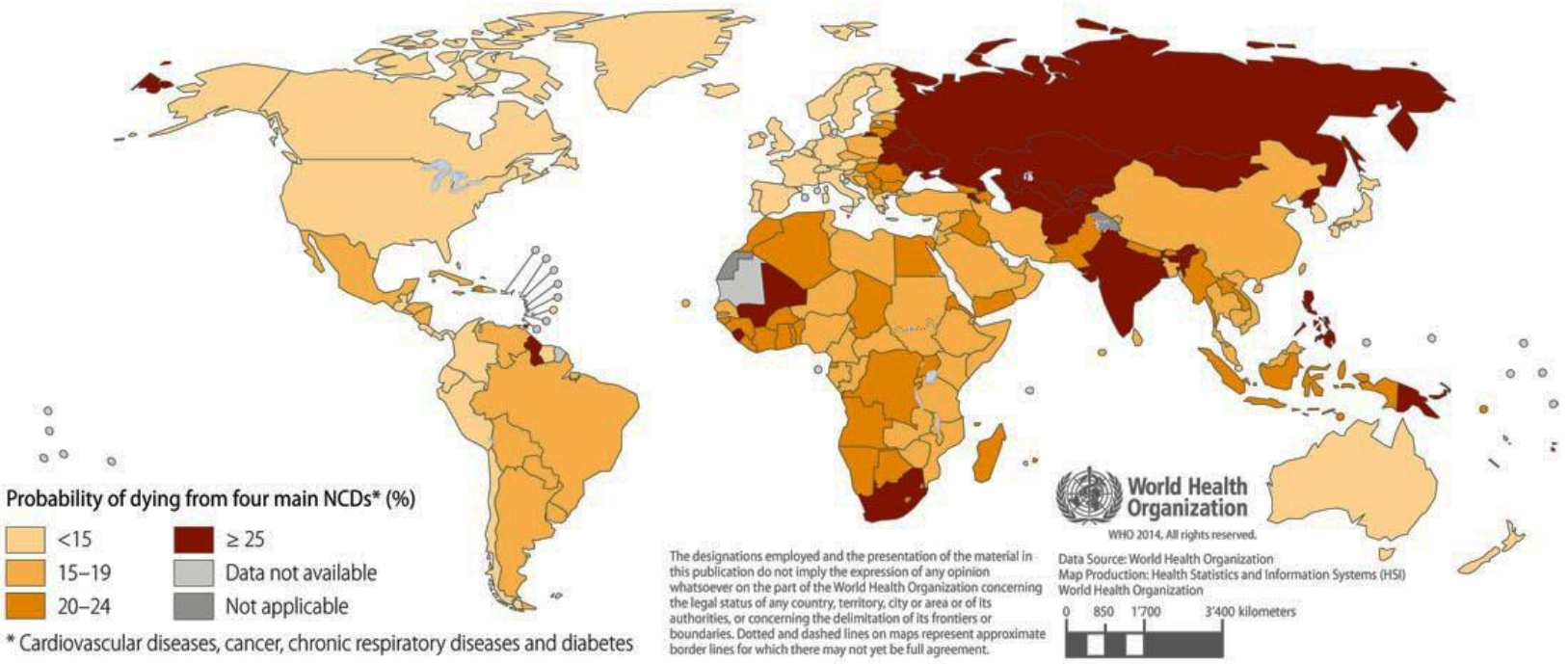
Introduction

- Non communicable diseases (NCDs) are the leading cause of death, disease and disability in the World
- The four major NCDs (cardiovascular disease, cancer, chronic obstructive pulmonary diseases and diabetes) account for nearly 86% of deaths and 77% of the disease burden
- Developing countries are undergoing an epidemiological transition, with a shift from mortality predominately driven by infectious diseases to mortality driven largely by non-communicable diseases (NCDs)

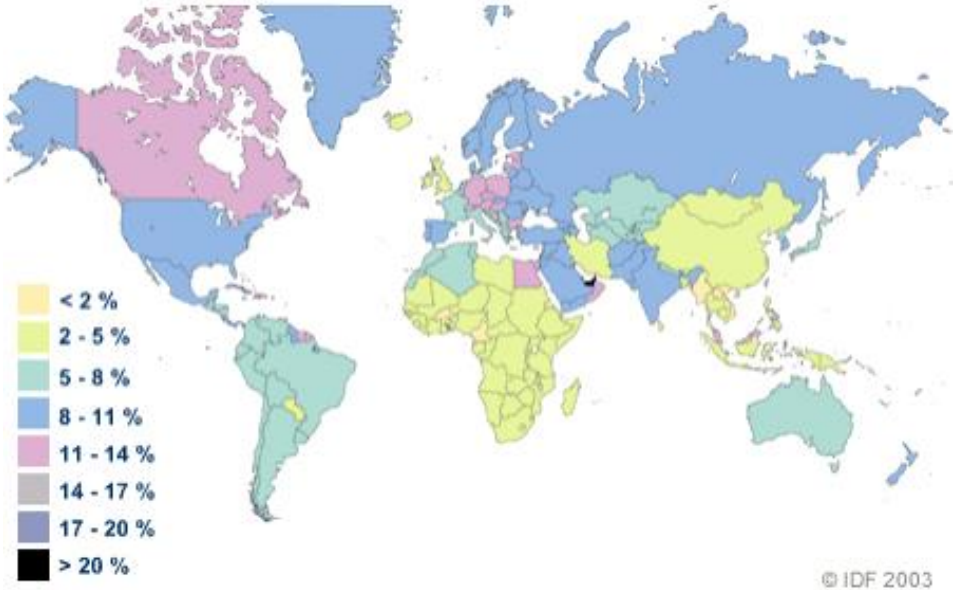
Fig. 1.5a Probability of dying from the four main noncommunicable diseases between the ages of 30 and 70 years, comparable estimates, 2012



Prevalence of diabetes in 2003

135 millions diabetics

Estimed prevalence of diabetes in 2025



300 millions diabetics

Introduction

- These diseases put increasing strain on the well-being of the population, health systems working to treat patients, and overall economic development

- It has been estimated that for every 10% increase in NCD mortality, economic growth is reduced by 0.5%

Introduction

- Fortunately, NCDs are largely preventable, and early detection and good case management can contribute to good quality of life and reduced morbidity and mortality

- This requires a comprehensive systemic approach combining large-scale population interventions (e.g. tobacco control) with effective individual health services (e.g. diabetes detection and management)

- The role of clinical laboratories is crucial in the management of NCDs

Role of laboratories in the management of NCDs

1. **Detection of NCDs**
2. **Follow-up of patients**
3. **Surveillance** : Laboratory is key component

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1. The Detection of NCDs

- The Early and accurate diagnosis of NCDs is an important step for control

✓ Although mass screening approaches are neither cost effective nor feasible

✓ There are demonstrated needs to develop and adopt affordable and effective point-of-care innovative diagnostic tools, devices, and technology

✓ These should be suitable for use in primary care settings and for use by community health workers for better screening and diagnosis of NCDs

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2.Follow-up of patients

- Due to their chronicity, NCDs require long-term follow up to verify their evolution, the effectiveness of treatments or their toxicity

3. Surveillance

- **The laboratory can provide data to:**

✓ Establish baseline rate of NCDs and detect increases
✓ Estimate magnitude of a health problem
✓ Determine geographic distribution
✓ Understand the natural history
✓ Generate hypotheses, stimulate research

Obstacles to NCDs Detection and Surveillance

- **Low priority NCDs or lack of political will to address this health problem**

- **Lack of infrastructure**

✓ Limited functional laboratories

✓ Limited availability of needed technology countrywide, allowing early detection

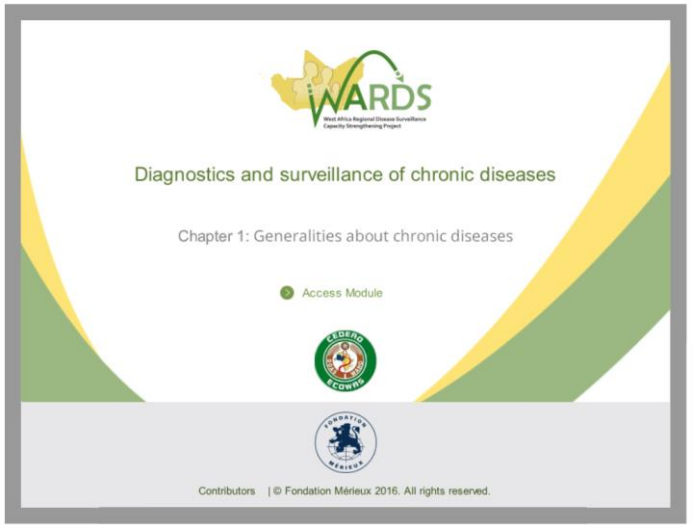
✓ Limited or no data collection mechanism

✓ Limited data transmission capability

Obstacles to NCDs Detection and Surveillance

- **Lack of workforce training capacity**

Fondation Mérieux has developed a module on chronic diseases



Need to develop functional laboratory Networks

- ✓ An integrated, connected, multilevel laboratory systems, with adequate human resources, training, laboratory infrastructure, and regulatory and quality assurance systems will provide efficient service delivery across various levels of the public health system to tackle the NCDs

- ✓ The World Health Organization Model List of Essential In Vitro Diagnostics First edition (2018) could be adopt and adapt by countries to develop their own national EDLs including IVDs for Early and accurate diagnosis of NCDs

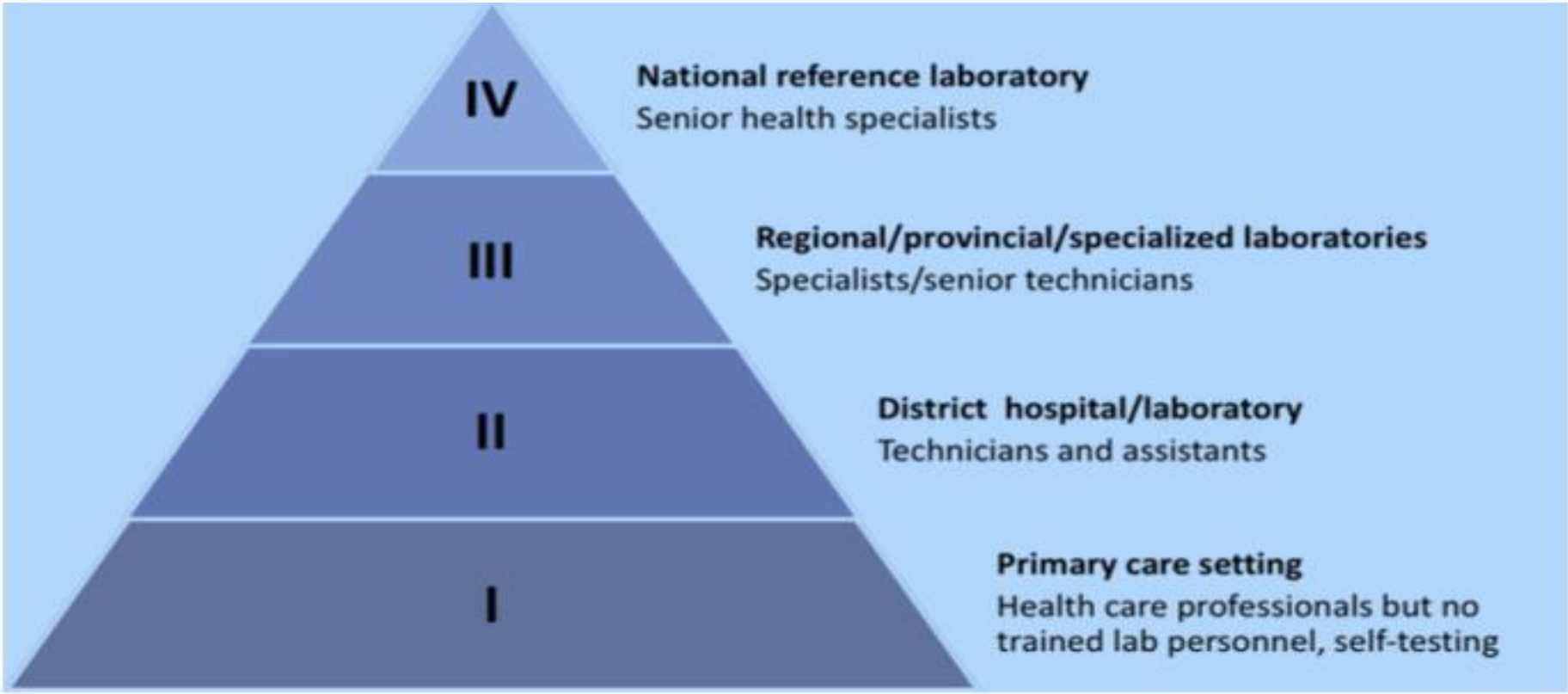
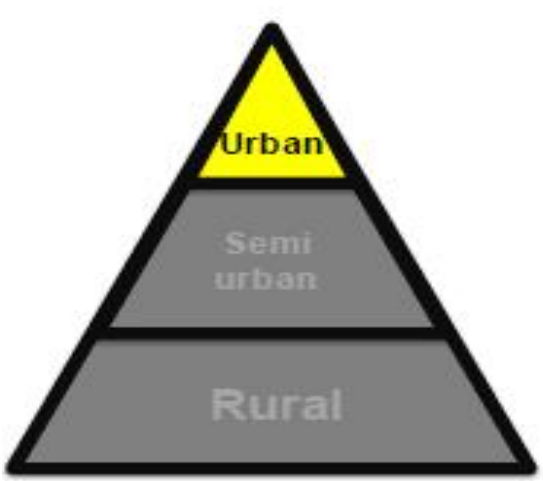
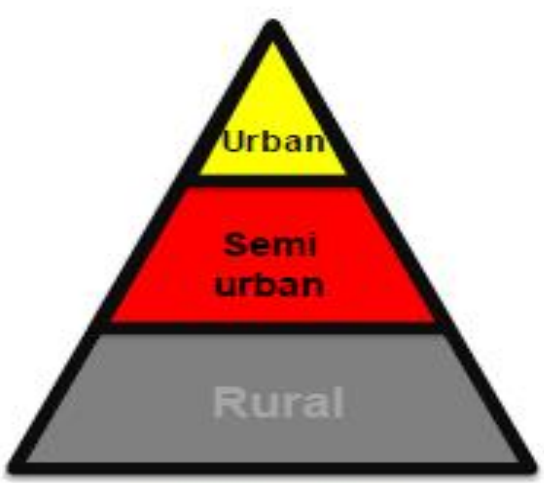


Figure 1. The types of testing that are appropriate at each level will be country-specific and will include, among others, factors such as access to electricity, reagent, grade water, phlebotomy, specialized human resources and the epidemiologic profile of NCDs

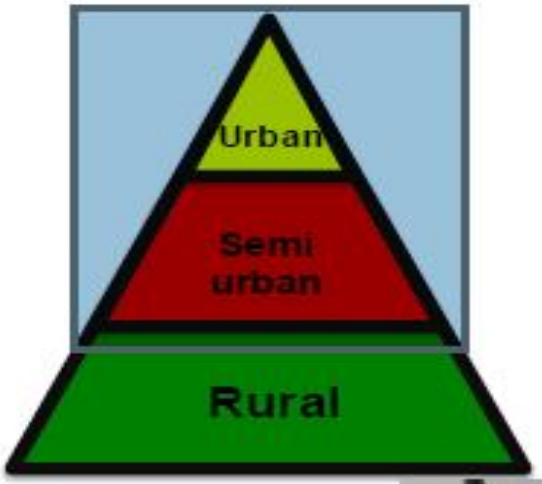
Profile of desirable technologies at each level



Accurate ✓✓✓
Cheap ×
Fast/simple ×



Accurate ✓✓
Cheap ✓
Fast/simple ✓



Accurate ✓
Cheap ✓✓
Fast/simple ✓✓

Profile of desirable laboratory tests for the management of NCDs

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Diabetes

Tests	Diagnosis	Follow up	Etiology	POCT
Glycemia	+++	+	0	Yes
Glycosuria	0	+	0	Yes
Glucose Tolerance Test	+	0	0	No
Insulin	0	0	+	No
Peptide C	0	0	+	No
Glycated Hemoglobin	++	+++	0	Yes
Fructosamin	0	++	0	No
Ketonuria	0	++	0	Yes
Lipids (TC, HDL, LDL, TG)	0	++	0	No
Microalbuminuria	0	+++	0	+/-
Immunity biomarkers	0	0	+	No

Cardiovascular disease

CVD	Tests	POCT
Hypertension	Lipids (TC, HDL, LDL, TG) Proteinuria CRPus, Homocystein	No Yes Yes
Myocardial infarction	Troponin Myoglobin CKmb	Yes Yes
Heart Failure	BNP, NT-ProBNP	Yes
Stroke	BNP, D Dimers, MMP9, NSE, S100B	Yes

Cancer

Biomarkers	Cancer	Diagnosis	Prognosis	Follow up
CEA	Colorectal	0	+	++
AFP	Liver	+	++	+++
PSA	Prostate	+/-	+	+++
CA15-3	Breast	0	+	++
CA 125	Ovarian	0	+	++
CA 19-9	Pancreatic	0	+++	

The limit of cancer biomarkers is that they are not specific in the diagnosis hence the need for histopathology

Challenges

- Diagnosing NCDs in remote and/or poor settings is difficult without access to :

✓ costly imaging modalities [e.g., computed tomography]

✓ well-equipped clinical laboratories (e.g., for histopathology)

✓ trained medical personnel

- The lack of predictive, validated biomarkers significantly limits the types of NCDs that can be detected at the POC

- To date, the majority of Lateral Flow Assays (LFAs) and other POC devices have been developed for infectious disease pathogens, such as HIV and malaria

Some promising approaches

- One promising approach is to detect disease biomarkers from readily accessible bodily fluids with point-of-care (POC) devices that are inexpensive, noninvasive, and do not require trained medical personnel

- Despite widespread interest, the lack of predictive, validated biomarkers significantly limits the types of NCDs that can be detected at the POC

Some Promising approaches

- Authors designed nanoscale agents that are administered to reveal the presence of diseased tissues by producing a biomarker in the urine that can be detected using paper strips similar to a home pregnancy test
- This platform does not require expensive instruments, invasive procedures, or trained medical personnel, and may allow low-cost diagnosis of diseases such as stroke, heart disease, and cancer at the point of care in resource-limited settings:
- e.g: A multiplexed LFAs is designed to detect NCDs from the urine similar to urine test strips

Innovative POC diagnostic of NCDs

Point-of-care diagnostics for noncommunicable diseases using synthetic urinary biomarkers and paper microfluidics
Andrew D. Warren, Gabriel A. Kwong, [...], and Sangeeta N. Bhatia

Nanoparticles That Sense Thrombin Activity As Synthetic Urinary Biomarkers of Thrombosis

Kevin Y. Lin,[†,◆] Gabriel A. Kwong,[‡,§,◆] Andrew D. Warren,[‡,§] David K. Wood,[‡,§,⊥] and Sangeeta N. Bhatia[‡,§,∥,#,▽,⊗,*]

***ACS Nano*. 2013;7(10):9001-9.**

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Role of Urinary Biomarkers in the Diagnosis of Adenoma and Colorectal Cancer: A Systematic Review and Meta-Analysis.

Altobelli E, Angeletti PM, Latella G.

***J Cancer*. 2016;7(14):1984-2004. Published 2016 Oct 8. doi:10.7150/jca.16244**

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Thank you for your attention

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