Pathology – the missing link in global health care delivery

Quentin Eichbaum

MD, PhD, MPH, MFA, MMHC, JD, BSc(Med)(Hons), BA(Hons), FCAP, FASCP

Professor or Pathology, Microbiology and Immunology

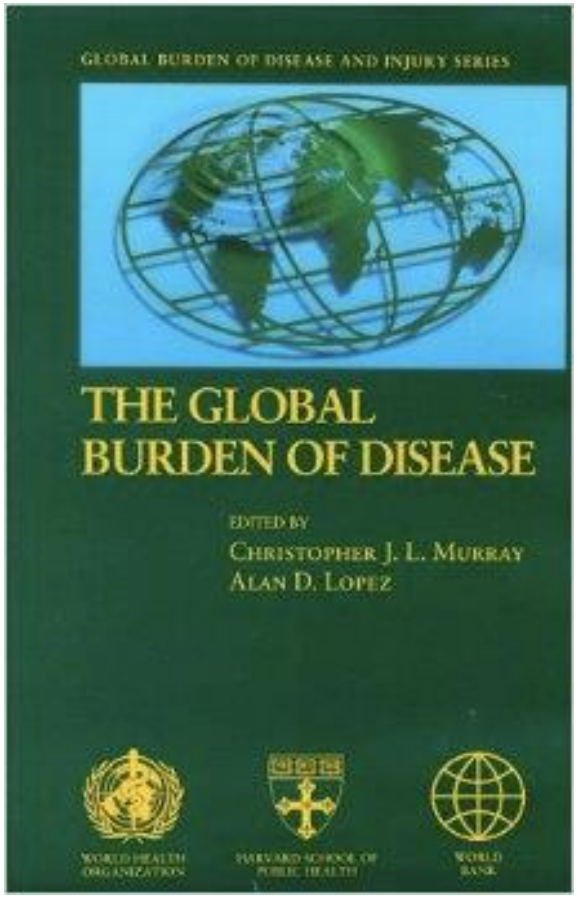
Professor of Medical Education and Administration

Director, Transfusion Medicine (TVHS VA) ((VUMC)

Director, Transfusion Medicine Fellowship Program

Director, Vanderbilt Pathology Program in Global Health

Consortium of Universities for Global Health



"It is difficult to deliver effective and high quality care to patients without knowing their diagnosis.

Chris Murray & Lopez, Global Burden of Disease.

Pathology Practice in LMICs –

a wide range of labs & health centers

Diagnostics/Pathology - vital link in Health Delivery System

GENERALLY APPRECIATED

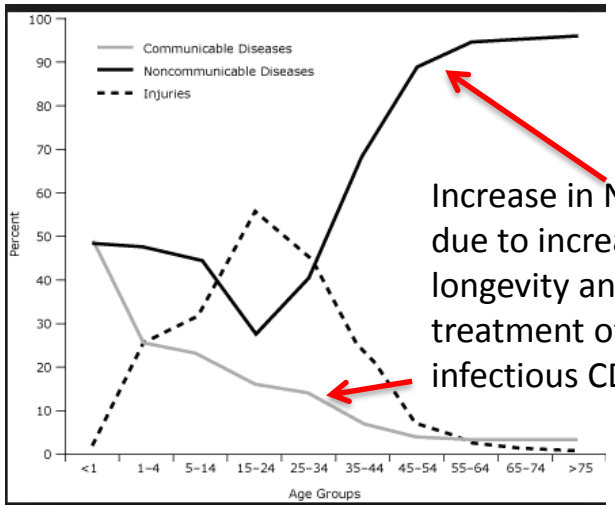
1. **Diagnosis – right dx, for right patient, at right time**

LESS APPRECIATED

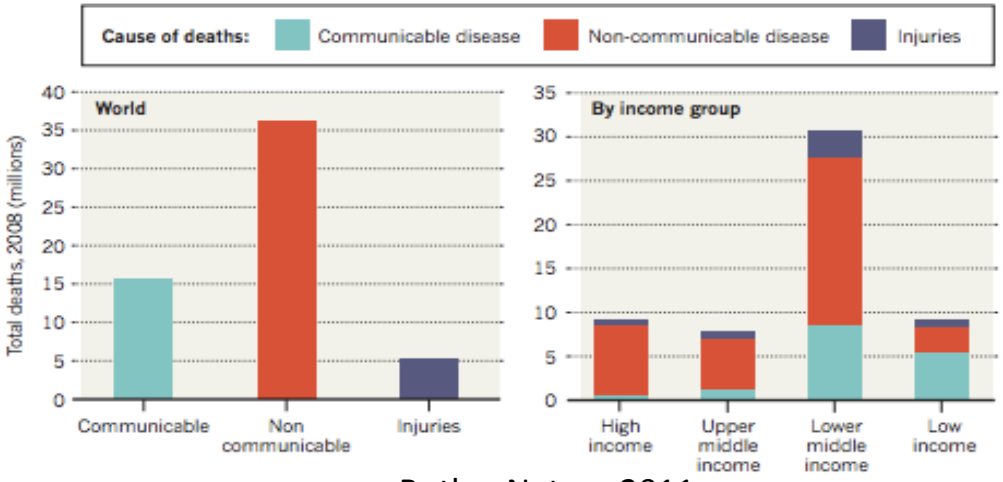
1. **Disease staging & prognosis -** ongoing assessment to support clinical care
2. **Monitoring clinical response to treatment**
3. **Disease surveillance** eg disease registries
4. **Laboratory quality assurance within health care system**

LMICs – Diagnostics needed not only for infectious/CDs but increasingly Non-Communicable Diseases (NCD)

-

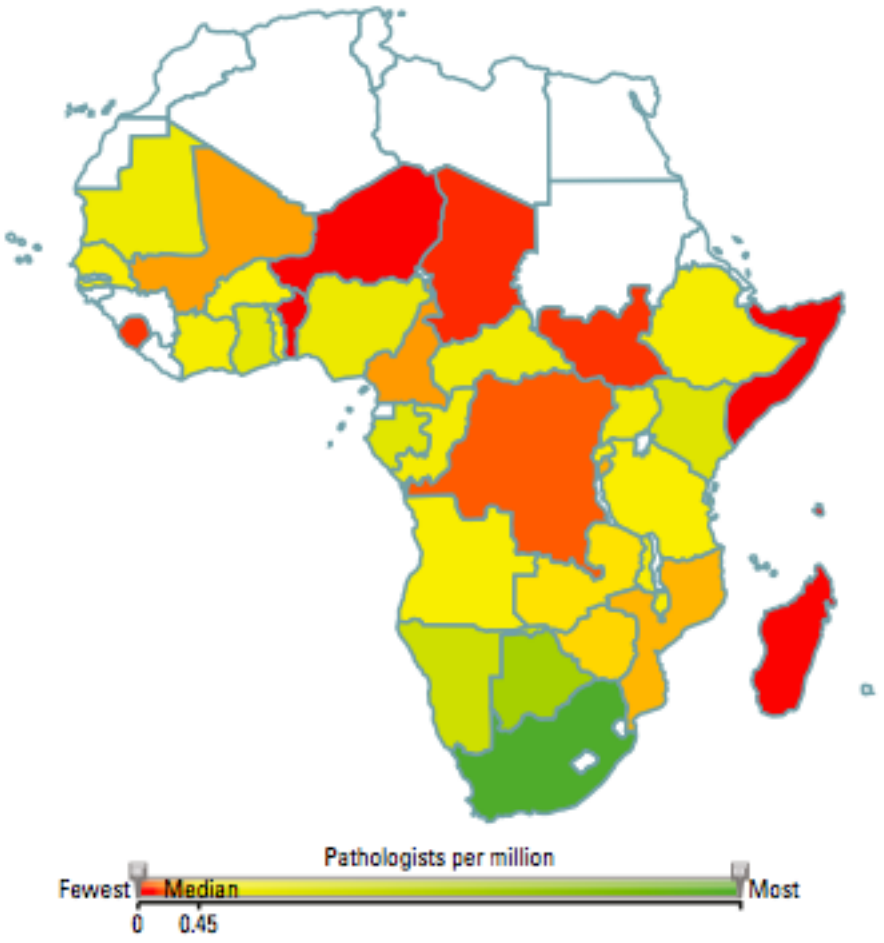


Increase in NCDs due to increased longevity and treatment of infectious CDs.



Butler, Nature 2011

Diagnostics Capacity in Africa -
number of pathologists, technologists



Country	Population (No.)	No. of Persons per Pathologist	Pathologists	Histopathology Technicians	Cytopathology Technicians
Angola	24,906,000	2,076,000	12	23	7
Benin	10,567,000	NA	0	4	0
Botswana	2,156,000	359,333	6	3	8
Burkina Faso	18,184,000	2,273,000	8	4	0
Burundi	9,684,000	3,228,000	3	3*	0
Cameroon	21,636,000	3,606,000	6	2	3
Central African Republic	5,462,000	1,365,500	4	3	0
Chad	13,439,000	6,719,500	2	2	0
Cote d'Ivoire	24,926,000	1,661,733	15	8	1
Democratic Republic of Congo	74,081,000	4,938,733	15	21	4
Ethiopia	89,060,000	1,619,273	55	19	†
Gabon	2,337,000	779,000	3	8	0
Ghana	27,379,000	912,633	30	6+	4
Kenya	43,558,000	725,967	60	10+	4
Madagascar	22,747,000	NA			
Malawi	16,056,000	1,784,000	9	1	1
Mali	17,512,000	3,502,400	5	3	0
Mauritania	3,716,000	1,238,667	3	4	1
Mauritius	1,262,000	84,133	15	4	3
Mozambique	25,392,000	3,174,000	8	17‡	6
Namibia	2,217,000	554,250	4	5	3
Niger	18,529,000	9,264,500	2	2	
Nigeria	182,396,000	1,072,565	170	1,400‡	‡
Republic of Congo	4,638,000	1,546,000	3		
Rwanda	11,180,000	2,236,000	5	10+	2
Senegal	13,950,000	1,992,857	7		
Sierra Leone	6,432,000	6,432,000	1	0	0
South Africa	54,425,000	224,897	242	69	94
South Sudan	12,165,000	6,082,500	2	0	0
Tanzania	48,126,000	2,187,545	22	20	20
Togo	6,967,000	2,322,333	3	2	0
Uganda	35,225,000	1,467,708	24	13	5
Zambia	15,254,000	2,542,333	6	4+	2
Zimbabwe	13,426,000	2,685,200	5	1	0

Nelson et al. J Clin Onc 2016

Uniqueness of Pathology as a medical specialty?

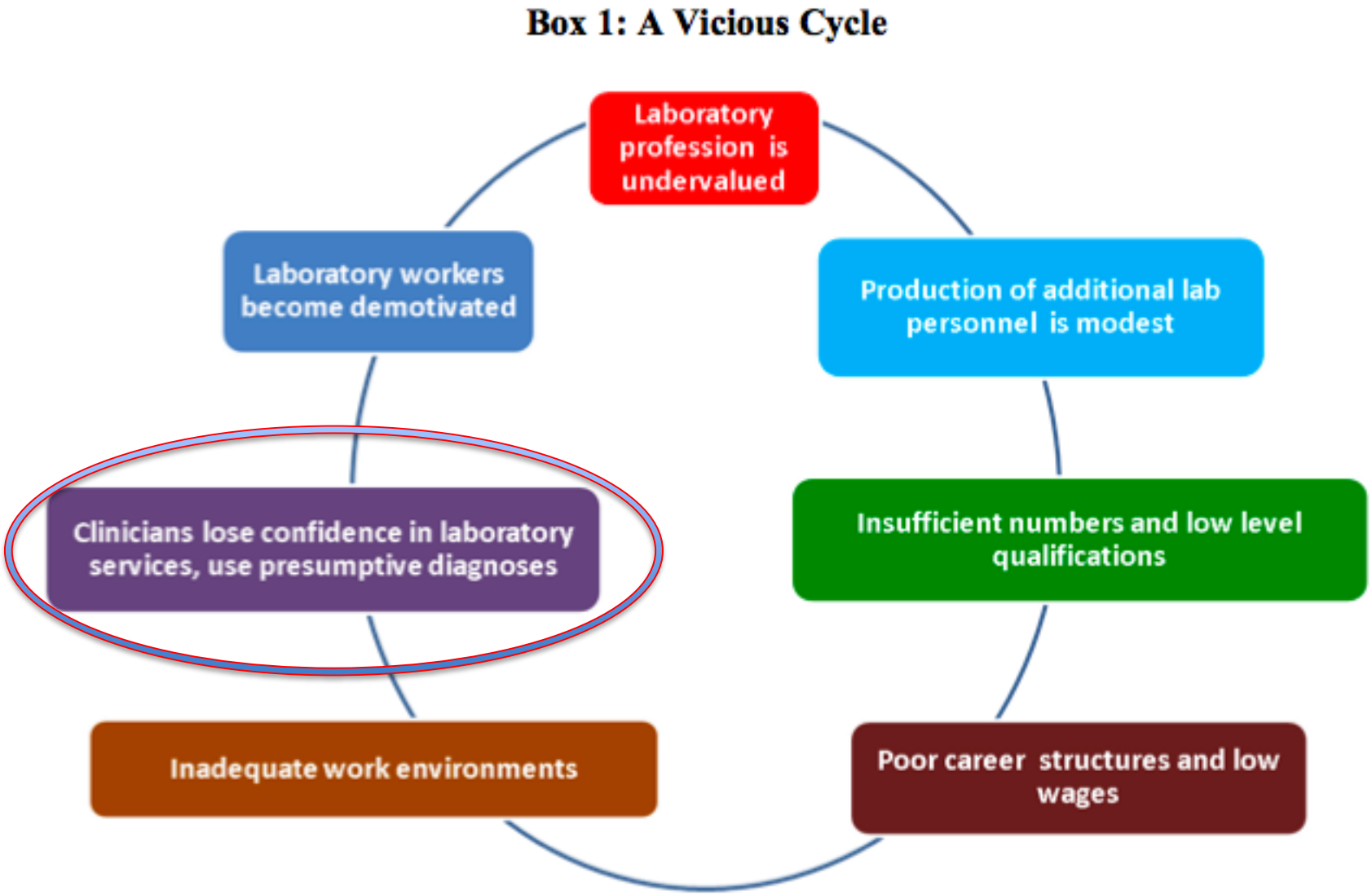
Built on another underlying discipline –

THE CLINICAL/ANATOMIC LABORATORIES

Interdependence of laboratory and clinical services

".. clinicians can lose confidence in laboratory services, and ***resort to presumptive diagnoses*** *rather than laboratory information. In return, laboratory staff can become demotivated by the lack of faith in their profession."*

World Bank Group 2014: Laboratory professionals in Africa: the backbone of quality diagnostics



World Bank Group 2014: Laboratory Professionals in Africa: backbone of quality diagnostics

Effect of Inadequate Pathology Diagnostic Services in Low Resource Settings

Mis/under-diagnosis leads to inadequate treatment referral

↓

Inadequate referral > inadequate follow-up

↓

Treatment delays
Poorer clinical outcomes
Suboptimal/wasteful use of limited resources in LRS.

↓

Inadequate reporting of disease rates, incidence, prevalence, mortality
Limits ability to plan for medical care needs in LRS

World Health Organization
REGIONAL OFFICE FOR Africa

The Maputo Declaration
2008

The Maputo Declaration on Strengthening of Laboratory Systems

Call on national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan. Governments should establish a department of laboratory systems within the Ministry of Health.

Call on national governments with support of their donors and partners in resource-limited settings to develop national strategic laboratory plans that integrate laboratory support for the major diseases of public health importance including HIV, tuberculosis, and malaria.

Call on donors and implementing partners to ensure that in supporting laboratory strengthening that proper consideration is given to fostering national ownership.

Call on countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing.

Call on donors and development partners to **commit** to work collaboratively with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated national laboratory network. These laboratory strengthening efforts should seek to build public private partnerships.

Call on academic institutions and research funders to accelerate efforts to develop new diagnostic tools applicable to resourced-limited settings

Become a Member | AILM | Lab Culture | ASLM2016 | Job Opportunities

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Advancing the Laboratory Profession and Networks in Africa

Who We Are | What We Do | Resource Centre | Stay Informed | Get Involved | Sponsors

SLIPTA and SLMTA

Home / What We Do /

Figure 1: Stakeholder governance structure

What is SLMTA?

Strengthening Laboratory Management Toward Accreditation

What is SLIPTA?

Stepwise Laboratory Quality Improvement Process Towards Accreditation

SLMTA	SLIPTA
A toolkit for training and mentoring	A framework for auditing and monitoring
Prepares and supports laboratory quality improvement	Checks and monitors the improvement process using the SLIPTA checklist
Develops work plans and executes improvement projects	Identifies gaps, non-conformities and provides recommendations for corrective actions
Implemented by laboratory personnel (laboratory managers)	Audits performed by ASLM-certified SLIPTA auditors
Graduates on SLMTA and prepares for inspection	Determines star level and provides Certificate of Recognition (1-5 star levels)

Improving efficiency and effectiveness of Diagnostic Testing in LMICs?

1. Essential Diagnostics Lists (HICs > LMICs?)

2. Tiered laboratory testing

1

Time for a Model List of Essential Diagnostics

Lee F. Schroeder, M.D., Ph.D., Jeannette Guarner, M.D., Ali Elbireer, Ph.D., M.B.A., Philip E. Castle, Ph.D., M.P.H., and Timothy K. Amukele, M.D., Ph.D.

N ENGL J MED 374;26 NEJM.ORG JUNE 30, 2016

Essential Medicines List (EML) of 300 medicines matched with lab tests essential for at least one of them – 147 tests sorted into 57 categories

(1) diagnosing conditions for which medicine indicated

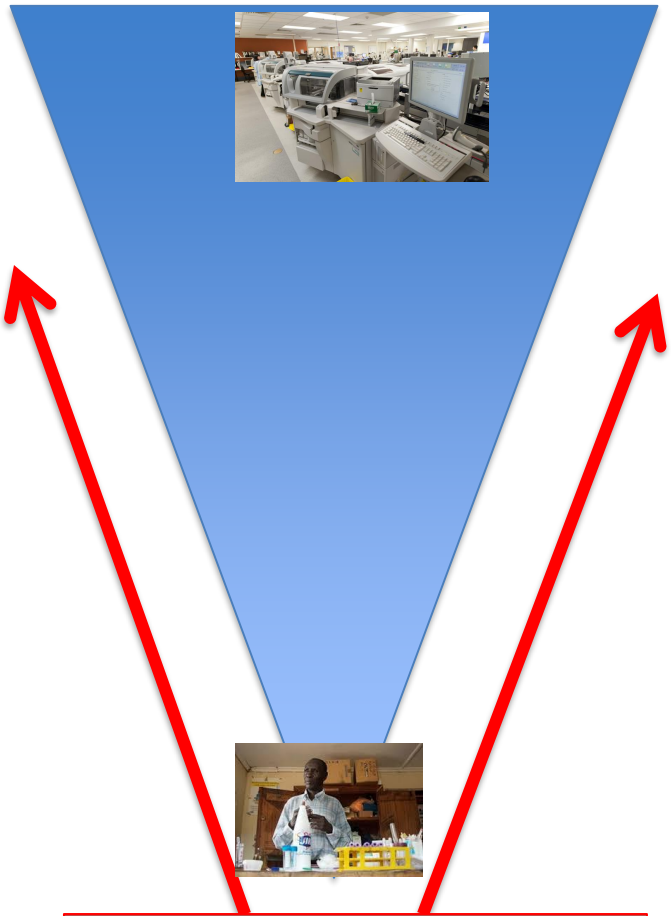
(2) monitoring medication efficacy

(3) monitoring medication toxicity.

Selected Laboratory Tests That Are Required for Use of Medicines on the WHO Model List of Essential Medicines (EML).

Test	No. of Medicines on EML	EML Categories
Complete blood count	136	Affecting blood; anesthetics; antidotes; antiepileptics; antihepatitis; antiinfectives; antimigraine; antiparkinsonism; blood products; cardiovascular; dermatologic; diuretics; gastrointestinal; hormones; immunologics; ophthalmic; oxytocics; palliative; psychiatric; rheumatologic
Liver enzymes	104	Anesthetics; antidotes; antiepileptics; antihepatitis; antiinfectives; antimigraine; antiparkinsonism; cardiovascular; diuretics; gastrointestinal; hormones; oxytocics; palliative; psychiatric; rheumatologic; vitamins
Renal function	92	Anesthetics; antiallergics; antidotes; antiepileptics; antihepatitis; antiinfectives; antimigraine; antiparkinsonism; blood products; cardiovascular; diagnostic agents; diuretics; ear, nose, and throat; gastrointestinal; hormones; immunologics; palliative; psychiatric; respiratory; rheumatologic
Microscopy	85	Antiinfectives; blood products; dermatologic; hormones
Urinalysis	64	Anesthetics; antidotes; antiepileptics; antihepatitis; antiinfectives; blood products; cardiovascular; electrolyte solutions; gastrointestinal; hormones; immunologics; oxytocics; psychiatric
Nucleic acid testing, microbiology	62	Antihepatitis; antiinfectives; hormones; immunologics; ophthalmic
Electrolytes	56	Anesthetics; antiallergics; antidotes; antiinfectives; cardiovascular; diuretics; electrolyte solutions; ear, nose, and throat; gastrointestinal; hormones; ophthalmic; palliative; psychiatric; respiratory
Microbiologic culture (includes drug sensitivities)	51	Antiinfectives; dermatologic; immunologics; ophthalmic
Glucose	42	Affecting blood; antiallergics; antidotes; antiinfectives; cardiovascular; electrolyte solutions; gastrointestinal; hormones; immunologics; neonatal; palliative; psychiatric
Antigen testing (microbiology)	42	Antihepatitis; antiinfectives; gastrointestinal; immunologics
Serology (microbiology)	41	Antihepatitis; antiinfectives; hormones; muscle relaxants; ophthalmic
Human chorionic gonadotropin	30	Affecting blood; antidotes; antihepatitis; antiinfectives; hormones; immunologics; psychiatric
Biochemical bacterial typing	27	Antiinfectives; immunologics; ophthalmic
Lipid panel	24	Antiinfectives; cardiovascular; hormones; psychiatric
Lymphocyte CD4	21	Antiinfectives; immunologics
Blood-gas testing	18	Affecting blood; anesthetics; antidotes; antiinfectives; electrolyte solutions; hormones; muscle relaxants; neonatal
Coagulation function	14	Affecting blood; antiepileptics; antiinfectives; blood products; hormones; immunologics; psychiatric
Glycated hemoglobin	11	Antiinfectives; cardiovascular; hormones; immunologics; neonatal; psychiatric
Calcium	10	Antiallergics; antidotes; cardiovascular; diuretics; ear, nose, and throat; gastrointestinal; palliative; respiratory; vitamins

2. Tiered Approach to Pathology Testing



Tier 4

National teaching hospital. Referrals from Tier 1, 2 and 3; own patients. All routine and specialized tests. Urban, regional. Education/training for network

Tier 3

Regional/provincial hospitals - receive Tier 1 & 2 referrals, own pts; all routine tests in major pathology disciplines

Tier 2

District hospitals - receive specimens from Tier 1; plus own patients.

Tier 1

Rural/Primary care/health centers serving outpatients in a community

Pathology Tiers 1 & 2 – Proposed Tests

(Adapted from Fleming et al, WHO, Cheesebrough, Kost, others)

Tier 1	Tier 2 (includes Tier 1 capabilities)
1.POCT and single user tests -malaria, TB, HIV urinalysis, pregnancy tests, blood glucose 2. Slide microscopy (eg malaria, wet preps, stool parasites); 3. Preparation of FNAC and tissue specimens to send to Tier 2	**Routine and prognostic tests:** Clinical biochemistry - Electrolytes ; Hgb A1c, LFTs, renal, bone (T3?), lipid profiles, Hematology – CBC, CD4, whole blood transfusion/blood type, coagulation, thalassemia Microbiology – Cultures – blood (T1?), urine, cerebrospinal fluid, sputum Basic microbial antibiotic resistance testing; Serology testing for hepatitis A/B/C , common infections Anatomic Pathology – FNAC, tissue biopsies, surgical excisions – processing of H&E stain and interpretation; hospital autopsy

Tiered Pathology Test Approach –

Integrated network of labs working across tiers with clinicians

1. Testing appropriate to geographic and healthcare **CONTEXTS**
2. **LESS COSTLY** than attempting full menu testing everywhere
3. **EASIER TO MAINTAIN** fewer quality standards, less equipment
4. More **EFFECTIVE HEALTH DELIVERY**

Is Point of Care Testing (POCT) the Solution –

easy to perform, interpret, communicate?

"…unplanned and uncoordinated growth of point of care testing, to the detriment of controlling health and improving outcomes."

P.O.C.T – Effectiveness Criteria-

1. Test must provide results for a specific clinical problem to guide clinical decisions in a time frame for monitoring disease status or response to therapy, or to collect data for disease surveillance

2. Establish performance criteria prior to development of test

3. Test platforms must be affordable, usable and stable in locations of intended use

1. Meet procurement requirements for supply chain, maintenance, availability of quality control standards, durability, climate stability

Box 11: A Virtuous Cycle

World Bank Group 2014: Laboratory Professionals in Africa: backbone of quality diagnostics

Take Home Messages

1. **Inaccurate diagnostics = waste and higher costs downstream**
   - Low resource settings cannot afford such waste

2. Pathology is an **integral part of health system that links the right diagnosis, right person, right time with effective treatment outcomes**

1. **Sustainability of diagnostic services** depends on (1) Effective laboratory systems (2)education, training and accreditation systems; (2) quality standards; (3) buy-in of MOHs; (4) lab information systems; (5) reimbursement

THANK YOU

quentin.eichbaum@vanderbilt.edu

TEL: 615-936-5124