Pathology – the missing link in global health care delivery

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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).

Butler, Nature 2011

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

Butler, Nature 2011
Diagnostics Capacity in Africa - number of pathologists, technologists

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
Box 1: A Vicious Cycle

- Laboratory profession is undervalued
- Production of additional lab personnel is modest
- Insufficient numbers and low level qualifications
- Poor career structures and low wages
- Inadequate work environments
- Laboratory workers become demotivated
- Clinicians lose confidence in laboratory services, use presumptive diagnoses
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
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.
What is SLMTA?

**Strengthening Laboratory Management Toward Accreditation**

What is SLIPTA?

**Stepwise Laboratory Quality Improvement Process Towards Accreditation**

<table>
<thead>
<tr>
<th>SLMTA</th>
<th>SLIPTA</th>
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</thead>
<tbody>
<tr>
<td>A toolkit for training and mentoring</td>
<td>A framework for auditing and monitoring</td>
</tr>
<tr>
<td>Prepares and supports laboratory quality improvement</td>
<td>Checks and monitors the improvement process using the SLIPTA checklist</td>
</tr>
<tr>
<td>Develops work plans and executes improvement projects</td>
<td>Identifies gaps, non-conformities and provides recommendations for corrective actions</td>
</tr>
<tr>
<td>Implemented by laboratory personnel (laboratory managers)</td>
<td>Audits performed by ASLM-certified SLIPTA auditors</td>
</tr>
<tr>
<td>Graduates on SLMTA and prepares for inspection</td>
<td>Determines star level and provides Certificate of Recognition (1-5 star levels)</td>
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</table>
Improving efficiency and effectiveness of Diagnostic Testing in LMICs?

1. Essential Diagnostics Lists (HICs > LMICs?)

2. Tiered laboratory testing
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).

<table>
<thead>
<tr>
<th>Test</th>
<th>No. of Medicines on EML</th>
<th>EML Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete blood count</td>
<td>136</td>
<td>Affecting blood; anesthetics; antidotes; antiepileptics; anti-infectives; anti-inflammatory; antimalaria; antineoplastic; cardiolipid; dermatologic; diuretics; gastrointestinal; hormones; immunologic; ophthalmic; oxicoc; palliative; psychiatric; rheumatologic</td>
</tr>
<tr>
<td>Liver enzymes</td>
<td>104</td>
<td>Anesthetics; antidotes; antiepileptics; anicariates; anti-infectives; antineoplastic; antimalaria; antineoplastic; cardiolipid; dermatologic; diuretics; gastrointestinal; hormones; oxicoc; palliative; psychiatric; rheumatologic</td>
</tr>
<tr>
<td>Renal function</td>
<td>92</td>
<td>Anesthetics; antiallergic; antidotes; antiepileptics; anicariates; anti-infectives; antineoplastic; antimalaria; blood products; cardiolipid; diagnostic agents; diuretics; ear; nose; and throat; gastrointestinal; hormones; immunologic; palliative; psychiatric; respiratory; rheumatologic</td>
</tr>
<tr>
<td>Microscopy</td>
<td>85</td>
<td>Antinfecives; blood products; dermatologic; hormones</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>64</td>
<td>Anesthetics; antidotes; antiepileptics; anicariates; anti-infectives; blood products; cardiolipid; electrolyte solutions; gastrointestinal; hormones; immunologic; oxicoc; psychiatric</td>
</tr>
<tr>
<td>Nucleic acid testing, microbiology</td>
<td>62</td>
<td>Anticariates; anicariates; hormones; immunologic; ophthalmic</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>56</td>
<td>Anesthetics; antiallergic; antidotes; anicariates; anti-infectives; cardiolipid; diuretics; electrolyte solutions; ear; nose; and throat; gastrointestinal; hormones; ophthalmic; palliative; psychiatric; respiratory</td>
</tr>
<tr>
<td>Microbiologic culture (includes drug sensitivities)</td>
<td>51</td>
<td>Anticariates; dermatologic; immunologic; ophthalmic</td>
</tr>
<tr>
<td>Glucose</td>
<td>42</td>
<td>Affecting blood; antiallergic; antidotes; anti-infectives; cardiolipid; electrolyte solutions; gastrointestinal; hormones; immunologic; neonatal; palliative; psychiatric</td>
</tr>
<tr>
<td>Antigen testing (microbiology)</td>
<td>42</td>
<td>Anticariates; gastrointestinal; immunologic</td>
</tr>
<tr>
<td>Serology (microbiology)</td>
<td>41</td>
<td>Anticariates; hormones; muscle relaxants; ophthalmic</td>
</tr>
<tr>
<td>Human chorionic gonadotropin</td>
<td>30</td>
<td>Affecting blood; antidotes; anicariates; anti-infectives; hormones; immunologic; psychiatric</td>
</tr>
<tr>
<td>Biochemical bacterial typing</td>
<td>27</td>
<td>Anticariates; immunologic; ophthalmic</td>
</tr>
<tr>
<td>Lipid panel</td>
<td>24</td>
<td>Anticariates; cardiovascular; hormones; psychiatric</td>
</tr>
<tr>
<td>Lymphocyte CD4</td>
<td>21</td>
<td>Anticariates; immunologic</td>
</tr>
<tr>
<td>Blood-gas testing</td>
<td>18</td>
<td>Affecting blood; anesthetics; antidotes; anti-infectives; electrolyte solutions; hormones; muscle relaxants; neonatal</td>
</tr>
<tr>
<td>Coagulation function</td>
<td>14</td>
<td>Affecting blood; antiepileptics; anti-infectives; blood products; hormones; immunologic; psychiatric</td>
</tr>
<tr>
<td>Glycated hemoglobin</td>
<td>11</td>
<td>Anticariates; cardiovascular; hormones; immunologic; neonatal; psychiatric</td>
</tr>
<tr>
<td>Calcium</td>
<td>10</td>
<td>Anticariates; antidotes; cardiovascular; diuretics; ear; nose; and throat; gastrointestinal; palliative; respiratory; vitamins</td>
</tr>
</tbody>
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2. Tiered Approach to Pathology Testing

Tier 1
- Rural/Primary care/health centers
  - Serving outpatients in a community

Tier 2
- District hospitals
  - Receive specimens from Tier 1; plus own patients.

Tier 3
- Regional/provincial hospitals
  - Receive Tier 1 & 2 referrals, own pts; all routine tests in major pathology disciplines

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

Increasing test complexity - refer to higher tier
# Pathology Tiers 1 & 2 – Proposed Tests

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

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

- Laboratories are mainstreamed in health systems agenda
- Production of lab personnel and in service training are expanded
- Larger pool of qualified laboratory workers who are integral part of health system
- Clear career paths and improved remuneration
- Laboratory workers are more motivated, better recognized, and more performant

Confidence in laboratory services is restored
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

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