Access to Medical Devices: IVDs as an example

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Presentation outline

- Role of Diagnostics
- Current diagnostic tools
- Diagnostic landscape in LMICs
- WHO work on Dx
Diagnostics are essential tools

- Identify causes of disease
- Select appropriate treatments
- Prevent the development of long term complications
- Interrupt transmission of disease
- Outbreak investigations
- Surveillance
Current diagnostic tools in LMICs

- Clinical diagnosis
- Microscopy: bacterial and parasitic infections
- Culture: viral or bacteriological diagnosis
- Antigen or antibody detection:
  - agglutination
  - enzyme immunoassays
  - immunochromatography (lateral flow)
- Nucleic acid amplification technology
Other diagnostics

- Clinical chemistry (e.g. iSTAT, glucometers)
- Whole cell assays
- Next Generation Sequencing (NGS)
Health care facilities in LMICs

Health Centre –
Nothing/RDT

Large HC/District Hospital/Central Hospital –
Smear microscopy/ELISA

Reference Hospital/NRL –
Expensive, complex tests:
Culture, ELISA, PCR
Diagnostics in LMICs: lack of appropriate diagnostics

- Although high-quality diagnostics are available for many infectious diseases, they are usually not accessible to most patients in the developing world (too costly, too complicated, require equipment and trained staff, low temperature,..)

- many areas with no electricity, no refrigeration, no trained medical staff...
## Access to health care

Distance to the nearest health facility for the poorest fifth of the population in selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Distance (km)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>7.5</td>
</tr>
<tr>
<td>Bolivia</td>
<td>11.8</td>
</tr>
<tr>
<td>Chad</td>
<td>22.9</td>
</tr>
<tr>
<td>Haiti</td>
<td>8.0</td>
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<tr>
<td>Madagascar</td>
<td>15.5</td>
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<tr>
<td>Niger</td>
<td>26.9</td>
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<tr>
<td>United Republic of Tanzania</td>
<td>4.7</td>
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<tr>
<td>Uganda</td>
<td>4.7</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>8.6</td>
</tr>
</tbody>
</table>

Source: World development report 2004
Shipping difficulties

- Getting supplies such as diagnostics, disposables and reagents to the end-users is often difficult in the developing world.

- Long delays at customs

- Refrigeration often not available or unreliable.

- Temperatures above 40°C are common in many developing countries.
Low investment

- Little industry interest in developing quality diagnostics for diseases prevalent in the developing world, due to a perceived lack of return for investment
Lack of regulatory control

Tests are sold and used without evidence of effectiveness, discouraging companies with quality products from competing.
WHO activities in diagnostics
The broad picture

- Policies, recommendations, guidelines (about use), evaluation, roll out,..
  - In Control Departments (e.g. TB, malaria, NTD, influenza...) but also in EMP

- Diagnostics Prequalification + regulatory strengthening
  - In HIS/EMP

- Diagnostics Innovation
  - HIS/EMP

- (+ UNITAID for HIV/AIDS, malaria & TB)
WHO activities in diagnostics
Example: WHO

1. define diagnostic needs for diseases of poverty and standards for diagnostics quality

2. facilitate research on test development

3. assess and assure diagnostic performance and quality

4. increase access to and use of appropriate diagnostics in the developing world
Examples
Needs and Standards

- TB: Change in diagnostic policies based on research, systematic reviews and convening expert meetings

- *Nature Reviews. Microbiology* supplements. Series of guides to evaluate diagnostics


Examples

Tools to facilitate the development of Dx

- TB Specimen and strain banks
  - Have been used for TB GeneXpert

- Specimen banks for malaria, dengue and VL

- Development of Target Product Profiles (e.g. for VL, Ebola, Zika, HbA1c, Bacterial vs Viral differentiation)
Examples
Test evaluations

- TB
- malaria
- Dengue
- VL
- Syphilis
- H1N1

Results used for prequalification and procurement
Examples
Increase access and use

- Guides for using the tests
  - VL
  - Syphilis
  - H1N1

- Implementation research
  - TB
  - Malaria

- More recently: Technology transfer and local production
  - HbA1c test for diabetes treatment monitoring