The Impact of Point of Care Technologies: Challenges and Needs

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Outline

• Development and introduction
• Impact
• Challenges and barriers
• Consequences of failed
Development and Introduction of Point of Care Technologies
Process of Bringing POC Tests to Bed Site

1. **Feasibility**
   - Identify Diagnostics Advances and Support Research

2. **Development**
   - Ensure test are optimized for low-resource settings by assessing their performance through field trials

3. **Evaluation**
   - Demonstrate impact of new diagnostic test on patients and disease control programs

4. **Demonstrations**
   - Submit to WHO for approval

5. **Pre-Scale Up**
   - Work with local authorities to upgrade laboratories and strengthen technical capacity

6. **Scale Up**
   - Support the roll-out of WHO-endorsed diagnostics in endemic countries

**Process: Cost about $10-100 Million; 2 – 10 year**
GeneXpert: TB POCT Revolution?

The NEW ENGLAND JOURNAL of MEDICINE

Rapid Molecular Detection of Tuberculosis and Rifampin Resistance

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ABSTRACT

Global control of tuberculosis is hampered by slow, insensitive diagnostic methods, particularly for the detection of drug-resistant forms and in patients with human immunodeficiency virus infection. Early detection is essential to reduce the death rate and interrupt transmission, but the complexity and infrastructure needs of sensitive methods limit their accessibility and effect.

METHODS

We assessed the performance of Xpert MTB/RIF, an automated molecular test for Mycobacterium tuberculosis (MTB) and resistance to rifampin (RIF), with fully integrated sample processing in 1790 patients with suspected drug-sensitive or multidrug-resistant pulmonary tuberculosis. Eligible patients in Peru, Azerbaijan, South Africa, and India provided three sputum specimens each. Two specimens were processed with N-acetyl-L-cysteine and sodium hydroxide before microscopy, solid and liquid culture, and the MTB/RIF test, and one specimen was used for direct testing with microscopy and the MTB/RIF test.
Point-of-Care Viral Load and EID Technologies in the Pipeline*

UNITAID: 2011 HIV/AIDS Diagnostic Technology Landscape; semi-annual update October 2011
CD4 Point of Care Technology Pipeline

- PIMA
- Dakarti
- Zyomyx
- Burnet PoC

Source: Trevor Peter
Impact of POC Tests and Testing
POC CD4 is Effective at Reducing Patient Loss to Follow-Up and Reducing Time to Initiation in Mozambique

A. Patients starting therapy

B. Patient loss to follow-up

Field situations for use of POCT
Different delivery settings of POCT
Many Tests are Performed but Results are Never Delivered to Patients

Sources: National volumes for Mozambique, Malawi and South Africa based on CHAI data
3 Challenges and Barriers to Introduction and Uptake of POC Tests
The Case for Strengthening Laboratory Systems

Laboratory Systems and Services Are Critical in Global Health

Time to End the Neglect?

John N. Nkengasong, PhD,1 Peter Nsabuga, MD, MPH,2 Okey Nwanyanwu, PhD,3 Guy-Michel Gershy-Damet, PhD,4 Giorgio Roscigno, MD,5 Marc Bulterys, MD, MPH,1 Barry Schoub, MD,7 Kevin M. DeCock, MD, MPH,8 and Deborah Birx, MD1

Key Words: National laboratory systems; Laboratory strengthening; Global health; Public health; Infectious diseases

DOI: 10.13779/AJCP/PSN038RMU6

A Shifting Paradigm in Strengthening Laboratory Health Systems for Global Health

Acting Now, Acting Collectively, but Acting Differently

John N. Nkengasong, PhD

DOI: 10.1377/CP-USR310

Neglected Lab Infrastructure
Programs to Combat: HIV/AIDS, Viral, Bacterial, Sexually Transmitted Infections, Vaccine Preventable, NTDS, FLU, Tuberculosis, Malaria

POCT vs Laboratory Systems?

- Quality Management System
- Training & Retention Systems
- Equipment Maintenance Systems & Biosafety
- Supply Chain Management Systems
- Laboratory Information & Data Management Systems
- Sample Referral Systems
- Institutions & Policies

Laboratory Systems

- Serology
- Molecular Testing
- Hematology
- Chemistry
- CD4
- Culture
- Microscopy

Strengthening Laboratory Health Systems
Sustainability
What is Necessary to Implement New Point-of-Care tests: Lessons from HIV Rapid Tests?

- Quality Monitoring
- Appropriate Placement (healthcare level)
- Quality assurance
- Human Resources: Who does the testing?
- Select Quality Assay (performance characteristics)
- Acceptability
- Availability
- Harmonization with Country Standards
- Post-marketing surveillance
  - Assay failure – reporting of problem
  - Lot-to-lot evaluation
- Algorithm
  - All reactive tests need for confirmatory test
Certification requirements – an important policy issue

SITUATION

- RTs are simple, anyone can perform it
- Testing with minimal training
- No certification or training requirements
- No site requirements
- No QA to monitor testing quality

SOLUTIONS

- Should be part of MoH policy
- Developing a check list for sites and personnel
- Use of proper QA/QC measures including proper record keeping
- Ongoing data review
- Ability to trouble shoot and recommend additional testing when needed
- Display of certificates, a must
- Gives confidence to clients
QC and Proficiency Testing

- Very limited or non-existent
- No 4 C/-20 C storage for QC specimens
- Logistical challenges due to large number of testing sites
- Traditional PT program can be expensive (cold chain)
- Difficult to implement

Dried tube specimens: A simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings

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Lessons learned from implementing rapid HIV testing

<table>
<thead>
<tr>
<th>HIV Rapid Testing</th>
<th>Challenges</th>
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</thead>
<tbody>
<tr>
<td>Human Resources</td>
<td>Training, competency, turnover</td>
</tr>
<tr>
<td>HIV Test Kit</td>
<td>Poor quality and inconsistent test kit lots; not evaluated</td>
</tr>
<tr>
<td>Test Algorithm</td>
<td>None in place, not followed</td>
</tr>
<tr>
<td>Patient and Specimen ID</td>
<td>No standards</td>
</tr>
<tr>
<td>Reporting</td>
<td>Poor and inadequate records, logs and reports</td>
</tr>
<tr>
<td>Quality Testing (QA/QC)</td>
<td>Neither done nor monitored</td>
</tr>
<tr>
<td>Supply Chain</td>
<td>Stock outs, expired reagents</td>
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</tbody>
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Parekh et al. AJCP 2010 134:573-584
Consequences of Failed POC Testing
Bioline Recall

- 1st invalid lot observed during random QC
- Subsequently confirmed 15 kit lots with high invalid rates in 14 countries
- Recall of kit lots by SD
- Bioline removed from USAID waiver list
- All kit lots in warehouse quarantined
Kenya recalls 'faulty' South Korean HIV kits

Kenya has recalled one million HIV testing kits because of fears about their accuracy, a health official has said.

The WHO had raised an alert about the kit after finding half the test results could be wrong, said Shahnaz Sharif.

The South Korean company, however, says it volunteered to withdraw the kits and that the problem is that they give "invalid" results, rather than ones which are inaccurate.

Kenya, like most of Africa, is trying to contain the HIV/Aids pandemic.

International aids charity Avert says HIV testing has increased sharply in

Related Stories

Aids deaths 'down 21%'
Govt recalls defective HIV/Aids reagent

BY NEEMA RUGEMALIRA

6th January 2012

 Minister: It does not indicate whether one is HIV positive or negative

Following the recent quality alert by the World Health Organisation (WHO) the government has recalled the invalid HIV/Aids reagent ‘SD Bioline’ to the Medical Stores Department (MSD).

Minister of Health and Social Welfare Dr Haji Mponda said yesterday in Dar es Salaam that MSD will immediately stop its importation and distribution and order new batches.

The story of the defective medical product’s presence in the country was first broken by The Guardian last week.

“We have taken a number of measures in ensuring all the ineffective batches of reagent ‘SD Bioline’ distributed across the country are returned to MSD,” Dr Mponda said.

Explaining, the Minister said that the disqualified reagents do not indicate whether one is HIV positive or negative. He said they also take a long time in establishing the results.

Dr Mponda said the SD Bioline currently used in the country was pre-qualified by WHO and other international organisations including the Centers for Diseases Control & Prevention (CDC), Private Health Laboratories Board and Tanzania Food and Drug Authority (TFDA).

He said apart from ordering MSD to stop importation, they have taken other measures such as giving precautions to regional and district medical officers whose task is to follow up on the presence of the batches in their areas.
De-listed HIV test kits still in use

BY THE GUARDIAN REPORTER

31st December 2011

While the World Health Organisation (WHO) alert on the invalid rapid HIV test kits ‘SD Bioline’ went out last month to all Global Funds recipient nations including Tanzania, the kits are still in use in the country.

Reliable sources told The Guardian that the kits were still in use in the country raising fears that many people might have been affected. The Guardian yesterday inadvertently referred to the kits as ARV drugs.

The test kits SD Bioline HIV-1/2 3.0 which Tanzania has registered as the main testing devices have proved failure worldwide, according to the WHO’s field safety notice issued on November 16th, 2011.

When called to clarify on action taken after the alert on the devices, the Permanent secretary ministry of health and social welfare, Blandina Nyoni said she was attending a meeting and that she would call later, but until we went to press she had not called. Efforts to reach the Chief Medical Doctor, Deo Mtasiwa also proved futile as his phone went unanswered.
Consequences

- Lack of a coherent message
- No coordinated approach
- Huge impact on programs
- Countries left on their own
Need to Strengthen Institutions
Role of the African Society for Laboratory Medicine

ASLM MISSION
To advance professional laboratory medicine practice, science, systems and networks in Africa needed to support preventive medicine, quality care of patients and disease control through partnership with governments and relevant organizations.
The 8 Pillars of ASLM

- Laboratory-Clinic Interface
- Technical Assistance
- Research Capacity and Publication
- Laboratory Policy Development
- Laboratory Network Strategy
- Laboratory Accreditation
- Laboratory Workforce Development
- Advocacy and Communication
Conclusion: Can it be done?

Development of National Policy and Standards

- Government (MOH) leadership and ownership will be critical for success

Guidance Document for Countries

- Site selection
- Implementation plan
- Networking testing facilities
- Harmonizing
- On-site mentoring
- How close to universal access?
- Where does it fit into national algorithm?
Thank You

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