The Diagnostic Evidence Hub: *Its role in Accelerating Uptake of Diagnostic Innovations*

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Special ECHO Session
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Tremendous effort and innovation has gone into Covid-19 testing. We now have rapid tests as well as home-based, self-tests for Covid-19, and have come up with easier and simpler ways of taking testing closer to people’s homes and schools. Mobile testing sites, drive-through testing, and sample collection via community health workers, neighborhood pharmacies, schools and workplaces are all happening. We need to do the same for many other areas in global health and ‘democratize’ access to testing....
Easy access to diagnostics is far from guaranteed.

Global commitments:
  - Universal health coverage (UHC)
  - Health-related Sustainable Development Goals
  - Global Health Security (IHR)

47% of global population lack access to basic diagnostics for many common diseases

Gap greatest in primary care => 19% in LMICs have access to the simplest diagnostic tests (other than for HIV or malaria)
In vitro diagnostic devices (IVD) registration process in Africa

- Highly variable registration process across the regions:
  - Technical documentation (dossier)
  - Samples
- Different regulations for registration, renewals and changes
- Import permit issues

- Different lead-time, validity period and costs
- Informal/inaccessible registration regulation in some countries
- Limited human resources capacity/trained personnel

1. Inability to register all product ranges in each country
2. Inability to launch new products in all African countries at the same time
3. Prevent some countries to access to quality innovative and affordable IVD

Models suggest early diagnosis could have controlled 30–70% of cases, potentially saving thousands of lives and billions of dollars in the cost of response alone.
1. Technology introduction pathway

- Need assessment
- In-country regulatory approval (3 – 6 months)
- Supply to the programme (3 months)
- In-country regulatory approval
  - Process time: ~36 months (40% time on validation)

Source: FIND
Some repeat evaluations have not added value!

Poor recognition & reliance leading to multiple, similar laboratory validation studies

Multiple > 20 Countries have conducted the evaluation of the PIMA point-of-care CD4+ count machines in various settings

Source: FIND
Enabling IVD registration process through harmonised regulation will improve access to new diagnostics

- Unified or convergent regulations/process across regions
- Formal, clear and established process
- Adequate human resources capacity/skilled personnel
- Predictable lead-time – short and timely
- Reasonable costs
Prequalification of IVDs and the Collaborative Registration Procedure

In vitro Diagnostics assessment Team

Dr Susie Braniff

December 2021
The Diagnostic Evidence Hub

Hosted on ASLM’s website at https://aslm.org/diagnostic-hub/

➢ Aims to accelerate in-country registration and adoption of new diagnostic innovations
➢ Knowledge platform for quick access to published studies & field evaluations for diagnostic innovations evaluation studies
➢ Target audience: National regulatory bodies, Policy Makers, Diagnostics experts, Lab. Scientists
➢ Access to consolidated regulatory and performance data for POC assays/new in vitro diagnostic innovations
➢ Pooled data for already performed field evaluations at a one stop point
➢ Helps stakeholders reduce on time searching for new diagnostic innovations’ performance characteristics
➢ Evaluation data presented at the hub are from published works, field based experiences
➢ Only data on for WHO PQ & independent re-known bodies is included

Current products:
- HIV - Already built
- \textit{TB} ▪ In development
- Malaria ▪ In development
- More diseases to be considered in future
▪ ASLM and its Partners do not necessarily endorse any specific manufacturers

▪ Only presents: facts and data from WHO PQ, Independent bodies & published data sources/information
Accessing and navigating the Diagnostic Evidence Hub
Accessing and navigating the Diagnostic Evidence Hub

The Diagnostic Evidence Hub is a knowledge platform that provides national reference laboratories, national regulatory authorities, and diagnostics stakeholders with key information from published studies on the technical performance of new in vitro diagnostic products. It seeks to improve access to publicly available technical data in order to inform decision-making and support in-country registration and adoption of new, impactful, and quality-assured diagnostic products.

Regulatory decision making with regards to the quality, safety and performance of medical devices and in vitro diagnostics highly depends on expertise that is available within laboratories. Good reliance
Accessing and navigating the Diagnostic Evidence Hub

New Diagnostic Products

Click on a category below to explore the available products.

Only products that have been WHO prequalified have been included. Products that receive WHO prequalification in the future will be added to the Hub.

ASLM and partners do not endorse any specific manufacturers. Products are listed alphabetically.

- HIV
- TUBERCULOSIS
- MALARIA

Evaluation and Verification Resources

Listed below are resources that can be used by laboratories for method verification and validation when a new diagnostic is introduced into a national program.
Accessing and navigating the Diagnostic Evidence Hub
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**Xpert HIV-1 Qual** is a qualitative in vitro diagnostic test designed to detect Human Immunodeficiency Virus Type 1 (HIV-1) total nucleic acids using human whole blood (WB) and dried blood spot (DBS) specimens from individuals suspected of HIV-1 infection.

**Manufacturer:** Cepheid AB (Sunnyvale, CA, United States)

**Instrument Compatibility:** GeneXpert Dx, GeneXpert Infinity-48s and GeneXpert Infinity-80

**Dectes:** HIV-1

**Quality Standards:** WHO PQ; CE marked

**WHO PQ Number:** PQ Dx 0259-070-00

**WHO Listing Date:** 13 June 2016

One systematic review has been published (Agutu et al 2019) which includes data from five studies that have assessed the performance of Xpert HIV-1 Qual Assay as compared with current reference standards. The assay performed well across the studies with high sensitivities (range: 93.3-100%) and high specificities (range: 99.5-100%).

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Diagnostic Product Data

View a preview of the data for this product below or click the following button to view the full data summaries.

CLICK TO SEE FULL DATA
Accessing and navigating the Diagnostic Evidence Hub

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Verification, intended for assays used without modification, is conducted as part of good laboratory practice, fulfilling requirements of internal quality standards to confirm with evidence that manufacturer performance claims have been met. Calculations are based on experimental data, often using very minimal numbers of samples between 10 to 20.

Validation, a more complex process, is required for modified or "in-house" tests. Validation is necessary if a standard method has been modified or is used outside its intended scope. Similar to verification, tests are validated according to clinical test purpose and impact of the result on the clinical decision. Technical specifications to be evaluated (e.g., error rate, allowable specificity and sensitivity) are selected accordingly.
Other Useful Resources

WHO LIST OF ESSENTIAL IN VITRO DIAGNOSTIC TESTS TO IMPROVE DIAGNOSIS AND TREATMENT OUTCOMES

A technical committee under the African Medicines Regulatory Harmonisation (AMRH) initiative, AMDF focuses on building effective regulatory networks for IVDs and medical devices.

AFRICA MEDICAL DEVICES FORUM (AMDF)

INTERNATIONAL MEDICAL DEVICES REGULATORY FORUM

Discusses future directions in medical device regulatory harmonisation and works to accelerate international medical device regulatory harmonisation and convergence.

INTERNATIONAL DIAGNOSTICS CENTER

Facilitates the development, evaluation, and implementation of accessible, quality assured IVDs for global health through information sharing and advocacy.

ASLM RESOURCE CENTER

Additional resources posted on ASLM's website resource center.
ASLM is considering expanding the Diagnostics Evidence Hub and is interested in feedback from stakeholders

- What challenges are countries still facing when trying to introduce a new diagnostic product?

- Which aspects of the Diagnostic Evidence Hub are most helpful in addressing these challenges?

- How can the Diagnostics Evidence Hub be expanded to better support stakeholders to rapidly introduce new diagnostics?
  - Including additional types of HIV diagnostics e.g. dual HIV/syphilis RDTs?
  - Including diagnostics for other diseases e.g. TB?
  - Including evidence and tools for implementation and scale up of new diagnostics?
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Thank you...