UNITAID investments to innovate and scale up access to HIV diagnostics

WHO Annual meeting with Diagnostic Manufacturers and Stakeholders

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Working definition of a healthy market: UNITAID/Global Fund

**Innovation/Availability**
- There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers
- New and/or superior evidence-supported, quality-assured, adapted, products are timely introduced in the market and made available in LMICs

**Quality**
- The medicine or technology is available at stringent standard of quality, and there is reliable information on the quality of the product
- This includes also the quality of starting and intermediary materials

**Affordability**
- The medicine or technology is offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers
- Market concentration is adequate

**Demand/adoption**
- Countries, programmes, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products (within their local context)

**Delivery**
- Supply chain systems (including quantification, procurement, storage, and distribution) function effectively to ensure that products reach end users in a reliable and timely way
- Adequate and sustainable supply exists to meet global needs.

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2011 challenges: HIV Dx market

- Pipeline delayed. Lack of investment for last mile innovation
- Unclear regulatory pathways; duplication at country-level. Use off-label
- High upfront investment and cost per result; emerging POC still expensive
- Monitoring: clinical and CD4. Lack of demand for VL.
- Implementation challenges with centralized and high LTFU: underutilized. Procurement complexities. Lack of guidance on POC deployment.
UNITAID’s crosscutting approach in diagnostics

**Development**
- WHO PQ Diagnostics (22.6M) (2009-2016)
- Open Polyvalent Platforms (6.4M) (2013-04/2016)
- WHO PQA
- ERPD with Global Fund
- LSHTM: accelerating in-country availability (4.9M) (07/2013-06/2016)

**Evaluation**
- Landscape Analyses; Consultations; Partner Coordination
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**Approval**
- WHO HIV Department (Dx Adviser) (2015-2016)
- MSF viral load (28M) (2013-2016)

**Market**
- Demand/Adoption
- Affordability
- EGPAF: Early infant diagnosis (63M) (08/2015-07/2019)
- PSI self-testing (23M) (09/2015-08/2017)
Key goals of UNITAID investments in EID and VL

Public health

• To increase the number of HIV+ infants whose HIV status is known to facilitate early ART initiation
• To enable earlier interventions for patients with poor treatment adherence and timelier switching to more effective second-line regimens in cases of failure

Market shaping

• To accelerate availability of quality-assured and adapted products at lowest possible cost
Overview of UNITAID investments in VL/EID

- **Status:** Consideration of a 4-yr extension to 2020
- **Focus:** Optimizing VL and EID networks through strengthening conventional/laboratory systems and introduction of POC EID and VL commodities
- **Commodity envelope:** 50% of grant value

- **Status:** USD 63m, 4 year duration (until mid-2019)
- **Focus:** Optimizing EID networks and introduction of POC EID commodities where gaps are.
- **Commodity envelope:** ~USD 25m

- **Status:** USD 28m, 4 year duration (until end-2016)
- **Focus:** Introduction of viral load and POC VL and EID testing; demonstration project with strong operational research focus
- **Commodity envelope:** limited in size

Catalytic introduction of new technologies; demand creation; evidence generation
Geographical scope of UNITAID investments in VL/EID
# Introducing new tools: Key principles

## National response
- National priorities and plans as a point of departure
- Dialogue with ministries of health and partners, coordination for alignment and transition

## Systems approach
- Optimizing existing systems and national EID networks: **Right product at the right place**
- Laboratory-based system as the backbone (training, QA, data management, etc.)

## Realistic pace
- Product availability – on the market and in country
- Country and site preparation
- Phased approach with initial pilots: understanding how the product works in settings for intended use

## Evidence generation
- Public health goods: implementation tools, publications, lessons learnt
Realistic pace of new technologies introduction

Policy and Guidelines development → Product Selection and Procurement

Product evaluations (sites) → Product evaluations (Labs)

in-country Registrations → Pilot/Operational Research

Monitoring & Evaluation → Phased Scale-up

ROUTINE USE
Malawi example: Introducing POC EID technologies

1. National POC policy development + lessons learnt from POC Cd4 introduction
2. Site mapping; product selection
3. Authorization for use based on in-country clinical performance study supported in Mozambique
4. Ongoing: POC EID pilot
5. Next step: scale up phase
Malawi POC pilot

POC EID Pilot Objective

- To assess the operational characteristics of device to inform an optimal national deployment strategy if decision to scale up is made.

Selection of product: Alere Q

- HIV-1 and HIV-2 detection results in <1 hour
- Suitable for use in laboratory and non-laboratory environments at all levels of health system
- Suitable for use by non-laboratory operators

Placement of 6 devices

Factors influencing POC EID placement include:

- **High burden**: HIV prevalence among women >10% at each site
- **High volume**: High EID volumes maximize patient impact based on 2014 LIMS data
- **Strong buy-in**: Sites expressed interested in implementing POC EID
- **Patient / clinic flow**: Facility-specific patient / clinic flow informed device placement strategies

### Device placement strategies within a facility

- **Testing at various entry points**
- **In-patient testing**
- **Testing from mother-infant-pair (MIP) clinic**
- **Testing all HEIs in peripheral low volume sites**

- Device in a common lab
- Device in pediatrics ward
- Device in MIP clinic
- Device shared between 2 primary HCs or networked with peripheral sites
First 30 days: results and lessons learnt

<table>
<thead>
<tr>
<th>Total POC EID tests</th>
<th>Total HIV positive results</th>
<th>Impact on LTFU/ ART Initiation</th>
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| 193                 | 11                        | • 10 infants initiated onsite on the same day of testing following receipt of HIV-positive result on Alere Q  
|                     | (5.7%)                    | • 1 infant sent to referral facility for ART initiation |

**Advantages of POC EID**
1. Clinicians find POC EID convenient
2. Operators find device user-friendly
3. Mothers are happy to wait for the same-day results

**Opportunities for Improvement**
1. Deployment strategy may need to consider how to handle peaks and valleys in patient volumes – average daily patient volume may not be an appropriate criteria to use at some sites
2. Better SOPs are needed to support operators in interpreting results and error codes to minimize device downtime
3. Higher than expected error code occurrence has increased patient waiting times
4. Clinicians have commented that they would prefer if more than one sample could run at a time to reduce waiting times to manage fluctuating patient volumes
Lessons learnt: Key barriers to VL scale up

Countries have aggressive targets to increase coverage, but access to VL testing is still very low

- Footprint large and instrument capacity often sufficient; funds for commodity/reagent procurement not optimal to meet targets
- Demand creation: both with clinicians and patients; change in practices takes more time than foreseen – not only requesting the test, collecting right samples but acting up on results
- Sample transportation/results return networks weak and unreliable
- Shifts in laboratory and clinical workflow; clinical decisions (adherence support, switch to second line)
- Investment in “surround” activities: training and mentoring, quality assurance, data management, procurement and supply management
UNITAID/PSI HIV Self-testing Africa (STAR-project)

**Increase access to HIVST**
Optimise distribution models for the safe scale-up of HIVST, including effective linkage into care & prevention for both general and key populations

**Increase Informed Demand**
Define the best marketing and demand creation strategies for HIVST

**Reduce Policy and Regulatory Barriers**
Support the full integration of HIVST into national policy & algorithms; establish WHO normative guidance; include HIVST in global HIV planning and projection tools

**Remove structural barriers**
Establish market landscape (including market size) to encourage market entry and competition; support establishment of a harmonised regional regulatory approval framework
UNITAID/PSI HIV Self-testing Africa (STAR-project)

The project will distribute 2.7 million kits over 4 years

**Phase 1**
- 2015-2017
- 742,922 kits

**Phase 2**
- 2017-2019
- 1,920,578 kits
Key research questions

What performance and accuracy can be achieved by self-testers?
Does HIVST increase uptake & frequency of HTS? Is uptake equitable?
Effective linkage to care & VMMC after HIVST?
What are User’s preferences? How can demand for HIVST & linkage be maximised?
How can possible social harm following HIVST be anticipated & reported?
What are delivery costs of adding HIVST?
What is the population-level cost-effectiveness of introducing HIVST?

STAR distribution models

- OPEN ACCESS
  - Pharmacies

- SEMI-RESTRICTED
  - Peer Educators; Community Distribution Agents

- CLINICALLY RESTRICTED
  - HIV testing sites; Private providers

High HIV prevalence locations

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THANK YOU!

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