

Global Diagnostics Working Group

IAS 2015, Vancouver

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Why?

- In the wake a global product alert for a specific product, all agencies conducted parallel discussions and investigations, that might have lead to different actions = uncoordinated and duplicative efforts
- Countries prefer harmonized recommendations



GDWG Members

- Clinton Health Access Initiative (CHAI)
- The Global Fund to fight AIDS, Tuberculosis and Malaria
- Médecins sans Frontières (MSF)
- United Nations Children's Fund (UNICEF)
- UNITAID
- US Agency for International Development (USAID)
- PEPEFAR
- World Health Organization
 - Prequalification Team – Diagnostics and HIV Department



The Global Fund
To Fight AIDS, Tuberculosis and Malaria



USAID
FROM THE AMERICAN PEOPLE



5 Objectives

1. To strengthen communication, collaboration & coordination towards the optimal selection and use of quality-assured products
2. To effectively respond in a timely and coordinated manner to urgent quality-related issues
3. To provide aligned messages to global, regional, and country level users on quality assurance for product selection and testing implementation
4. To provide aligned messages to manufacturers
5. To advocate for diagnostic tests that are appropriate and affordable



Significant milestones

- Establishment of WHO/CDC assessment mechanism
 - ↓ duplication of work between WHO and CDC
 - Increases potential sample size for EID evaluations
 - Allows for adult claim to be evaluated at same time
- Use of GF/UNITAID ERPD for innovative products that are not yet WHO PQed or stringently assessed



Recent meeting outcomes

- Support for maintenance of GDWG website
 - Currently Global Fund hosted
http://www.theglobalfund.org/en/procurement/updates/2014-11-28_Update_on_HIV_Global_Diagnostic_Working_Group/
- Clarity on role vis-à-vis DAI
 - GDWG to support Pillar 6 "strengthen normative and regulatory guidance for diagnostics"
 - Also Pillar 4 (pricing) and Pillar 7 (coordination).



Recent meeting outcomes cont'd

- Global Fund framework agreements for HIV NAT technologies (viral load and EID)
 - 7 suppliers selected (Abbott, Alere, bioMérieux, Cepheid, Hologic, QIAGEN, Roche)
 - Benchmark pricing agreed for period of 3 years
 - Transparency on contract terms and conditions
- Better collaboration on planning and quantification for deployment of NAT technologies
 - Including use of DBS on existing VL platforms



Challenges for paediatric IVDs

- Integrated NAT platforms are available
 - Requires better planning with other programmes, e.g. HIV ART, TB, viral hepatitis, HPV, STI, etc.
- Quality
 - Provision of EQAS and QC when testing takes place at POC or near to POC
 - Other quality assurance measures such as training, maintenance, corrective action, etc.



Challenges for paediatric IVDs

- Tracking targets through harmonized recordkeeping
 - With unique client ID numbers and specimen ID numbers
 - Standardised logbooks or testing registers
 - To better track how many infants are newly tested, how many are retested for confirmation, when they are tested, mortality rates, etc.



Contact

- Joint secretariat: Global Fund/USAID
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