Global Diagnostics Working Group

AMDS Meeting with Stakeholders and Manufacturers, 2016

Anita SANDS, on behalf of the GDWG
Why a GDWG?

• In the wake of a global product alert for a specific product
  – all agencies conducted their own discussions and investigations in parallel that might have lead to different actions
  – uncoordinated and duplicative efforts

• Countries prefer harmonized recommendations on procurement and on product selection
GDWG Members

• CHAI
• The Global Fund
• Gates Foundation
• MSF
• WHO

– Prequalification Team – Diagnostics and HIV Department

• OGAC
• UNICEF
• UNITAID
• USAID
5 objectives

1. To strengthen communication, collaboration & coordination towards the optimal selection and use of quality-assured IVDs

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 QA for product selection and testing implementation

4. To provide aligned messages to manufacturers

5. To advocate for IVDs that are appropriate and affordable
Significant GDWG milestone

• Establishment of WHO/CDC joint mechanism for assessment of quality, safety and performance of IVDs
  – ↓ duplication of work between WHO and CDC
  – Increases potential sample size for evaluation of EID IVDs and other difficult to acquire specimen panels
  – Allows for quality aspect of assessment, in addition to performance assessment
Alignment of recommendations on IVDs

• WHO PQ lists IVDs that meet PQ requirements to be procured by UN agencies, WHO Member States, etc.
• USAID issues recommendations on IVDs to be procured by procurement partners for use in PEPFAR-supported countries

• Goals of alignment
  – to reduce duplication of effort for each organization and for the manufacturers, leverage each other's resources for laboratory performance evaluation, and to create one list of "approved" products
Comparison of scopes – WHO PQ and CDC

• WHO PQ - current scope
  – HIV and HIV-related IVDs
    • RDTs, EIAs, CD4, qualitative/quantitative NAT
  – HCV and HBsAg IVDs
    • RDTs, EIAs, qualitative/quantitative NAT
  – Malaria RDTs
  – Also G6PD and HPV

• CDC - current scope
  – HIV-related IVDs
    • RDTs, CD4, qualitative/quantitative NAT
Publication of findings

• **WHO**
  - PQDx laboratory evaluation reports
  - PQDx public reports
  - List of IVDs eligible for UN procurement, used by Global Fund

• **USG**
  - USAID list of approved HIV rapid test kits
  - CDC note to the field
Process for joint mechanism

• Advisory Panel consists of:
  – WHO PQ
  – USAID
  – CDC

• AP decision making
  – AP decides on scheduling for jointly prioritized products
  – Through regular teleconference every 2 weeks
Process for joint mechanism cont'd

- WHO reviews dossier
  - Feeds results back to AP
- WHO conducts site inspection
  - USG as observer

WHO and/or CDC conducts laboratory evaluation

- CDC for 3rd generation RDTs, CD4, qual/quant NAT
- WHO for 4th generation RDTs, EIAs, CD4, qual/quant NAT
- Two sites are required for prospective CD4 and NAT, if capillary WB
First product for joint mechanism

• AQUIOS CL flow cytometer (Beckman Coulter Life Sciences, USA)
• Dossier assessed and site inspected by WHO
• Laboratory evaluation conducted in 2 sites
  — CDC (Atlanta); and
  — WHO (at ITM, Antwerp)
• Listed by WHO and CDC in Q4 2015
CDC/WHO/NHLS collaboration for EID IVDs

- Evaluation protocol agreed by all partners
- First 2 products eligible for abbreviated PQ
  - WHO does not require submission of product dossier
- PQ site inspections conducted for both products
- Laboratory evaluation is nearly complete at 2 sites
  - CDC (Atlanta);
  - WHO (at NHLS, South Africa)
- Expecting final PQ in Q1 2016
Other GDWG activities

- Expanded use of GF/UNITAID ERPD mechanism for IVDs that are not yet WHO PQed nor stringently assessed
  - Round 3 just completed

- How to support revised WHO guidance on HIV testing services (including impending HIV self-testing) and expanded monitoring of ART in the "test and initiate" era
Other GDWG activities

• Exchange of information on each others activities

• Support for maintenance of GDWG website
  – WHO to take the lead

• Fundraising for secretariat to continue its functions
Contacts

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