

Strengthening Cholera Diagnostics – Molecular Diagnostics

Lee Hampton, MD, MSc and Beth Evans, MSc
May 4, 2023



Potential Gavi Cholera Molecular Diagnostic Test Procurement Funding Support

- **Greater use of cholera Dx tests has potential to improve targeting of oral OCV preventive campaigns**
 - Using data on diagnostic-confirmed cholera instead of suspected cholera may allow more efficient and effective OCV preventive campaigns, especially repeat preventive campaigns
 - Gavi budgeted ca. \$240 million for preventive OCV campaigns in 2021-2025, so small improvements can have major impact
- **Improved efficiency and effectiveness of cholera outbreak responses would also be extremely helpful**
- **Rapid diagnostic tests expected to be mainstay of testing**
- **Molecular tests can potentially help with quality assurance and assessing toxigenicity**

Cholera Molecular Diagnostic Tests Potentially Useful as Part of Larger Testing System

- **Molecular testing of samples of positive and negative RDTs can potentially be used to monitor performance of RDTs, for example:**
 - Cholera rapid diagnostic tests' sensitivity and specificity have been shown to vary in different settings
 - Molecular testing of samples of RDTs can help indicate RDT accuracy in a specific setting
 - Incidence of cholera calculated from RDT results can be adjusted to reflect RDT accuracy in that setting as indicated by molecular results
- **Molecular testing can also indicate cholera toxigenicity**
- **RDT testing expected to be decentralized while molecular testing expected in reference laboratories**

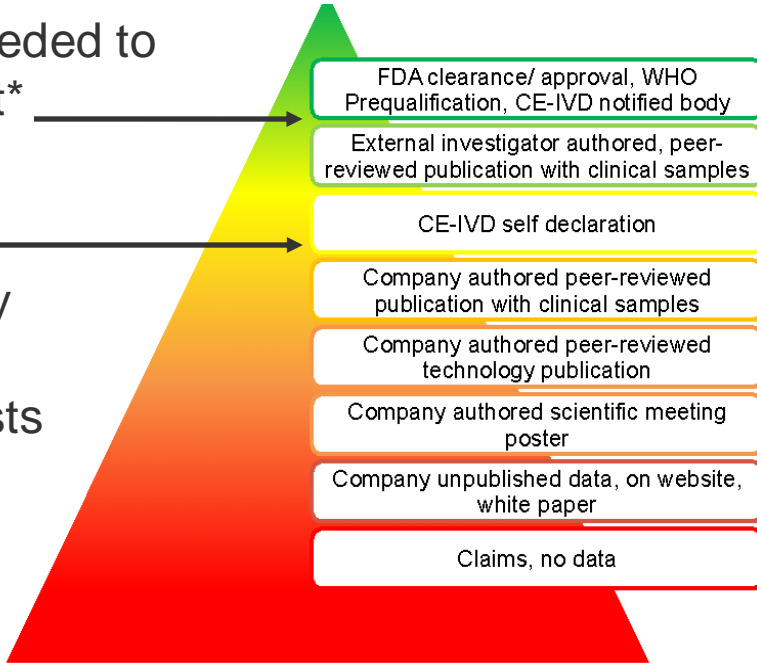
Gavi Can Potentially Fund Procurement of Range of Supplies for Cholera Molecular Testing

- **Once conditions met, Gavi can potentially cover:**
 - Validated commercial cholera molecular diagnostic test kits
 - Cholera molecular diagnostic test consumable supplies, e.g., centrifuge tubes and pipette tips
 - Equipment needed for commercial cholera molecular diagnostic test
- **As with Gavi vaccines, country governments would eventually need to fund procurement of cholera diagnostic test supplies**
 - Expectation that transition of financial responsibility would be gradual, with co-financing starting within a few years of start of Gavi procurement funding support
 - Tests would be accessible at UNICEF prices to all countries

Commercially Available Cholera Molecular Tests Currently Have Limited Scientific Evidence of Accuracy

Level of evidence needed to warrant Gavi support*

Strongest level of evidence for currently available commercial cholera molecular tests



*Interim recommendation for use from WHO expert panel also acceptable for triggering Gavi support

What Needs to Happen to Facilitate Gavi Cholera Diagnostic Procurement Funding Support

- **Development of target product profiles & test evaluation protocol for cholera molecular test kits**
- **Evaluation of cholera molecular test kits and identification of test kits that are worth scaling up**
 - 3 tests on market are CE-IVD
 - 15 test kits on market are RUO
- **Development of clear guidance on how to distribute cholera molecular test kits and supplies across a country**
 - Efficiency, e.g., minimizing costs, critical because financial responsibility for procuring cholera tests will transition to countries
- **Country submission of applications for Gavi support**

Gavi Yellow Fever Diagnostic Procurement Support Indicates This Model Can Work

- **When Gavi yellow fever diagnostic procurement support began in 2018, no validated yellow fever molecular test kits on market**
- **WHO yellow fever laboratory network:**
 - Developed target product profiles and evaluation protocol in 2019
 - Evaluated YF commercial test kits in 2020-2021
 - Identified test kit worth procuring (Altona RealStar Yellow Fever)
- **Validated YF molecular test kits now being shipped to reference laboratories across Africa**
- **Commercial interest has increased:**
 - One company applied to have test kits evaluated in 2020
 - Seven applied in 2023

Questions?

Beth Evans: bevans@gavi.org

Lee Hampton: lhampton@gavi.org

Extra Slides

Steps for addressing laboratory capacity gaps parallel steps for addressing immunization gaps

Lead organization for vaccines

SAGE

Product guidance

Expanded Dx*

WHO (w/ FIND support)

WHO PQ

Product quality assurance

WHO PQ + ERPD. (w/ FIND support)

Gavi secretariat + WHO + UNICEF

Country outreach and applications

Gavi sect. + WHO + GTFCC partners

Gavi secretariat + UNICEF SD

Procurement and market shaping

UNICEF + Gavi secretariat

UNICEF SD + Gavi secretariat

Transportation and distribution*

UNICEF SD

UNICEF + WHO + Expanded partners

Health systems QA and TA

WHO + CDC + GTFCC partners

WHO + UNICEF + Expanded partners

Monitoring and evaluation

WHO + Gavi secretariat + GTFCC partners

Gavi secretariat

Sustainability

Gavi secretariat

Scope of Gavi Diagnostic Capacity Funding

- Gavi can provide funding for:
 - Procurement of diagnostic test kits validated by WHO Prequalification team or interim WHO expert review groups and associated consumable supplies and equipment
 - Independent evaluation of test kits
 - Development of guidance on use and distribution of new tests
 - Quality assurance assessments on use in surveillance systems across multiple countries
- Gavi cannot provide funding for:
 - Diagnostic test research and development
 - Procurement of tests not validated by WHO