

Gavi, the Vaccine Alliance

Supporting Cholera diagnostics

Agenda and objectives for today

1



Gavi & Gavi diagnostics background

For info

2



Cholera RDT pilot studies

For info

3



Gavi Cholera RDT support

Feedback

Areas for feedback throughout are in blue callouts

1

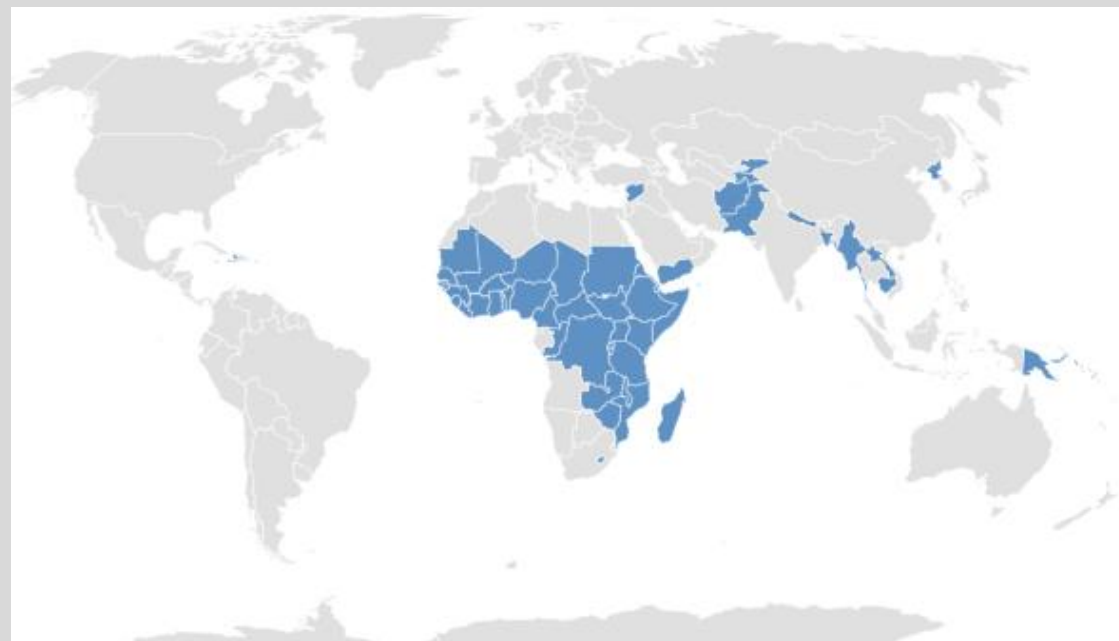
FOR INFORMATION

Gavi & Gavi diagnostics background

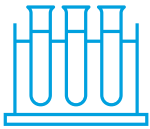
Gavi supports vaccine procurement and health system strengthening

- **Gavi support key childhood vaccines**, e.g., Penta, PCV, Rota, as well as **outbreak prevention or response vaccines**, e.g., Ebola, Cholera. New vaccines such as HPV and malaria are also supported and rolling out.
- Countries pay **co-financing for vaccine procurement**, with the amount determined by their income group. Countries will eventually need to assume financial responsibility, but **diagnostics support currently has no co-financing – confirmed until end-2025**.
- **Gavi fund health systems improvements** through governments, WHO, UNICEF, and other technical partners – this **can include cash support for surveillance** (although this is not linked to diagnostic applications)

- **57 countries are eligible for new vaccine introduction support** – see map. This also applies for diagnostic tests, and includes most countries on the GTFCC Roadmap



Gavi diagnostic support – started with Yellow Fever and expanded to additional disease areas including Cholera



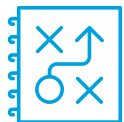
Gavi diagnostics support started with Yellow Fever (YF) in 2018 – 21 countries have successfully applied for and received Gavi YF Dx procurement support, now with WHO validated YF IgM ELISA, IgM RDT, and real-time PCR tests -> % African YF samples tested has risen from 80% to 97-98%



In 2022, building on YF success and potential impact for other vaccine areas, Gavi expanded diagnostics support to cover **cholera, measles, meningococcus, rubella and typhoid**



Gavi diagnostics support aims to (1) **improve diagnostic testing capacity** in country, (2) **use improved epidemiological data to improve vaccine support effectiveness, efficiency, and equity**



Gavi support focuses on (a) **market shaping support** to ensure fit for purpose diagnostics available in market, and (b) providing **funding for procurement of diagnostics** in Gavi-eligible countries



Gavi Board have approved a **US\$ 55 Million envelope** to support diagnostics during 2022-2025 – total across all six disease areas

2

FOR INFORMATION

Cholera RDT pilot studies

CDC, JHU, and Epicentre/MSF are leading pilot studies across DRC, Niger and Nepal to understand RDT testing strategies

Objectives:

- Derive and compare estimates of the true clinical incidence of cholera based on RDTs using different sampling schemes
- Assess effectiveness and feasibility of alternative RDT deployment strategies across a range of incidence settings

Timelines and approach (vary across research group):

Q2 2023

- Identify **sites** within countries
- Finalise study **protocol**
- Prepare and conduct **training** of health workers etc.

Q3 2023

- **RDT deployment and data collection** across sites with varying cholera endemicity
- **Testing different sampling schemes**, aligned with GTFCC guidelines, and supervision across sites to assess implementation feasibility

Q3 2024

Q1 2024 – Q4 2024

- **Analysis** of results, reporting and insights
- Qualitative analysis of **stakeholder views** on RDT usage and strategies

For information: Potential relevance to GTFCC – outputs from studies may be useful for future revisions on surveillance guidelines. Gavi will use outputs to inform revisions to Cholera diagnostics support and guidance.

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FOR FEEDBACK

Gavi Cholera RDT support

We aim to open applications for Gavi Cholera Diagnostics support in June 2023, to support RDT usage & insights

Timelines



- Mid-June 2023: Anticipated start of distribution of applications
- Q4 2023: Applications received by mid-July can be reviewed for decision in September, and by October can be reviewed for decision by end-2023
 - Applications received by mid-July could result in RDTs being shipped to countries by end 2023
- 2024: Revision of materials (and potentially scope of support) alongside revisions to other guidelines, e.g., GTFCC diagnostic testing guidance

Scope of support



Confirmed scope of support:

- Funding for procurement, with no co-financing, of cholera RDTs
- No directly-linked cash or operational support – however, other Gavi cash grants, such as health systems strengthening funding, can be utilised

Requirements



Requirements:

- Calculation of number of RDTs required per year
- Documentation that indicates country readiness and capacity to introduce RDTs with Gavi support

Key areas for input today – on following pages:

- Products for procurement
- Quantification methodology
- Service delivery and logistics questions in application kit

We plan to procure Arkray and Abbott RDTs in the short-term, with preference for WHO PQ'ed product(s) in long-term

- In the absence of a WHO Pre-Qualified (PQ'ed) RDT, based on inclusion in UNICEF supply catalogue and current procurement and usage by WHO, Gavi intends to procure the following products through Gavi support – see table
- Once one (or more) RDT(s) are WHO PQ'ed, this/ they will be the preferred product(s) for procurement

Developer	Details	Regulatory status
Arkray Healthcare	Crystal VC: Rapid Visual Immunochromatographic Test for Detection of V. cholerae O1 and O139 antigen in Stool	CE-IVD ¹
Abbott	Bioline Ag O1 and O139 Antigen Test	CE-IVD ¹

For no objection: please flag if any objections or questions to this proposed RDT approach. In the absence of this we will assume endorsement of the procurement strategy.

¹ CE-IVD= approved CE Marking according to the Requirements of European Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD) or its successor Directive

² This test is not yet in the UNICEF Supply Division catalogue – it would need to be added before Gavi-funded procurement could happen

Our proposed RDT quantification approach builds on GTFCC RDT interim guidelines to produce annual national demand

Regular testing areas



The GTFCC recommending testing **up-to 3 suspected cases per day** at health facilities used for identifying and treating cholera in **surveillance units known to have regular cholera transmission in recent years** (e.g., endemic areas)

Surveillance units¹ known to have regular cholera transmission in recent years²



Number of designated health facilities that identify and/or treat suspected cholera cases



3-tests per day



Number of weeks per year with at least 1 suspected cholera case reported³



Test requirement for monitoring incidence

As-needed testing areas



For everywhere else (i.e., **surveillance units not known to have regular cholera transmission in recent years**) RDTs are recommended for **ad-hoc testing of suspected cholera cases**. Tests may be stored centrally (as a “stockpile”) and deployed as needed. These RDTs are **not** intended for routine daily use.

Number of surveillance units **not** known to have regular cholera transmission in recent years



120-tests per year



Additional tests for identifying imported cases or outbreaks

Supply Buffer



A 20% buffer on-top of total ‘regular testing’ and ‘as-needed’ requirements will be provided for use by the country, e.g., during outbreaks, and to facilitate adequate flow of supplies. No additional inputs or calculations are required for this buffer.

1 Here and throughout, "surveillance unit" typically refers to district, local government area, county, etc.

2 These surveillance units may be identified through following PAMI guidelines, or through a simpler approach of looking at suspected cases over recent year (if PAMI identification and/or NCP development are not yet completed)

3 This may be based on average over recent years. This is also known as ‘persistence’

We have developed a simple Excel tool to quantify and tested the approach

Based on information in country National Cholera Plan's, and other health facility data, we have estimated the following annual demand for countries using our proposed formula:

- **Kenya:** 62,000 RDTs
- **Ethiopia:** 270,000 RDTs
- **Bangladesh:** 210,000 RDTs

If countries have an alternative quantification methodology to estimate demand, this can be used instead

For input: Any feedback on this proposed approach and recommendations of alternative or improved approaches?

Gavi The Vaccine Alliance

Tool for quantifying Cholera rapid diagnostic test requirements

INSTRUCTIONS
Before you start using this tool, download and save the file in your computer.
1. Table 1 – facility-based testing: Complete inputs on surveillance unit names, historic suspected cholera cases (if known), and health facility data in light blue cells.
2. Table 2 – as needed testing: Enter the number of surveillance units nationwide that are not included in regular testing.
3. Output – Copy the output total testing requirement (cell F14) into the application form.

(1) Test requirements for facility-based testing in regular testing surveillance units					(2) Test requirements for as needed testing in other surveillance units			(3) Total testing requirements	
Surveillance unit	Number of suspected cholera cases in latest available year, e.g., 2022	Number of identification/ treatment health facilities	Number of weeks per year with at least one suspected cholera case reported in	Testing requirement (annual)	Number of surveillance units (not including those in part 1)	Test provision per district	Testing requirement (annual)	Facility-based	As needed
Manual entry	Manual entry	Manual entry	Manual entry (0-52)	Calculation	Manual entry	Automated	Calculation	15,921	12,000
District 1	341	2	20	843					
District 2	202	1	45	948					
District 3	707	3	43	2,773					
District 4	324	2	48	2,022					
District 5	1784	4	16	1,348					
District 6	120	1	4	85					
District 7	338	2	8	337					
District 8	564	3	-	-					
District 9	557	1	27	563					
District 10	588	3	36	2,275					
District 11	286	1	25	523					
District 12	384	4	8	674					
District 13	419	1	24	506					
District 14	282	2	47	1,880					
District 15	64	1	47	393					
				-					
				-					
				-					
				-					
				-					
				-					
				-					
				-					
				-					
TOTAL	6,940	31		15,921			12,000		27,921

Click + to expand if more districts needed

↑

↑

↑

Total

Regular testing:

Surveillance-unit level health facility testing requirements based on inputs for –

- Surveillance units
- Number of health facilities
- Number of weeks per year with 1+ cholera case

As-needed testing: Ad-hoc testing requirements based on inputs for –

- Total number of remaining surveillance units

We would value your input to help further refine clear application materials, aligned with relevant guidelines



Supply planning

- To reduce risk of RDT expiry or wastage we encourage push-pull supply chain management at national and sub-national levels
- For input:** Any recommendations on how to ask about, and encourage, this?



Documentation

- To minimise duplication, for some questions, we provide countries with the option of writing a response or providing supporting documentation and referencing the relevant section.
- For input:** What documents, other than National Cholera Plan's, may already have relevant information on RDT strategy, supply planning and surveillance?



Distribution

- To understand if RDT distribution could be integrated into a relevant supply chain from national level to surveillance unit health facilities we wish to ask about medical supply chains and proxy commodity distribution.
- For input:** We currently ask about proxies including ringer lactate. Any additional ideas?



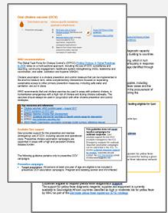
Country interest

- Gavi could provide funding for consultants (or a team member) to support application completion, particularly for countries interested in applying this year, particularly those in July-October
- For input:** Are you aware of any countries that may be particularly interested in applying in the first round? Please reach out if so to bevans@gavi.org and lhampton@gavi.org

We will share the draft package of materials for offline review for those interested

- There are three components to the application materials:

Funding guidelines



3-page summary of purpose and eligibility for cholera Dx support

Application form



- Short, standalone form (~8 pages)
- Country input details on demand, rationale, surveillance etc.

Quantification approach



Simple (optional) methodology for estimating test demand, if country does not have method

For input: Please respond via email with comments or suggestions by Wednesday May 17th 2023

Looking further ahead...

Expansion of Gavi cholera diagnostics support to include PCR testing: In order to expand Gavi support to cover PCR testing in the future, we would need Target Product Profiles (TPPs) and available, validated, products; as well as an understanding of operational approach (i.e., site and quantity of testing in countries). If this is of interest to the GTFCC and countries, we would like to organise a follow-up with relevant partners to discuss next steps to address gaps here.

Complementarity of Gavi support and GTFCC guidance: We plan to continue to ensure Gavi materials complement GTFCC surveillance recommendations, and during the upcoming GTFCC materials revision process will share a few suggestions of how to refine specificity of guidelines related to supply planning, e.g., clarifying level of health facility for RDT testing, including quantification scenarios.

Continued engagement with manufacturers: Based on yellow fever diagnostics initiative experience, Gavi procurement of cholera diagnostic tests may help to increase interest in cholera diagnostic tests among manufacturers, potentially leading over time to development and availability of improved commercial cholera tests

Thank you