Gavi, the Vaccine Alliance

Supporting cholera diagnostics

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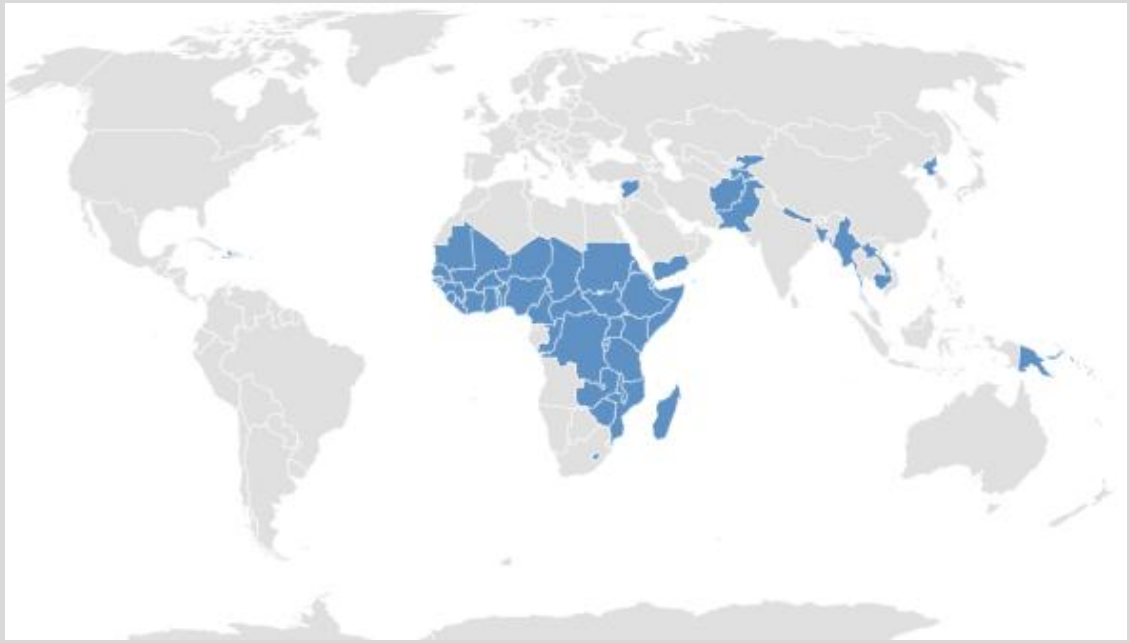
Gavi diagnostics: context

Gavi support 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 malaria and MMCV, are also supported and rolling out.
- Countries pay **co-financing for vaccine procurement**, with the amount determined by their income group. Diagnostics procurement 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)

- **52 countries are eligible for new vaccine introduction** – see map. This also applies to diagnostics, 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 – 22 countries receiving Gavi support for PCR, ELISA, IgM RDTs; lab capacity strengthening of national and regional reference labs

In 2022, building on YF success and potential impact for other vaccine areas, Gavi expanded diagnostics support to cover **cholera, measles, meningitis, 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 bring (innovative) diagnostics to 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 until end 2025 – total across all six disease areas

Gavi Alliance diagnostics work includes several complementary organisations

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Cholera RDT pilot studies

CDC, JHU, and Epicentre are leading pilot studies in DRC, Niger & Nepal to understand RDT deployment & testing strategies

Objectives:

- Assess effectiveness and feasibility of alternative cholera RDT deployment strategies across a range of incidence settings for surveillance-based assessment of disease burden
- Use evidence-based data to inform planning of preventive vaccination campaigns (and other multi-sectoral interventions) required for sustainable cholera control

Q2 2023

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

Q3 2023 Q4 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

Q1- Q2 2024

- **Analysis** of incidence, reporting and insights
- Qualitative analysis of **feasibility and stakeholder views** on RDT use and strategies

Learning from studies may inform future revisions on GTFCC surveillance guidelines. Gavi will use outputs to inform revisions to cholera diagnostics funding guidance for countries.

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Gavi cholera RDT support

Gavi opened applications for Gavi Cholera Diagnostics support to countries in June 2023

Timelines

- Mid-June 2023: Opened for applications
- Q4 2023: Applications received by mid-July reviewed for decision in September, and by October reviewed for decision by end-2023
- 2024: Revision of materials alongside revisions to other guidelines, e.g., GTFCC diagnostic testing guidance; applications received by 18 April for June decision; and received by 23 September for November decision

Scope of support

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

Requirements

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

Key topics on the following slides:

A. Products for procurement
B. Quantification methodology
C. Gavi application materials
D. Overview of UNICEF SD delivery and logistics materials

Gavi is currently procuring Arkray and Abbott RDTs, with preference for WHO PQ'ed product(s) in long-term

- In the absence of a WHO Pre-Qualified (PQ'ed) RDT, based on current procurement and use by WHO and UNICEF, 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]

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

Our current RDT quantification approach is based on GTFCC RDT guidelines to estimate annual national demand & plan supply

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 units[1] known to have regular cholera transmission in recent years[2]

✖

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 reported[3]

=

Test requirement for monitoring incidence

As-needed testing areas

*For everywhere else (i.e., **surveillance units <u>not</u> 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 <u>not</u> intended for routine daily use.*

Number of surveillance units <u>not</u> known to have regular cholera transmission in recent years

✖

120-tests per year

=

Additional tests for identifying imported cases or outbreaks

Supply Buffer

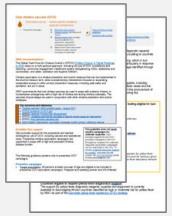
A 20% buffer on-top of total 'regular testing' and 'as-needed' requirements will be provided for use by the country, e.g., during outbreaks, and to facilitate adequate flow of supplies. No additional inputs or calculations are required for this buffer.

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'

Gavi application materials

- **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

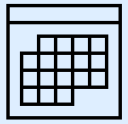
Application review & decision by Gavi's Independent Review Committee

Programmatic considerations

Based on interim findings from on-going cholera RDT pilot projects in three countries, and recommendations from experts and the Global Task Force on Cholera Control (GTFCC), several points for consideration…

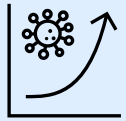
Product selection

- **Context: Two options are available for procurement, both are combined 01/0139 tests**: Arkray Crystal VC (dipstick format) and Abbott Bioline (cassette format).
- **Recommendations:**
  - Due to differences in formats, it is advisable to **select only one and train healthcare workers accordingly** on use and interpretation
  - **It may be programmatically easier to select previously used product(s)** dependent on scale of previous usage, since healthworkers may already be more familiar
- **Resources: Job aids for RDT usage are available** on the GTFCC website here[1].



Phasing of shipments

- **Context:** Given the large increase in allocated RDT volumes versus previous year utilisation, the Independent Review Committee **advised phasing shipments throughout the year** to minimise risk of expiry and allow for scale-up.
- **Recommendation:** We would **recommend planning for at least 2 deliveries** across the year, with **<40% of volumes delivered in the first shipment** to allow for initial rollout
- **Resources:** Please reach out to diagnostics@unicef.org if there is a wish to discuss shipment phasing options or scenarios



Learning period

- It is well understood that we are in a **learning period for scale-up and on-going surveillance use of RDTs** (at both a country and global level).
- We therefore are **keen to hear about challenges and successes during rollout**, to compile as best practice and share across countries
- Please reach out to diagnostics@gavi.org with any feedback, recommendations, or questions

1 Further resources are in advanced development, to be shared shortly.

Process Flow to Distribute Gavi-funded Supplies to Countries

EPI /MoH Surveillance Units/Laboratories

GAVI Secretariat

UNICEF Supply Division

Suppliers and Freight Forwarders

1. Request for Gavi Support
2. Communicates Programme Approval
3. Requests Gavi Procurement Funds
4. Approves Funds Request
5. Places Purchase Orders
6. Ship to Country
7. Issue Invoices
8. Process Payments to Suppliers
9. Settlement of Accounts between GAVI and UNICEF

3. Request deliveries from UNICEF

Process Flow – Documents and Key Information

EPI /MoH Surveillance Units/Laboratories

GAVI Secretariat

UNICEF Supply Division

Suppliers and Freight Forwarders

1 **Request for Gavi Support**

2 **Communicates Programme Approval**

DECISION LETTER

3 **Request deliveries from UNICEF**

4 **Approves Funds Request**

Requests Gavi Procurement Funds

Incoterm: CIP

CONSIGNEE DETAILS

5 **Emission des bons de commandes**

POs

6 **Ship to Country**

NGR

EXPORT DOCS

Draft AWB

7 **Issue Invoices**

ADDITIONAL EXPORT DOCS

8 **Process Payments to Suppliers**

9 **Settlement of Accounts between GAVI and UNICEF**

STATEMENT OF ACCOUNTS (SOA)

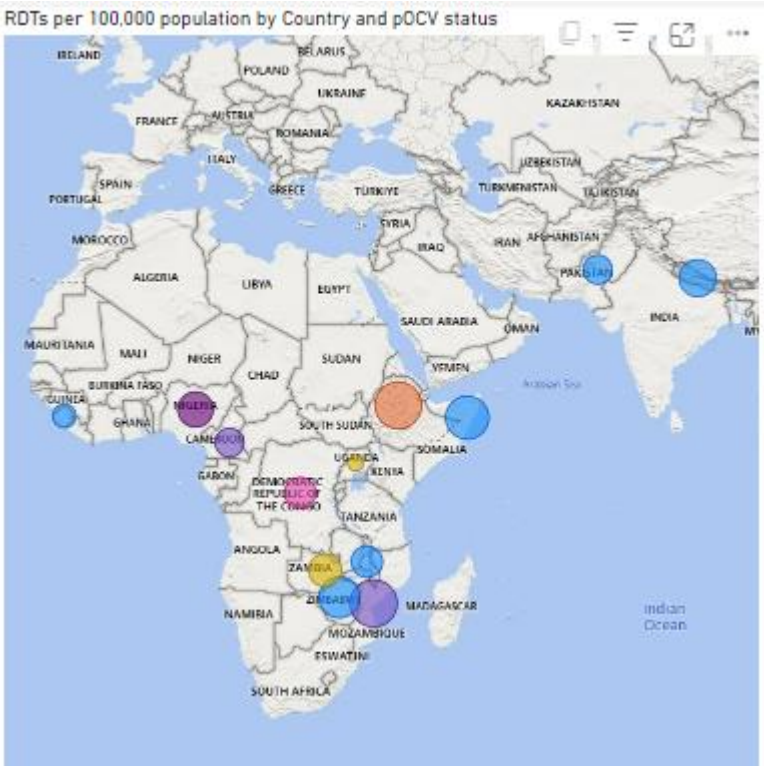
REQUEST FORM

GREEN LIGHT

PRE-ADVICE

Overview: Countries approved for Gavi cholera RDT support; countries in the pipeline

	RDTs Approved	RDTs delivered/GL issued	Status
Cameroon	21.500		GL pending
DRC	91.760		Procurement request received
Ethiopia	296.100	70.000	Partial delivery
Malawi	19.020	9.520	Partial delivery
Mozambique	81.260		Procurement request pending
Nepal	43.660	13.000	Partial delivery
Nigeria	276.400		Procurement request pending
Pakistan	184.380	55..311	Partial delivery soon
Sierra Leone	4.060		GL pending
Somalia	36.400		GL pending
Syria	76.320	63.620	Partial delivery
Uganda	12.640		IRC approved
Zambia	20.920	5.920	Partial delivery
Zimbabwe	51.260		GL pending



Applications under review:

- N. Yemen
- S. Yemen
- Kenya

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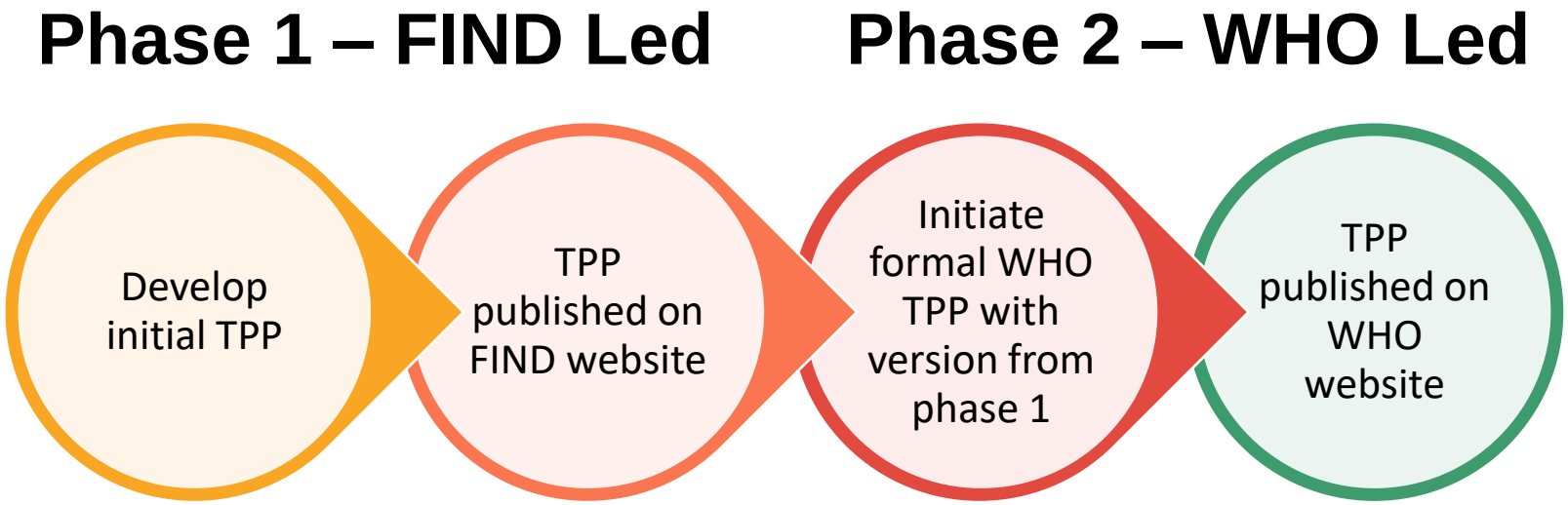
Cholera surveillance: TPP development – RDTs, molecular tests

Key considerations for TPP development

Purpose of a TPP is to facilitate the development of products to address an unmet public health need

- They are targeted at product developers, regulatory agencies, procurement agencies and funders.
- TPPs define the minimal and preferred characteristics to meet an **unmet clinical or public health need and align development goals across organizations for harmonized development efforts.**
- Specifications should be driven by the **use case, not the available technology.**
- Must **be useable** and not overly complex.
- Should include comprehensive footnotes/narrative directing readers to relevant supporting evidence and WHO guidance.
- They are 'living' documents which are **updated** as new evidence becomes available.
- **WHO TPP SOP** process defines who should be involved, overall process to follow and how often TPPs should be updated.

TPP development overview



Looking ahead…

Strengthening Gavi cholera diagnostics support:

- Publication of cholera RDT target product profiles (TPPs) completed (on FIND and GTFCC website)
- TPPs for cholera molecular tests close to finalization (estimated by end May)
- Independent evaluation of products across platform technologies
- Strengthening programmatic and operational understanding of RDT deployment, uptake and outcomes: multi-country learning from roll out of cholera RDT support and implementation (Ethiopia, Malawi, Mozambique)

Alignment of Gavi support with GTFCC guidance: We plan to continue to align Gavi materials with GTFCC surveillance recommendations

Thank you