**Country name**

**CHOLERA DIAGNOSTICS REQUEST FORM**

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| **This template is for countries requesting Gavi support for procurement of cholera rapid diagnostic tests (RDTs) under the Gavi Board-approved Diagnostics initiative. This support aims to facilitate access to cholera RDTs for timely testing and rapid identification of probable cholera cases. This aims to enable more effective and efficient oral cholera vaccine (OCV) usage – particularly for preventative campaigns – by helping build an evidence-base of affected areas and trends in cholera transmission.****The following are mandatory requirements to be submitted alongside this request form:*** Signatures required to endorse this request before submission to Gavi:
	+ Minister of Health (or delegated authority)
	+ Director of Finance for Ministry of Health

NOTE: The signature of the Minister of Finance (or their delegated authorities) is recommended but not required. The endorsement of this request by the Director of Finance for the Ministry of Health is required to ensure government awareness of its responsibility for the funding of cholera diagnostics in the medium-to-long term. Cholera diagnostic procurement support is provided to allow more timely testing of suspected cholera cases to inform cholera control and prevention activities, including – but not limited to –preventative or outbreak OCV vaccination efforts. All countries eligible for Gavi new vaccine support may apply. Gavi cholera diagnostic procurement funding support is expected to be particularly helpful for countries considering or intending to conduct preventative OCV (pOCV) campaigns.The request will be reviewed by members of the Independent Review Committee (IRC) who will make a recommendation to Gavi. Following the independent review there will be a clarification period (30 working days) for countries to respond to any ‘issues to be addressed’ ahead of final Gavi approval. **Submit this request form and the aforementioned requirements to:** **proposals@gavi.org***Countries requesting Gavi support for pOCV campaigns should consult the* [*Vaccine Funding Guidelines*](https://www.gavi.org/sites/default/files/document/2022/Vaccine_FundingGuidelines_0.pdf) *for more information on the process and requirements.*  |

# Gavi Grant Terms and Conditions

## Gavi terms and conditions

The terms and conditions of the Partnership Framework Agreement (PFA) between Gavi and the Country, including those provisions regarding anti-corruption and anti-terrorism and money laundering, remain in full effect and shall apply to any and all Gavi support made pursuant to this application. The terms and conditions below do not supersede those of the PFA. In the event the Country has not yet executed a PFA, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

#### GAVI GRANT APPLICATION TERMS AND CONDITIONS

**SUPPLIES AND EQUIPMENT USED SOLELY FOR APPROVED PROGRAMMES**
The applicant country ("Country") confirms that all material provided by Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's application. Any significant change from the approved programme(s) must be reviewed and approved in advance by Gavi. All decisions for the supply application are made at the discretion of Gavi and are subject to IRC processes and the availability of funds.

**AMENDMENT TO THE APPLICATION**
The Country will notify Gavi in its Joint Appraisal, or in any other agreed annual reporting mechanism, if it wishes to propose any change to the programme(s) description in its application. Gavi will document any change approved by Gavi according with its guidelines, and the Country's application will be amended.

**CONFIRMATION OF LEGAL VALIDITY**
The Country and the signatories for the Country confirm that its application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its application, as amended, if applicable.

**COMPLIANCE WITH GAVI POLICIES**
The Country confirms that it is familiar with all Gavi policies, guidelines and processes relevant to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and complies with the requirements therein. All programme related policies, guidelines and processes are available on Gavi’s official website and/or sent to the Country.

**ARBITRATION**
Any dispute between the Country and Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either Gavi or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by Gavi. For any dispute for which the amount at issue is greater than US$ 100,000 there will be three arbitrators appointed as follows: Gavi and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

Gavi will not be liable to the country for any claim or loss relating to the programme(s) described in the application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. The Country is solely responsible for all aspects of managing and implementing the programme(s) described in its application.

**REPORTING**
The Country should report information on cholera testing activity as well as suspected and confirmed cholera case counts, to the World Health Organisation (WHO). This reporting should be completed in-line with technical recommendations on reporting and using templates available from the Global Task Force on Cholera Control (GTFCC) guidance on the [GTFCC website](https://www.gtfcc.org/wp-content/uploads/2023/02/gtfcc-interim-cholera-regional-and-global-reporting-technical-recommendations.pdf). This includes reporting of: number of suspected cholera cases, number of cases tested (stratified by testing method), number of positive tests, and number of cholera deaths. To simplify reporting and avoid duplication, Gavi will be relying on information from WHO to inform future decisions on whether to renew cholera diagnostic funding procurement support for individual countries. Countries may also be asked to provide information on cholera diagnostic testing through surveys. Gavi expects that (i) future renewal requests for Cholera diagnostic equipment, and (ii) future applications for preventative OCV support should reflect improved diagnostic capabilities and reporting. In the future, Gavi may require that country applications for Gavi funding support for preventive OCV campaigns use data from routine cholera testing to substantiate plans on where such campaigns should be conducted.

**ELIGIBILITY**

All countries eligible for Gavi new vaccine support may apply for Cholera diagnostic test procurement funding support. This funding support is expected to be particularly helpful for countries considering or intending to conduct preventative Oral Cholera Vaccine (pOCV) campaigns because the diagnostic testing results should help inform decisions on whether and where to conduct such campaigns.

**OPERATIONAL FUNDING**

Operational funding for introduction or expansion of cholera diagnostic funding is not available through this mechanism. Gavi Health System Strengthening (HSS) and Targeted Country Assistance (TCA) funding can be utilised to support disease surveillance and diagnostic testing capacity as described – please see the [Vaccine Funding Guidelines](https://gavinet.sharepoint.com/%3Aw%3A/t/COP/vip/EUxnBtJloIRDtNbIw5urZRYBYVafH1OgoSZM42M2JgzbSw?e=6ESl8G) – Cholera Diagnostics section for further details.

# Review and update country information

### **Country profile**

Please confirm the country is eligible for Gavi new vaccine introduction support:

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### **National customs regulations**

Please describe local customs regulations that are instrumental for the delivery of imported diagnostics tests, and estimated time that these procedures will take:

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Please describe requirements for pre-delivery inspection of imported goods that are instrumental for the delivery of diagnostic tests:

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Please describe any special documentation requirements that are instrumental for the delivery of imported diagnostic tests:

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### **National Regulatory Agency**

Please provide information on the National Regulatory Agency in the country, including presence of a regulator of medical devices and in-vitro diagnostics (IVDs):

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Please identify at least one point of contact with phone number and e-mail address at the National Regulatory Agency. UNICEF will need to communicate authorisation requirements to manufacturers:

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# Cholera epidemiology, surveillance, and testing

### 3.1 Epidemiology and testing

Please complete the following table detailing the country’s cholera situation in the last 5-years:

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| --- | --- | --- | --- | --- | --- |
| **Year** | **Number of suspected cholera cases** | **Number of cases tested by RDT** | **Number of RDT positive cases** | **Number of cases tested by culture/ PCR**  | **Number of culture/ PCR positive cases** |
| 2022 |  |  |  |  |  |
| 2021 |  |  |  |  |  |
| 2020 |  |  |  |  |  |
| 2019 |  |  |  |  |  |
| 2018 |  |  |  |  |  |

## 3.2 Surveillance system *– Guidance on cholera surveillance from the GTFCC is available* [*here*](https://www.gtfcc.org/wp-content/uploads/2023/02/gtfcc-public-health-surveillance-for-cholera-interim-guidance.pdf)*.*

* **Option A** – Provide written details to describe the surveillance system and structure in-country as relevant for cholera – including details of what data systems are linked electronically and how cholera surveillance reports and analysis inform decision-making.
* **Option B** – Alternatively, attach a copy of a document that describes cholera surveillance, e.g., country’s Integrated Disease Surveillance and Response (IDSR) guidelines, the country’s most recent National Cholera Plan, and below, write the document name and relevant section number(s) that detail information on the in-country surveillance system.

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## 3.3 Laboratory referral system

* **Option A** – Provide brief written details to describe the cholera testing referral system in-country – including details on district-level (i.e., sub-national) laboratory capacity, specimen transport, and laboratory data reporting systems, especially in areas affected by cholera.
* **Option B** – Or attach a copy of a document that describes this, e.g., laboratory system overview or the country’s most recent National Cholera Plan, and write the document name and relevant section number(s) that detail information on referral systems here.

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### 3.4 Strategic considerations and rationale for the request

* **Option A** – Briefly describe how expanded cholera diagnostic capacity fits into your country’s plan for preventing cholera. In particular, please describe your country’s interest in or plans for conducting preventative Oral Cholera Vaccine (pOCV) campaigns now or in the future?
* **Option B** – Or attach a copy of a document that describes this, e.g., the country’s most recent National Cholera Control Plan, and write below the document name and specific relevant section number(s) that detail relevant aspects of surveillance activities towards the country’s cholera elimination strategy.

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# Cholera diagnostics volumes and logistics

## 4.1 Quantification

In order to guide quantification of annual rapid diagnostic test requirements, Gavi has developed the following guideline methodology in consultation with the GTFCC. Countries may either:

1. Use the guideline quantification approach and provide details of country inputs to derive totals. This may be facilitated by optional use of [this supporting Excel spreadsheet](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gavi.org%2Fnews%2Fdocument-library%2Fcholera-quantification&data=05%7C01%7Clhampton%40gavi.org%7C6653124ef7e04dfc2ed808db7111b938%7C1de6d9f30daf4df6b9d65959f16f6118%7C0%7C0%7C638228093165559067%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2du8qxJfwoX6sYEYX4mB2hhgzW1XHsOiu6CfjGxc7Lw%3D&reserved=0).
2. Provide written rationale and supporting documentation for quantities derived from an alternative approach.

By surveillance units, here and throughout, we are typically referring to sub-national areas e.g., districts, local government authority areas, counties, etc.

**A. Guideline quantification approach**

**Step 1 – identify endemic surveillance units for regular testing**

Identify surveillance units known to have regular cholera transmission in recent years (e.g., endemic) areas that warrant regular testing. These may be identified through (a) following [GTFCC guidance](https://www.gtfcc.org/resources/identification-of-priority-areas-for-multisectoral-interventions-pamis-for-cholera-control/) for identification of PAMIs, (b) confirmed or suspected case data, or (c) through other methods, e.g., districts likely to be targeted for pOCV campaigns

**Step 2 – health facility mapping**

For each surveillance unit identified in step 1, confirm the number of designated health facilities used to detect and/ or treat suspected Cholera cases in those districts. For example, this may include district hospitals, sub-district hospitals, or cholera treatment centres (CTCs)

**Step 3–calculate RDT quantities**

Use the provided formulas, or another method, to calculate the testing requirements for both 1) surveillance units with regular testing and 2) all other surveillance units (see below in step 3)

*The following questions should help countries estimate how many cholera diagnostic tests they need using the guideline testing quantification methodology. Although this methodology should aid planning, in practice countries should deploy cholera rapid diagnostic tests according to their needs and contexts. In addition, the guideline quantification methodology may not be suitable for all country contexts, e.g., countries with suspected or known cholera endemicity in almost all surveillance units. In such situations, adaptations to formulas (e.g., number of tests per day at health facilities) or alternative quantification approaches may be preferred.*

Please respond to all questions in this section even if proposing RDT volumes based on an alternative methodology.

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| **Step 1a**: List the names of identified target surveillance units[[1]](#footnote-2) known to have regular cholera transmission in recent years for regular testing  |  |
|  |  |
| **Step 1b**: How many other surveillance units1 are there in the country, i.e., excluding those listed in step 1a)? It is noted that RDTs may not be requested for all of these surveillance units, e.g., due to operational capacity and/ or lower risk of cholera. |  |

**Step 2:** Provide brief details on health facilities relevant for cholera diagnostic testing, namely:

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| Types of health facilities used for identification and treatment of cholera, e.g., sub-district hospital, Cholera Treatment Centre, etc. |  |
|  |  |
| Total number of such health facilities (i.e., those named above) across all identified selected surveillance units for regular testing |  |

**Step 3:** Follow formulas – if deemed appropriate for country context – to calculate testing requirements for (1) surveillance units with regular testing needs, and (2) as-need testing in all other surveillance units.



The [provided Excel tool](https://www.gavi.org/news/document-library/cholera-quantification) is set-up to calculate these testing requirements based on inputs on (i) the number of surveillance units for regular testing and as-needed testing, (ii) the number of health facilities in each regular testing surveillance unit, and (iii) cholera persistence over time.

1. **Alternative approach**

*Please skip this section if you have followed part ‘A. Guideline Methodology’ above.*

If the country is proposing an alternative quantification for RDTs needed, please provide detailed description of the quantification approach, rationale, inputs, and outputs, to be able to calculate the total annual number of diagnostic tests required. Please attach additional supporting documents if available, such as country guidelines on diagnostic testing strategy for cholera surveillance.

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### 4.2 Volume request

**Total request**

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| Total annual number of rapid diagnostic tests requested.  |  |

*If the Excel tool was used, please submit the completed Excel tool along with this form*

### 4.3 Logistics

### **4.3.1 Supply delivery**

*The country is responsible for paying or securing waiver of customs clearance, insurance, handling, and storage upon arrival of RDTs.*

What is the name, address and, if available, geocoordinates of the first international airport of entry on CIP, Named Airport (Incoterms 2020) that UNICEF Supply Division will ship all diagnostics tests to?

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| --- | --- |
| First international airport of entry on CIP: |  |
| Name: |  |
| Address: |  |
| Geocoordinates: |  |

To facilitate timely delivery of supplies, the country will be responsible for providing the green light to UNICEF in order to enable the scheduling of shipments with UNICEF Supply Division. The consignee is responsible for clearing the goods promptly upon arrival. What is the country’s plan for securing the necessary customs clearance and any other import authorizations, e.g., tax waivers?

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Please identify at least one point of contact with phone number and e-mail address at the desired delivery location. If the application is approved, UNICEF will reach out to that person to discuss delivery of supplies.

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| Name: |  |
| Phone number: |  |
| Email address: |  |

### **4.3.2 In-country supply distribution**

*The country is responsible for storage of RDTs in suitable (e.g., appropriate temperature) locations and distributing RDTs from the previously identified port of entry to lower levels and health facilities.*

Please provide brief details on the medical supply chain system in-country to provide examples of the ability to distribute RDTs from central to lower levels. For example – has this supply chain been used previously for distribution of RDTs for cholera or other diseases (e.g., malaria), and is it suitable for cholera RDT distribution? And/ or are there existing medical supplies that are periodically delivered to the same locations that will receive RDTs that will be able to integrate cholera RDT distribution, e.g., for essential supplies such as ringer lactate or measles sample collection materials?

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### **4.5 Diagnostic procurement funding**

*While no cost-sharing requirement is requested in the current window of support (i.e., until end-2025), a cost-sharing requirement will eventually be introduced for cholera diagnostic tests. More information will be provided by your Gavi Senior Country Manager (SCM) as it becomes available. To ensure long-term financial sustainability, countries will be expected to eventually contribute some of their resources and gradually assume full responsibility for funding cholera diagnostics.*

Please provide information about the domestic budget for diagnostic testing supplies and equipment procurement for this fiscal year and, if available future years.

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### **Surveillance systems funding**

*Operational funding for introduction or expansion of cholera diagnostic funding is not available through this mechanism. Revision of surveillance guidelines, training, development of reporting tools, and distribution of cholera RDTs should be funded through other means. Guidance on cholera surveillance from the GTFCC is available* [*here*](https://www.gtfcc.org/wp-content/uploads/2023/02/gtfcc-public-health-surveillance-for-cholera-interim-guidance.pdf) – *this may inform future surveillance systems strengthening activities.*

* Option A – If any, please provide information about any existing or planned funding and activities for cholera surveillance training and other surveillance strengthening activities. Please detail the source of funding, e.g., domestic funding, Gavi’s Health Systems Strengthening (HSS) funding, or support from other partners.
* **Option B** – Or attach a copy of a document that describes this, e.g., the country’s most recent National Cholera Plan or an approved HSS grant activity list and write below the document name and relevant section number(s) that detail health system strengthening activities.

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Contacts

Person(s) who should be contacted in case Gavi needs to ask for more information regarding the application.

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| --- | --- | --- | --- | --- |
| Name | Position | Phone Number | Email | Organisation |
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#### **Comments**

Please provide any comments you have about this application and how to improve it:

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#### Government signature form

The Government of COUNTRY would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for cholera diagnostic testing, specifically cholera rapid diagnostic tests, as outlined in this request form.

The Government of COUNTRY commits itself to developing national immunisation services, including diagnostic testing that helps guide immunisation services, on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of the Minister of Health and the Director of Finance for the Ministry of Health (or their delegated authorities).

*We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for procuring cholera diagnostics will be included in future annual budgets of the Ministry of Health, including funds for co-financing of future Gavi-supported procurement of supplies once the details of the Gavi co-financing requirements are available.*

*We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[[2]](#footnote-3)*

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| Minister of Health (or delegated authority)  | Director of Finance, Ministry of Health (or delegated authority) |
| Name:  | Name:  |
| Date:  | Date:  |
| Signature:  | Signature:  |

1. By surveillance units, here and throughout, "surveillance unit" typically refers to district, local government area, county, etc. [↑](#footnote-ref-2)
2. In the event the Country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application. [↑](#footnote-ref-3)