Yellow Fever Diagnostics Support Guidelines

This document provides detailed guidelines on the programmatic requirements and process to request Gavi support for procurement of yellow fever diagnostic reagents, supplies, and equipment.

Overview of Gavi Support for Yellow Fever Diagnostics

The Global Strategy to Eliminate Yellow Fever Epidemics (EYE) recommends a three-pronged yellow fever control strategy for at-risk countries:

- The nationwide integration of the yellow fever vaccine in routine immunisation programmes for infants.
- The implementation of preventive mass vaccination campaigns to rapidly increase population immunity in high-risk areas.
- Rapid outbreak response, through prompt case detection, reactive vaccination, good case management, vector control and community mobilisation.

In November 2018, the Gavi Board approved support for yellow fever diagnostic capacity strengthening through provision of laboratory supplies, equipment and capacity building to countries through at least 2021. The aim of this support is to facilitate more reliable yellow fever laboratory testing, which in turn should allow more effective and efficient yellow fever vaccine usage, particularly in response to outbreaks and in addressing the gaps in routine immunization coverage identified through detection of yellow fever cases.

Gavi support for yellow fever procurement is focused on consumable supplies, including reagents, needed for tests to confirm yellow fever infection in suspected yellow fever cases and the equipment specifically needed to conduct those tests (Annex 2). Gavi may support procurement of consumable yellow fever laboratory supplies for a country without supporting the procurement of yellow fever diagnostic equipment.

Countries requesting Gavi support for yellow fever vaccination, either for the introduction of yellow fever vaccine into the routine immunisation schedule, or yellow fever preventive mass vaccination campaign should consult the Application guidelines (section 5.3.8) for more information on the process and requirements. Countries requesting Gavi support for rapid outbreak response for yellow fever (via the International Coordinating Group (ICG)), should consult the yellow fever Application guidelines in the ICG site.

Eligibility

The support for yellow fever diagnostic reagents, supplies, and equipment is currently available to Gavi-eligible African countries classified as “high-risk” for yellow fever by WHO as part of the EYE strategy[1] (list provided in Annex 1). Requests must be submitted by the national government to the Gavi Secretariat.

In addition, this support is provided to **only a country’s national public health yellow fever reference laboratory**. To receive support, the national public health yellow fever reference laboratory must have a solid basis for expecting to test at least 50 yellow fever samples a year so that it maintains adequate testing proficiency.

[1] World Health Organization. Eliminate Yellow fever Epidemics (EYE): A global strategy, 2017-2026. Wkly Epidemiol Rec 2017;92:193-204.

Currently, **Gavi-supported yellow fever laboratory supplies and equipment will be procured via UNICEF Supply Division (SD)**; that is, self-procurement or procurement via other mechanisms are not possible for Gavi-funded procurement of yellow fever laboratory supplies and equipment.

Available support and requirements

Funding is available for procuring yellow fever diagnostic reagents, supplies and equipment for i) enzyme-linked immunosorbent assay (ELISA) tests and ii) polymerase chain reaction (PCR) tests (types of reagents, supplies, and equipment available in Annex 2). However, provision of supplies and equipment for PCR testing is not expected to start until a PCR test kit validated for use in the World Health Organization-coordinated Yellow Fever Laboratory Network becomes available.

Gavi will provide funding for the purchase of consumable supplies from the categories described in Annex 2 to test up to 120% of samples expected to be received for ELISA testing and 120% of samples eligible for PCR testing through 2021. Support beyond 2021 will be subject to Gavi's Board approval of continuation of a program of Gavi support for yellow fever diagnostic capacity strengthening. The additional 20% will serve as a reserve (buffer) in case more samples are received than expected. The initial country application will identify the number of samples expected to be tested in the first year, with subsequent annual renewals allowing revised estimates of sample testing volumes based on new experience and information. Gavi will also annually fund support for the purchase of consumable supplies for testing approximately another 30 samples with ELISA and 20 samples with PCR for training and quality assurance purposes. The amounts and types of consumable supplies needed for testing a given number of samples will be determined based on input from the World Health Organization (WHO) and UNICEF.

Supported equipment

Gavi may also fund procurement of some yellow fever ELISA and PCR testing equipment (types of equipment available in Annex 2) if the need for such equipment has been confirmed through a WHO associated laboratory capacity assessment visit for Gavi to fund the procurement of that equipment. The types of available equipment will be based on input from WHO and UNICEF. Countries should explain in their application how installation and maintenance services for the equipment will be secured.

Limitations and Other Sources of Support

Funding for basic laboratory infrastructure components such as staff, electricity, water, furniture, etc., is not available as part of Gavi support for yellow fever diagnostic capacity; such components should be funded through other means. Gavi Health System and Immunisation Strengthening (HSIS) funding may be available to support surveillance and laboratory capacity in the context of national plans that focus on achieving and maintaining high immunisation coverage and address underlying equity challenges.

In addition, technical assistance, such as training for laboratory staff, quality assurance /quality control testing, can be made available for yellow fever national laboratories and WHO regional reference laboratories. Please contact Dr. Mick Mulders, WHO global yellow fever laboratory coordinator, at muldersm@who.int for more information.

Requirements:

- Completed application form
- Mandatory signatures required to endorse the request before submission to Gavi: i) Minister of Health (or their delegated authorities), ii) Director of national yellow fever laboratory (or their delegated authority), and iii) Director of Finance for the Ministry of Health (or their delegated authority). The signature of the Minister of Finance (or their delegated authorities) is recommended but not required.
- The Coordination Forum (ICC, HSCC or equivalent body) is required to endorse the request before submission to Gavi. This can be done also through the ICC/HSCC endorsement of the Joint Appraisal (JA) and should be reflected in ICC/HSCC minutes

In order to ensure long-term financial sustainability, countries will be expected to eventually contribute some of their own resources and gradually assume full responsibility for the funding of yellow fever laboratory materials. However, such a contribution is not required at least through 2020. More information will be provided as it becomes available. 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 funding of yellow fever laboratory reagents, supplies and equipment. The signature of the Minister of Finance will reinforce that awareness but is not required at this time.

This Gavi support for laboratory diagnostic procurement is specific to yellow fever and does not apply to other diseases.

Application and review process

The step-by-step application and review process are as follows:

- Submit the application and any supporting documents to proposals@gavi.org
- Gavi screens applications to ensure that mandatory requirements have been met and reviews the validity and consistency of information submitted. Based on the information provided in the application and input from WHO and UNICEF, Gavi will calculate the cost of the reagents, supplies, and equipment to be provided and the associated costs of shipping them. If incomplete, Gavi will work directly with countries to address gaps before proceeding.
- The request is reviewed by independent reviewers from the Independent Review Committee (IRC).
- The reviewers will make one of the following recommendations to Gavi (to be captured in the independent review report):
  - **Recommend Gavi approval:** for a situation where there are no issues that require a re-review by the reviewers.
  - **Recommend the re-review of outstanding issues[2]:** for a situation where there are issues that require a re-review by the independent experts. This implies that there are material issues that need to be met and/or that there are major gaps to be addressed by the country before approval by Gavi should be considered.
- If recommended for approval: The independent reviewers may identify outstanding issues to be addressed and complementary strengthening actions. These outstanding issues need

[2] *This implies that there are fundamental issues with the new support requested that cannot be addressed by the Alliance's grant management processes following the independent review (i.e., operational deployment planning for YF diagnostics).*

to be clarified (i.e., either resolved or an action plan should be developed) by the country within 30 working days. The Gavi Secretariat reviews the country's responses and determines if the issues have been satisfactorily addressed. During this period, the Gavi Secretariat will work with the country to finalise details for the approval and "Decision Letter" to countries. Countries should note that the laboratory reagents, supplies, and equipment to be procured are subject to some change based on new information and/or discussions with the country following the review.

- If recommended for re-review: The country should respond to each issue by providing a detailed summary of the changes made in response to the issues raised. Depending on the nature of the issues identified by the reviewers, it may require a substantial revision of the request and submission of updated/additional information/documents.

Following the independent review

- Gavi's Chief Executive Officer (CEO) will consider and decide on the application and associated materials, taking into account recommendations from the independent review. Countries and partners are notified of the outcome through a "Decision Letter", explaining the support for procurement of yellow fever diagnostic reagents, supplies, and equipment as well as terms of Gavi support.
- Gavi will also initiate internal processes for the laboratory supplies and equipment purchase (with UNICEF SD). The national public health yellow fever reference laboratory should begin to plan activities to prepare for the laboratory supplies and equipment, for example, contacting UNICEF Supply Division regarding shipment plans, ensuring country product licensing requirements are met, etc.[3]
- The Ministry of Health or national public health yellow fever reference laboratory will be fully responsible for customs clearance and for either provision of a waiver or, in the absence of waiver, paying for any taxes or other duties for each shipment of yellow fever diagnostic reagents, test kits, supplies, and equipment. Ministry of Health or national public health yellow fever reference laboratory must provide UNICEF with confirmation of such waiver of taxes and other duties (or, in the absence of such waiver, confirmation of its commitment to pay for such taxes and other duties) prior to UNICEF arranging shipping for yellow fever diagnostic reagents, test kits, supplies, and equipment. The Ministry of Health or national public health yellow fever reference laboratory will also be fully responsible for any demurrage, storage or other charges resulting from failure or delay in customs clearance or changes in the delivery schedules agreed with UNICEF.
- National public health yellow fever reference laboratories should request from UNICEF only the amounts needed for testing the samples they actually receive, up to the amounts authorized for Gavi funding. If fewer samples than expected are received for testing, national public health laboratories should not request the full amount of yellow fever diagnostic consumable supplies authorized for Gavi funding from UNICEF. Also, laboratories experiencing difficulties with accurately testing for yellow fever in a consistent manner should limit their requests for consumable supplies from UNICEF to amounts needed for training and quality assurance purposes until they are accurately testing for yellow fever in a consistent manner.

[3] *Each country may have its own licensing requirement. The Ministry of Health is responsible for facilitating this process with National Regulatory Authority and the manufacturer of the chosen product. UNICEF SD may provide support.*

Annex 1: List of eligible countries[4]

Country
Benin
Burkina Faso
Cameroun
Central African Republic
Chad
Congo DR
Congo Republic
Côte d'Ivoire
Ethiopia
The Gambia
Ghana
Guinea
Guinea Bissau
Kenya
Liberia
Mali
Niger
Nigeria
Senegal
Sierra Leone
South Sudan
Sudan, Republic of
Togo
Uganda

[4] *To be updated based on changes in the WHO classification, if applicable.*

Annex 2: Types of reagents, supplies, and equipment for yellow fever diagnostic testing eligible for Gavi support

1. Enzyme-linked immunosorbent assay (ELISA) testing
   - ELISA reagents or test kits
   - ELISA testing consumable supplies, including ELISA reaction plates and pipette tips

2. Polymerase Chain Reaction (PCR) testing
   - PCR test kits
   - PCR testing consumable supplies, including PCR testing tubes
     Note: Gavi funding for PCR test procurement will start when a PCR test kit validated for use in the WHO-coordinated Yellow Fever Laboratory Network becomes available.

3. Personal protective supplies, including eye protection and disposable gloves

4. Equipment
   - ELISA washer
   - ELISA reader
   - PCR machine
     Note: Gavi funding for PCR equipment procurement will start when a PCR test kit validated for use in the WHO-coordinated Yellow Fever Laboratory Network becomes available
   - Biosafety cabinet

For purposes of Gavi funding for procurement of reagents, supplies, and equipment for yellow fever diagnostic testing, the specific amounts and types of consumable supplies procured for testing a given number of samples and the types of equipment procured for use in the Yellow Fever Laboratory Network will be determined based on input from the World Health Organization (WHO) and UNICEF.