

Summary of Satellite meeting
of the Global Technical
Taskforce (TTF) of the
Defeating Meningitis by 2030
Global Road map December
2022 and Resulting Action Plan

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December 13, 2023

“Planning the introduction of multivalent meningococcal conjugate vaccines in countries of the African meningitis belt”

A Satellite Workshop
8th meeting of the Global Technical Taskforce (TTF)
of the Defeating Meningitis by 2030 Global Road map
in person WHO/HQ, Salle M605
Geneva 13 December 2022, 9:00 – 12:00

Strategic Goals 2 and 3 of the Defeating Meningitis by 2030 Global Road map (resolution WHA73.9) include introducing effective and affordable new WHO prequalified vaccines targeting *Neisseria meningitidis* (Nm) and developing evidence-based policy on Nm vaccination strategies that result in optimal individual protection and, where possible, herd protection.

An affordable multivalent meningococcal conjugate vaccines (MMCVs) is expected to be WHO prequalified very soon. This workshop will focus on planning for the long-awaited first introduction of this vaccine, with the following objectives:

- 1) To review scenarios for various policy and financing pathways to accelerate introduction timelines for MMCVs.
- 2) To identify potential levers and actions that stakeholders can take to accelerate timelines.
- 3) To agree on a comprehensive and coordinated action plan for the introduction of MMCVs, which specifically includes the following core areas of work: research and evidence generation, recommendations and policy, regulation, financing, procurement, and vaccine deployment readiness.

By the end of the meeting, we will identify the information needed for country introduction acceleration, subject to partner agreement, including relevant normative policy bodies. We will also identify a preferred scenario (and one or two alternative scenarios) with critical pathways and clear action items/requests for each organization involved in the acceleration activities.

Agenda

Time	Topic	Presenters
9:00-9:10	Welcome and introductions	Chairs
9:10-9:20	Meeting objectives, Overview of current status of policy recommendation for use of multivalent meningococcal conjugate vaccines in countries of the African meningitis belt including evidence available	Marie-Pierre Preziosi
9:20-9:40	Summary of modeling evidence and geographical risk assessment	Caroline Trotter
9:40-9:50	Questions for clarifications	All
9:50-10:30	Review three scenarios for policy and introduction, including assumptions to be confirmed/agreed to by participants	PATH
10:30-10:45	Break	All
10:45-11:30	Identify potential levers and actions that stakeholders can take to accelerate timelines for three scenarios Rank scenarios	All
11:30-12:00	Outline action plan: Summary of actions agreed to and next steps to be taken by meeting participants	PATH (All)
12:00	Closing	Chairs, WHO

Meeting summary

Key Takeaways

- With careful planning and coordination there is opportunity for a WHO recommendation for the use of MMCV in a two-pronged strategy of routine immunization and campaigns in 2023.
- The policy and financing processes are necessary for long-term sustainable access and introduction of MMCV. However, the need remains for early preventive campaigns once a prequalified vaccine is available.
- A parallel and complimentary strategy to conduct preventive campaigns as early as late 2023 in select high-risk districts using stockpile doses is being evaluated. Partners agreed to pursue this strategy in addition to established policy and financing strategies to pursue early introduction for those districts most at risk for future outbreaks.

After welcoming attendees and framing the upcoming discussions, the TTF Chairs reviewed the current meningitis context, including recent outbreaks from serogroups X and C in the African Meningitis Belt, underscoring the urgent need for MMCV introduction.

Dr. Caroline Trotter presented on the importance of MMCV introduction into the routine EPI program to prevent an epidemic prior to 2024, emphasizing that introduction via campaign is insufficient. Currently available modeling data indicate the exponentially higher impact of mass campaigns *plus* routine introduction in the 7-8 highest risk contiguous countries. However, introduction of MMCV in medium- to low-risk countries may also be considered as part of meningitis control in the region. While peak transmission is seen in 5–14-year-olds, it is not considered equitable to leave 1–4-year-olds unimmunized. Dr. Trotter reiterated that while updated modeling evidence will be considered by the WHO SAGE WG for the recommendation slated for September 2023, modeling ultimately needs to be underpinned by good epidemiological evidence on carriage and disease.

PATH is working to accelerate the use of MMCV in the African Meningitis Belt by supporting partners and stakeholders to prioritize and advance the policy process. PATH collaborates with WHO and Gavi to identify and support critical activities that will accelerate MMCV access and ideally reduce the time between vaccine availability and country introduction. As a part of PATH's ongoing coordination work to support the acceleration of introduction of MMCV vaccine, PATH described their process of key stakeholder engagement that identified assumptions and critical dates for WHO and Gavi Board meetings to create three acceleration scenarios considered in a preparatory December 12th meeting. The primary prioritized scenario (Figure 1) was presented to attendees with the following input collected.

WHO recommendation

- A WHO recommendation is likely to be proposed at the SAGE meeting in September 2023. A recommendation for targeted campaigns plus routine immunization will fulfil the Gavi Board conditional approval requirements and allow for earlier country introductions.
- The WHO recommendation will consider vaccine introduction based on epidemiological evidence as well as emerging evidence from clinical development of the vaccine, such a recommendation could potentially include a component of campaigns beyond high-risk countries. Countries with medium- to low-risk have reported interest in MMCV introduction. Vaccine access equity in all countries with

meningitis burden must be considered. Accelerating campaigns in hard-to-access areas is also important.

Country decision-making

- Stakeholder engagement, deliberations, and decision-making in countries require sufficient time and detailed planning. EPI performance in countries should be considered when partners are providing technical assistance to develop national introduction strategies.
- Communication and advocacy should be emphasized in countries. It is imperative to introduce MMCV into the national health context rooted in the broader child health strategy.

Disease burden

- Countries that have carried out a monovalent meningococcal A conjugate vaccine (MenACV) mass preventive campaign are not recording serogroup A cases. However, cases from other serogroups *are* being reported in these countries. Niger is experiencing meningitis outbreaks (NM serogroup C).
- In 2022 South Sudan reported serogroup X epidemics; Angola is experiencing serogroup W epidemics; and DRC has been affected by epidemics caused by serogroups W and C.
- Surveillance, paired with vaccine introduction, is very important to eliminate meningitis hotspots.

MMCV will be available in the outbreak response stockpile for the 2023 meningitis season. Utilizing doses from the stockpile for preventive campaigns in areas considered high risk for outbreak occurrence represents an additional opportunity to accelerate access to MMCV in high-risk areas (*Figure 2*). Discussions garnered the following input:

- The vaccine stockpile is managed by ICG and funded by Gavi for outbreak response, following the [WHO meningitis outbreak response guideline](#).
- As part of the ICG mechanism, the ICG secretariat maintains a Standard Operating Procedure (SOP) that outlines the repurposing of stockpile doses that have a maximum 6-month shelf life remaining to avoid vaccine wastage and prevent epidemics in high-risk areas. These doses can be used for non-outbreak (preventive) campaigns focused in areas proximal to previous outbreaks.
- At times, countries are unwilling to utilize MMCV doses with 6 months or less of remaining shelf life, so despite the availability of doses, the risk of wastage is high.
- While the opportunity to use vaccine doses from the stockpile for preventive campaigns is promising in terms of enabling earlier access to vaccine in high-risk communities, further exploration with all stakeholders is warranted, including members of the ICG. There is precedent for this change since the oral cholera vaccine stockpile currently employs similar mechanism to deploy preventive vaccine in areas at high risk for outbreaks without the need for the vaccine to be close to expiry.

- In 2023 none of the MMCV (pentavalent) stockpile doses will have less than 6-month shelf life remaining as these doses are intended to be available for two meningitis seasons and will have just been purchased in 2023, rendering them unusable for preventive campaigns before the 2024 season unless the SOP is revised. Therefore the existing SOP may be evaluated and modified to extend the remaining shelf-life requirement to longer than 6 months, which could expand the time window for the preventive use designation. This might be considered a temporary provision in absence of a full preventive MMCV program available for countries at risk.
- MMCV deployment before the start of meningitis season in January, will maximize the impact of a preventive campaign that utilizes the stockpile doses.

Meeting participants, especially experts from affected countries, highlighted the scientific value of conducting a pre- and post-introduction carriage study, to understand potential impact of the vaccine on carriage of the meningococcal serogroups included in the vaccine as well as a good practice to inform policy in accordance with what is recommended in high-income countries.

At the conclusion of the meeting, participants identified the following levers as potential ways to accelerate MMCV introduction:

1. Use of ICG doses for preventive campaigns in high-risk areas of select countries that may be at high-risk of outbreaks in the 2024 meningitis season. This assumes the SOP is revised to remove the restriction for expiring doses and that the ICG members agree to a more proactive approach to vaccinate beyond areas that border districts affected by epidemics as per the current WHO meningitis outbreak response guidelines.
2. Country specific assistance will be needed to support multiple countries with a submission to Gavi as soon as possible following the opening of a funding window. As this is a new vaccine application, countries will need tailored support to gather data and information to prepare the plan of action and respond to donor questions.
3. Support national EPI and health system partners as well as decision makers including National Immunization Technical Advisory Groups (NITAGs) to prepare for MMCV introduction by gathering necessary data, sharing relevant information early and keeping policymakers up to date. With adequate information and support ahead of the Gavi approvals, a country could work to implement an MMCV campaign within months of receiving funding.
4. Development of draft implementation guidelines to inform introduction, as well as draft of Gavi program design guidelines ahead of the WHO recommendation.

Action items

Lever - Use of stockpile doses for preventive campaigns

1. Explore the option of using stockpiled doses for preventive campaigns in high-risk areas will all essential stakeholders, including ICG members and Gavi, as well as the manufacturer and countries in a second step, to understand requirements to operationalize vaccines use in a preventive campaign.
 - a. **Responsible:** WHO
 - b. **Timing:** As soon as possible and prior to the Gavi Board meeting June 2023
 - c. **Post meeting update:** WHO and Gavi had initial discussions and will draft feasible scenarios for the use of stockpile doses for consideration by ICG members.
2. Further develop and update timelines for use of ICG stockpile doses (Figure 2) to incorporate input from stakeholders
 - a. **Responsible:** PATH
 - b. **Prerequisite:** Gather input from WHO, Gavi, and UNICEF
 - c. **Timing:** February / March 2023

Post meeting update: PATH has revised timelines, and these are included in the annex

Lever – Support to eligible countries to prepare for Gavi funding

1. Develop implementation guide to aid national governments with MMCV introduction
 - a. **Responsible:** WHO
 - b. **Prerequisite:** Agreement from Gavi, WHO, and BMGF
 - c. **Timing:** Drafted prior to October 2023, finalized by December 2023
2. Determine if early technical assistance for program design can accelerate the timeline for development of application materials.
 - a. **Responsible:** Gavi
 - b. **Timing:** May 2023

MMCV Policy and Introduction Acceleration Action Plan

Following the key stakeholder and global technical task force satellite meeting held on December 13 in Geneva, PATH coordinated an action plan to accelerate MMCV policy decision-making and introduction. Key stakeholders will review the plan to confirm updated assumptions and information critical to implementation.

The plan identifies several critical milestones that drive MMCV acceleration:

- 1) WHO PQ of MMCV that includes indication for use in all ages included in the WHO recommendation.
- 2) Availability of data required for SAGE recommendation of MMCV that includes use of the vaccine in campaigns and RI.
- 3) Gavi Board approval to open a funding window that allows Gavi-eligible countries to apply for MMCV support.

PATH will convene regular meetings with WHO and Gavi to coordinate ongoing alignment of the action plan, to continuously refine discrete elements as new information becomes available, and to facilitate tracking of primary milestones in the plan throughout the project grant (October 2023).

Within the scope of our project to support MMCV vaccine development, PATH will monitor the completion of sample testing and data analysis availability of the Mali Phase 3 study, flagging any delays and assisting with risk mitigation measures to support the availability of data and documents to be provided to the WHO Meningococcal SAGE Working Group in due course to prepare for the WHO SAGE review in September 2023.

The generation of modeling evidence and geographical risk assessment effort led by Caroline Trotter, University of Cambridge, United Kingdom, will be used by the WHO SAGE to inform the vaccine introduction strategy, including the upper age range for the MMCV campaigns. An upper age range of 19 years is projected, which will support a target population aligned with the Gavi conditional approval of MMCV in the 2018 Gavi Vaccine Investment Strategy. Dr. Trotter estimates that the modeling evidence will be available in April/May 2023, which will allow for its consideration by the Meningococcal SAGE WG in July 2023, in preparation for WHO SAGE review in September 2023.

At the request of, and in coordination with WHO, PATH can support preparations for the September 2023 review of MMCV data to enable a SAGE recommendation. This may include evidence packaging and development and dissemination of materials to be considered by the WHO Meningococcal SAGE Working Group and SAGE.

Publication of the WHO recommendation in the *Weekly Epidemiological Record* is expected to require approximately 90 days after the SAGE recommendation. Gavi Board approval to open a funding window will require the WHO SAGE meeting report to be available before the Board meeting. Country

stakeholders and decision-makers rely on the availability of the WHO recommendation and Gavi financing to consider MMCV introduction.

To accelerate the availability of Gavi application materials, Gavi can initiate program design activities, upon the availability of modeling research evidence, with the intent to finalize after the WHO recommendation (Sept 2023) and submit to the Gavi Program and Policy Committee (PPC) (October 2023), followed by the Gavi Board approval (December 2023). The Gavi program design process includes preparations of country application guidelines and inclusion of the MMCV program in the Country Portal. The opening of the Gavi window is planned to be announced in May 2024. The announcement can only occur if the vaccine is prequalified with an indication for use in children younger than 1-year of age. Once the announcement is made, Gavi can further engage with country stakeholders to support Gavi-eligible countries that decide to introduce MMCV and submit an application for funding support. During the time between the projected announcement in May and mid-July application deadline it will be important to ensure countries have the information needed to make informed decisions and submit a quality application in time for the first eligible application window.

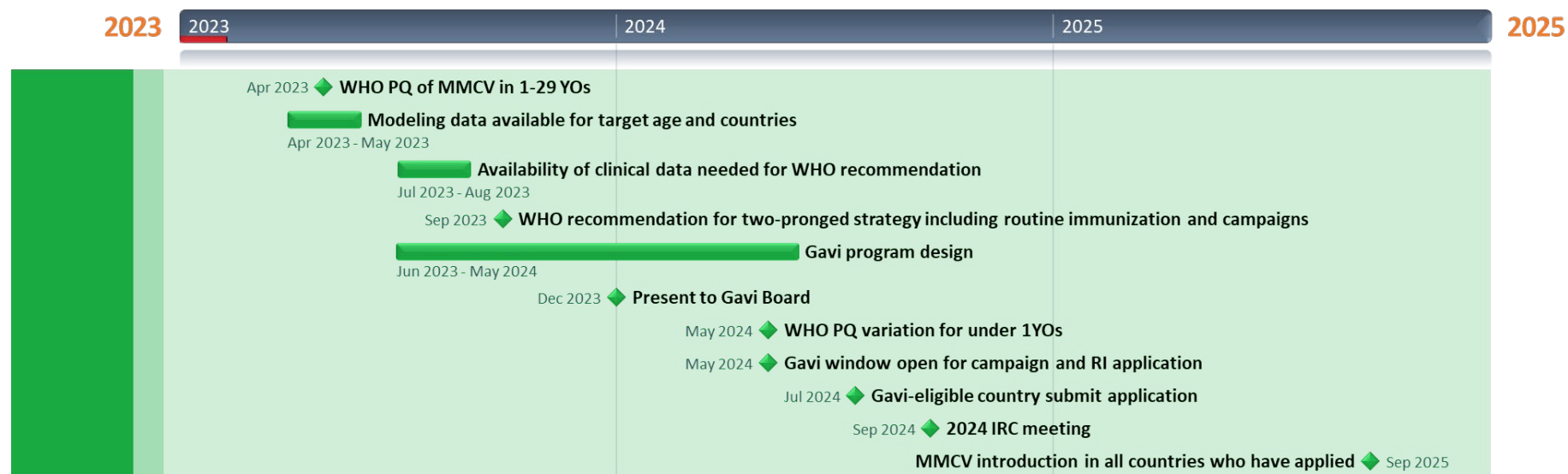
The use of MMCV doses in the stockpile following the 2023 meningitis season is a near-term option to accelerate access to MMCV, enabling earlier access to a life-saving vaccine in high-risk areas prior to availability for further deployment. Operationalizing this scenario requires several approved processes, such as:

- 1) ICG agreement to expand the window to repurpose doses for preventive campaigns.
- 2) The Gavi Board will be informed of the revised SOP.
- 3) Development of procedures that support timely calculation of available doses and available funding for operational support.
- 4) Identification of countries, and sub-national areas for preventive campaigns.
- 5) Deployment of vaccine according to SOP implementation guidance.

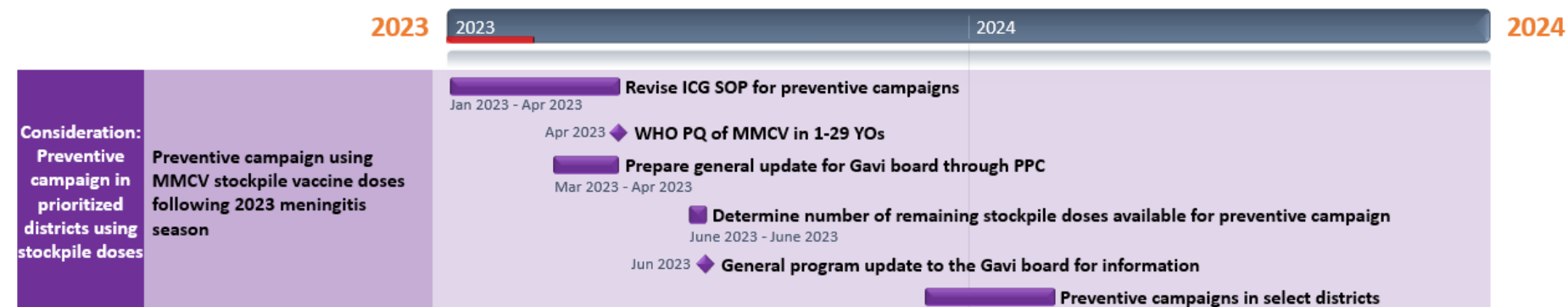
Note that carriage studies are not included here as they are the subject of a separate technical document. As carriage study planning is pursued, information will be included within the timelines as updates are provided.

An action plan schedule and Gantt chart have been prepared to track implementation progress, in addition timeline figures describing the updated processes can be found below.

WHO and Gavi process timeline



ICG Stockpile timeline



List of Participants for Satellite meeting on Dec 13, 2022

Global Technical Taskforce

Brian Greenwood, Chair

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Caroline Trotter, *joined remotely*

University of Cambridge, Cambridge, United Kingdom

Other Subject Matter Experts

Issaka Yameogo, *joined remotely*

Ministère de la Santé, Ouagadougou, Burkina Faso

Mahamoudou Sanou

Centre Hospitalier Universitaire Pédiatrique Charles De Gaulle, Ouagadougou, Burkina Faso

Ramatoulaye Lazoumar, *joined remotely*

Centre de Recherche Médicale et Sanitaire (CERMES), Niamey, Niger

Karimou Sani, *joined remotely*

Ministère de la Santé Publique, Niamey, Niger

John Neatherlin, *joined remotely*

Centers for Disease Control and Prevention, Atlanta, United States of America

Bill & Melinda Gates Foundation

Kate Fay, *joined remotely*

Keith Klugman, *joined remotely*

Gail Rodgers

Gavi

Francisco Luquero, *joined remotely*

Anna Osborne

Cassandra Quintanilla

International Federation of Red Cross and Red Crescent Societies

Tatiana Alvarez, *unable to attend*

Médecins sans Frontières

Miriam Alia Prieto

UNICEF

Sanjay Bhardwaj

PATH

Bill Hausdorff

Ashley Latimer, *joined remotely*

Farzana Muhib

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